UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094	)	***Docket ID No. EPA–HQ–OAR–2015–0072*** *Submitted via Regulations.gov* *June 29, 2020*

Clean Air Task Force, Earthjustice, Environmental Defense Fund, Environmental Law & Policy Center, Environmental Protection Network, Natural Resources Defense Council, National Parks Conservation Association, Sierra Club, Union of Concerned Scientists, Chesapeake Bay Foundation, Environment America, and U.S. Public Interest Research Group ("NGO Commenters") respectfully submit the following comments on the Environmental Protection Agency's ("EPA") "Review of the National Ambient Air Quality Standards for Particulate Matter," 85 Fed. Reg. 24,094 (Apr. 30, 2020). Our organizations represent millions of members and supporters across the country who are deeply concerned about the health, environmental, and economic impacts of air pollution and support implementation of strong, science-based National Ambient Air Quality Standards ("NAAQS") that ensure public health and the environment are protected.

Our comments discuss the following:

I. Introduction

Establishing the National Ambient Air Quality Standards ("NAAQS") for particulate matter ("$PM_{2.5}$") is one of the most consequential actions EPA takes to protect Americans' health and welfare. Under the Clean Air Act, EPA's review of the NAAQS must "accurately reflect" the "latest scientific knowledge." 42 U.S.C. § 7408(a)(2). The review must be "thorough." *Id.* § 7409(d)(1). The Clean Air Act also requires that EPA select standards which are requisite to protect public health and welfare, and which provide an adequate margin of safety to protect public health. It is a task which EPA should approach with the deepest sense of responsibility, because the decision's effects on public health and welfare are profound, and the law requires EPA to select a standard without relying on cost or technical feasibility of the standards set.

The proposal, however, does not set standards at the levels the statute's directive demands. It flies in the face of a coherent body of evidence which mandates strengthening revisions to the primary annual and 24-hour $PM_{2.5}$ standards, and the secondary welfare standard, to provide the requisite protection of health and welfare. It provides no margin of safety; indeed, the issue is not even addressed. The proposal results from a review process that marginalized scientific expertise, in part overseen by an advisory committee whose members lack the needed expertise to determine what the air quality criteria are, much less to conduct the thorough review the statute specifies. This followed the EPA Administrator's unlawful blocking of persons with that expertise from serving on the committee. The Administrator's rationale for not revising the standards, which is grounded in the notion that the science is "uncertain," is contrary to the evidence of record, and antithetical to the precautionary mandate of the Act. The statutory commands to provide requisite protection and an adequate margin of safety cannot be evaded by invoking nebulous and inflated uncertainties.

As we explain herein, these problems with the proposal require that the agency reverse course and reopen the process or finalize stronger revised standards that provide the protections the law requires. Given the evidence, NGO Commenters recommend an annual primary standard of 8 $\mu g/m^3$ and tightening the 24-hour standard to provide adequate protection. The NGO commenters further recommend that EPA consider readily available scientific information, which supports strengthening the level of the secondary NAAQS and aligning the monitoring methods—in numeric standard and averaging time—with today's science to correlate with how the public perceives visibility. The existing record supports these actions now.

II. EPA's Legal Obligations in Setting and Reviewing the NAAQS

A. EPA's role in setting and revising the NAAQS

The Clean Air Act Amendments of 1970 first introduced the requirement to establish enforceable NAAQS. The amendments were intended to be "a drastic remedy to what was perceived as a serious and otherwise uncheckable problem of air pollution." *Union Electric Co. v. EPA*, 427 U.S. 246, 256 (1976). The 1970 amendments "carrie[d] the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health." 116 Cong. Rec. 42,329, 42,381 (Dec. 18, 1970) (remarks of Senator Muskie).

The NAAQS drive the Clean Air Act's requirements for controlling emissions of conventional air pollutants. Once EPA establishes NAAQS, states and EPA identify those geographic areas that fail to meet the standards. 42 U.S.C. § 7407(d). Each state must prepare an "implementation plan" designed to control pollutant emissions in order to reduce the ambient concentrations of the pollutant to below the level of the NAAQS and maintain that improved air quality. *Id.* § 7410.

The Clean Air Act provides a clear process for establishing the NAAQS. The first step in establishing NAAQS involves identifying those pollutants, the "emissions of which, in [EPA's] judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare," and "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources." *Id.* §§ 7408(a)(1)(A), (B). Once EPA identifies a pollutant, it must select a NAAQS that is based on air quality criteria that "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." *Id.* § 7408(a)(2).

Primary NAAQS must be set at a level "requisite to protect the public health" with "an adequate margin of safety." *Id.* § 7409(b)(1). To ensure that the NAAQS keep pace with scientific understanding and continue to provide the necessary protection, EPA must review and revise as appropriate the underlying air quality criteria and the NAAQS themselves at least every five years. *Id.* § 7409(d)(1). Any primary NAAQS that EPA promulgates under these provisions must be adequate to protect public health and provide an adequate margin of safety, in order to prevent not only any known or anticipated health-related effects from polluted air, but also those that are scientifically uncertain or that research has not yet uncovered. Further, the statute makes clear that there are significant limitations on the discretion granted to EPA in selecting a level for the

NAAQS. In exercising its judgment, EPA must err on the side of protecting public health, and may not consider cost or feasibility in connection with establishing the level of the NAAQS and its other elements (e.g., indicator, the form of the standard, and averaging time). The D.C. Circuit summed up EPA's mandate succinctly:

> Based on these comprehensive [air quality] criteria and taking account of the "preventative" and "precautionary" nature of the act, … the Administrator must then decide what margin of safety will protect the public health from the pollutant's adverse effects – not just known adverse effects, but those of scientific uncertainty or that "research has not yet uncovered." … Then, and without reference to cost or technological feasibility, the Administrator must promulgate national standards that limit emissions sufficiently to establish that margin of safety.

Am. Lung Ass'n v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998) (citations omitted); *see also Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 464-71 (2001). Each of these requirements is discussed in more detail below.

B. EPA must issue air quality criteria that accurately reflect the latest scientific knowledge, and the primary NAAQS must protect public health with an adequate margin of safety based on the criteria.

In setting or revising a primary NAAQS, section 109 of the Clean Air Act requires that EPA assure the protection of public health with an adequate margin of safety. This mandate "carries the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health," 116 Cong. Rec. 42,329, 42,381 (Dec. 18, 1970) (remarks of Senator Muskie).

Standards must be based on an air quality level requisite to protect public health and not on an estimate of how many persons will intersect given concentration levels.[1] EPA interprets the Clean Air Act as providing citizens the opportunity to pursue their normal activities in a healthy environment. 44 Fed. Reg. 8,202, 8,210 (Feb. 8, 1979). Thus, as EPA has acknowledged, it cannot deny Americans protection from the effects of air pollution by claiming that the people experiencing those effects are insufficiently numerous, or that levels that are likely to cause adverse health effects occur only in areas that are infrequently visited.[2] Nor can EPA deny

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[1] *See* 116 Cong. Rec. 32,821, 32,901 (Sept. 21, 1970) (remarks of Senator Muskie) ("This bill states that all Americans in all parts of the Nation should have clean air to breathe, air that will have no adverse effects on their health.").

[2] *See* 116 Cong. Rec. 32,981, 33,114 (Sept. 22, 1970) (remarks of Senator Nelson) ("This bill before us is a firm congressional statement that all Americans in all parts of the Nation should have clean air to

protection against adverse health and welfare effects merely because those effects are confined to subgroups of the population or to persons especially sensitive to air pollution. See, e.g., *Nat'l Envtl. Ass'n's Clean Air Project v. EPA*, 686 F.3d 803, 810 (D.C. Cir. 2012).

Further, where scientific evidence confirms that, at levels allowed by current NAAQS, adverse effects occur year after year in numerous individuals, risks are by definition "significant" enough to require protection under the Act's protective and precautionary approach. *See* H. Rep. No. 95-294, 1st Sess., at 43–51 (1977); *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976) (en banc). That is all the more true where the effects involved include highly serious ones like death and hospitalization. See *Ethyl Corp*., 541 F.2d at 18 ("the public health may properly be found endangered … by a lesser risk of a greater harm").

1. The adequate margin of safety addresses uncertainties in the scientific information, and EPA must err on the side of protecting public health when there is scientific uncertainty.

The D.C. Circuit has characterized the NAAQS as "preventive in nature." *E.g.*, *Ethyl Corp.*, 541 F.2d at 15; *see also* H. Rep. No. 95-294, at 49-51 (explaining amendments designed *inter alia* "[t]o emphasize the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs"). The Act's mandate requires that in considering uncertainty EPA "must err on the side of caution" in terms of protecting human health and welfare: "The Act requires EPA to promulgate protective primary NAAQS even where … the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree.'" *E.g.*, *Am. Trucking Ass'ns v. EPA* (*ATA III*), 283 F.3d 355, 369, 378 (D.C. Cir. 2002) (quoting Particulate Matter NAAQS, 62 Fed. Reg. 38,652, 38,653 (July 18, 1997)).

Thus, in keeping with the precautionary and preventive nature of the NAAQS, EPA must set standards that protect against potential adverse health effects—not just those impacts that have been well-established by science. *See id.* at 369 (citing 1997 Ozone NAAQS, 62 Fed. Reg. 38, 856, 38,857 (July 18, 1997)) (section 109(b)(1)'s "margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information ... as well as to provide a reasonable degree of protection against hazards that research has not yet identified"); *see also Am. Petroleum Inst. v. EPA*, 684 F.3d 1342, 1352 (D.C. Cir. 2012).

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breathe, air which does not attack their health."); *See also id.* at 33,116 (remarks of Senator Cooper) ("The committee modified the President's proposal somewhat so that the national ambient air quality standard for any pollution agent represents the level of air quality necessary to protect the health of persons."); 116 Cong. Rec. 42,329, 42,392 (Dec. 18, 1970) (remarks of Senator Randolph) ("[W]e have to insure the protection of the health of the citizens of this Nation, and we have to protect against environmental insults—for when the health of the Nation is endangered, so is our welfare, and so is our economic prosperity"); *id.* at 42,523 (remarks of Congressman Vanik) ("Human health and comfort has been placed in the priority in which it belongs—first place.").

In the seminal case on the NAAQS, the D.C. Circuit found that Congress "specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980). Limited data is not an excuse for failing to establish the level at which there is no significant risk of adverse effects. To the contrary, "Congress' directive to the Administrator to allow an 'adequate margin of safety' alone 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 1154-55 (quoting H. Rep. No. 95-294, at 520 (1977), as reprinted in 1977 U.S.C.C.A.N. 1077, 1480)).

In another case dealing with this same "margin of safety" requirement, the D.C. Circuit rejected industry's argument that EPA was required to document "proof of actual harm" as a prerequisite to regulation, instead upholding EPA's conclusion that the Act contemplates regulation where there is "a significant risk of harm." *Ethyl Corp*., 541 F.2d at 12-13. Noting the newness of many human alterations of the environment, the court found:

> Sometimes, of course, relatively certain proof of danger or harm from such modifications can be readily found. But, more commonly, "reasonable medical concerns" and theory long precede certainty. Yet the statutes and commonsense demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.

Id. at 25; *accord Indus. Union Dep't v. Am. Petroleum Inst*., 448 U.S. 607, 655-56 (1980) (agency need not support finding of significant risk "with anything approaching scientific certainty," but rather must have "some leeway where its findings must be made on the frontiers of scientific knowledge," and "is free to use conservative assumptions in interpreting the data," "risking error on the side of overprotection rather than underprotection"). Rather, as discussed above, EPA must act in the face of "inevitable" scientific uncertainty, *Lead Indus. Ass'n*, 647 F. 2d at 1154, and take a protective and precautionary approach that errs on the side of caution in interpreting uncertainty.

2. EPA is required to establish NAAQS that protect vulnerable subpopulations.

Importantly, as noted above, the NAAQS must be set at levels that are not simply adequate to protect the average member of the population, but must also protect against adverse effects in vulnerable subpopulations, such as children, the elderly, socially disadvantaged, and people with heart and lung disease. The D.C. Circuit has repeatedly found that if a certain level of a pollutant "adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *Am. Lung Ass'n*, 134 F.3d at 390 (citation omitted); *see also Coal. of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 618 (D.C. Cir. 2010); *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 524 (D.C. Cir. 2009). EPA must also build into the NAAQS an adequate margin of safety for these sensitive subpopulations. *See Am. Farm Bureau Fed'n*, 559 F.3d at 526.

The drafters of the 1970 Clean Air Act Amendments made clear that the millions of Americans subject to respiratory ailments are entitled to the protection of the NAAQS: "Included among those persons whose health should be protected by the ambient standard are particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment." S. Rep. No. 91-1196, at 10 (1970). As the D.C. Circuit has explained:

> In its effort to reduce air pollution, Congress defined public health broadly. 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, 134 F.3d at 390 (citations omitted); *Nat'l Envtl. Dev. Ass'n's Clean Air Project*, 684 F.3d at 810. NAAQS must "be set at a level at which there is 'an absence of adverse effect' on these sensitive individuals." *Lead Indus. Ass'n*, 647 F.2d at 1153.

3. The only lawful consideration in setting NAAQS is the effect of the pollutant in the air on health and welfare.

It is well-established that the Act requires EPA to set health- and welfare-protective NAAQS for a pollutant based solely on the health and welfare effects caused by that pollutant in the ambient air, without regard to the sources of the pollutant or any costs of implementing the standards. *E.g.*, *Whitman*, 531 U.S. at 465, 469; *Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1040-41 (D.C. Cir. 1999), *reh'g granted in other part and denied in part*, 195 F.3d 4 (D.C. Cir. 1999) *aff'd in relevant part sub nom.Whitman,* 531 U.S. 457 (2001); *Nat. Res. Def. Council* v. *EPA*, 902 F.2d 962, 972-73 (D.C. Cir. 1990), *vacated in unrelated part by* 921 F.2d 326 (D.C. Cir. 1991); *Nat. Res. Def. Council v. EPA*, 824 F.2d 1146, 1157, 1159 (D.C. Cir. 1987) (en banc); *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); *Lead Indus. Ass'n*, 647 F.2d at 1148-50 & n.39.[3] This principle was reaffirmed last year in *Murray Energy Corp. v. EPA*, 936 F.3d 597,

[3] The briefing in *Whitman* further shows that, in rejecting consideration of "costs," the Whitman Court rejected consideration of "overall adverse … impacts" in NAAQS reviews. Industry parties themselves said in Whitman that they were there arguing that EPA must consider precisely those types of impacts: "Congress intended that EPA exercise its public health risk management judgment based on consideration

622-24 (D.C. Cir. 2019), where the Court held that EPA must set the primary NAAQS based exclusively on public-health considerations, without regard to "background" levels of the pollutant. "Attainability and technological feasibility are not relevant considerations in the promulgation of [NAAQS]." *Id.* (citation omitted).

III. EPA has Failed to Comply with the Clean Air Act's Requirements for Reviewing the NAAQS

A. EPA failed to comply with Section 108's requirement that the scientific criteria include the "latest scientific information" relevant.

This proposal is unlawful because EPA has failed to fulfill its statutory responsibilities under section 108 of the Clean Air Act for the NAAQS review process. Without resolving these critical issues, EPA cannot finalize this proposed rule.

1. Clean Air Act section 108.

The Clean Air Act provides a clear process for establishing the NAAQS. The first step in establishing a NAAQS involves identifying those pollutants, the "emissions of which, in [EPA's] judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare," and "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources." 42 U.S.C. §§ 7408(a)(1)(A), (B). Once EPA identifies a pollutant, it must select a NAAQS that is based on air quality criteria reflecting "the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air . . . ." *Id.* § 7408(a)(2).

2. The Proposal violates Clean Air Act section 108.

The Proposal is unlawful, arbitrary and capricious, and otherwise an abuse of discretion because EPA has failed to base its decision on air quality criteria reflecting "the latest scientific

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of the overall impact of its decision on society." Appalachian Power Co. Resp. Br. ("Power Co. Whitman Resp.") 34, *Whitman v. Am. Trucking Ass'ns*, No. 99-1257 (U.S.). Indeed, various parties argued to the Supreme Court that EPA must consider broad impacts beyond just the "costs of implementation." The Court found that the "text of § [74]09(b), interpreted in its statutory and historical context and with appreciation for its importance to the [Act] as a whole," foreclosed all these arguments about costs. *Whitman*, 531 U.S. at 471.The D.C. Circuit later explained, "[i]t is only health effects relating to pollutants in the air that EPA may consider." *Nat. Res. Def. Council*, 902 F.2d at 973 (emphasis in original); *see also Murray Energy v. EPA*, 936 F.3d 597, 621-22 (D.C. Cir. 2019) (making it again clear that costs—"however denominated"—cannot play any lawful role in standard-setting).

knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air . . . ." *Id.* § 7408(a)(2). This unlawful action is a direct result of the agency's failure to seek review of second drafts of the ISA and the PA. In prior reviews of NAAQS pollutants, EPA did conduct these additional reviews, in order to meet section 108's obligation to consider the "latest scientific knowledge."[4]

These additional review periods in the past provided EPA officials, members of the Clean Air Scientific Advisory Committee ("CASAC"), and the public an important opportunity to add potentially important new studies. The current review of the $PM_{2.5}$ standards denied these opportunities. EPA's process failed to review and consider "the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air . . . ." *Id.* § 7408(a)(2). EPA's ISA excluded studies published after January 2018. The CASAC majority relied on more recent studies, of its own selective choosing, to support maintaining unsafe $PM_{2.5}$ standards, *id.* (citing "Burns, *et al.*" 2019), while irrationally ignoring many more studies that support strengthening the annual and daily $PM_{2.5}$ standards (see section VII.D.2).[5] Then, the Administrator relied upon the arbitrary recommendations of the CASAC majority to reach the agency's own arbitrary, capricious, and unlawful decision to maintain unprotective standards in its Proposal. 85 Fed. Reg. 24,094 (Apr. 30, 2020).

We compile here and in section VII.D.2 important studies that EPA and CASAC have failed to consider, demonstrating the Proposal's unlawful, arbitrary and capricious failure to be based on "the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air . . . ." *Id.* § 7408(a)(2). EPA's illegal, arbitrary and capricious failure to have considered these studies, thus far, is exacerbated because commenters offered many of these studies, already, to both EPA and CASAC, during their review of the existing standards, prior to the Proposal. Moreover, as noted above, the agency cannot selectively consider some newer studies but refuse to consider others.

The weight of evidence, even though resulting from a deeply flawed process, is sufficient to compel revision to strengthen the primary standards. However, EPA must at least consider these later studies, then issue a supplemental proposal, or, as in past reviews, a Provisional Assessment available for public comment, to give the public an opportunity to comment on the agency's consideration of these studies. Such a supplemental proposal should propose strengthening

[4] *See*, *e.g.*, U.S. EPA, Quantitative Health Risk Assessment for Particulate Matter (Second External Review Draft) (Feb. 2010); https://www3.epa.gov/ttn/naaqs/standards/pm/data/20100209RA2ndExternalReviewDraft.pdf; U.S. EPA, Integrated Science Assessment for Particulate Matter(Second External Review Draft) (July 2009), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=210586.

[5] As explained below, ironically, CASAC misinterpreted most of the post-ISA studies it did cite.

revisions to the annual and daily $PM_{2.5}$ standards, consistent with the evidence in these studies, the existing evidence of record, and consistent with these comments. Any failure by EPA to meaningfully consider these studies, and to afford the public the required opportunity to comment, will be unlawful, arbitrary and capricious, and an abuse of discretion.

CASAC has ignored and EPA has not evaluated published studies that are directly relevant to the NAAQS. Specifically, a number of newer studies are of clear relevance to the Proposal and the links between fine particulate matter and adverse health outcomes. Several of these studies help to illuminate adverse health responses at levels below the NAAQS. These include studies focusing on a range of endpoints, including mortality[6] and reduced life expectancy.[7,8]

In the PA, EPA notes that "The CASAC members who support retaining the current annual standard express the view that substantial uncertainty remains in the evidence for associations between $PM_{2.5}$ exposures and mortality or serious morbidity effects. These committee members assert that "such associations can reasonably be explained in light of uncontrolled confounding and other potential sources of error and bias" (Cox, 2019, p. 8 of consensus responses). They note that associations do not necessarily reflect causal effects, and they cite recent reviews (*i.e.*, Henneman et al., 2017; Burns et al., 2019) to support their position that in intervention studies, "reductions of PM2.5 concentrations have not clearly reduced mortality risks" (Cox, 2019, p. 8 of consensus responses)."[9] CASAC distorts the degree of uncertainty remaining in the associations between $PM_{2.5}$ exposures and mortality by ignoring virtually the entire weight of evidence, also discussed below.

Moreover, CASAC and the Administrator cite review articles from 2019 while disregarding important recent studies, some from dates earlier than the (secondary) references to which they refer and rely. Especially notable is the 2018 meta-analysis of 53 cohort studies which found

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[6] Fan, Maoyong, and Yi Wang. 2020. "The Impact of PM2.5 on Mortality in Older Adults: Evidence from Retirement of Coal-Fired Power Plants in the United States." *Environmental Health* 19 (1): 28. https://doi.org/10.1186/s12940-020-00573-2.

[7] Schwartz, Joel D., Yan Wang, Itai Kloog, Ma'ayan Yitshak-Sade, Francesca Dominici, and Antonella Zanobetti. 2018. "Estimating the Effects of PM2.5 on Life Expectancy Using Causal Modeling Methods." *Environmental Health Perspectives* 126 (12): 127002. https://doi.org/10.1289/EHP3130.

[8] Bennett, James E, Helen Tamura-Wicks, Robbie M Parks, Richard T Burnett, C Arden Pope, Matthew J Bechle, Julian D Marshall, Goodarz Danaei, and Majid Ezzati. 2019. "Particulate Matter Air Pollution and National and County Life Expectancy Loss in the USA: A Spatiotemporal Analysis." *PLOS Medicine*, 18. https://doi.org/10.1371/journal. pmed.1002856.

[9] 3-98 of U.S. Environmental Protection Agency. 2020. "Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter." https://www.epa.gov/sites/production/files/2020-01/documents/final_policy_assessment_for_the_review_of_the_pm_naaqs_01-2020.pdf.

significant associations between PM2.5 well below 12 μg/m^3 and mortality.[10] This study was presented to CASAC during its deliberations, yet it goes unmentioned in the CASAC letter, in the comments of individual CASAC members, and by the Administrator. Not only is exclusion of the study arbitrary given consideration of other post-ISA studies, but the lack of consideration violates section 108(a)(2)'s express command to consider "latest" information that "accurately reflects" pollution science, and violates standard administrative law principles to consider best data as well.[11] It is further arbitrary for CASAC and the Administrator to rely on a secondary reference—which they turn out to largely misinterpret in any case, as discussed below in greater depth—rather than a highly specific meta-analysis of key available studies Cf. *City of Waukesha v. EPA*, 320 F. 3d 228, 254 (D.C. Cir. 2003) (failure of EPA to refer to a secondary source is not arbitrary and capricious, since that source is just a summary of published literature).

Another study necessitating consideration is the major study by Pope et al. (2019)[12], which evaluated $PM_{2.5}$ and mortality risks using a large cohort that is representative of the U.S. population and is based on recent public data, strengthens the evidence base demonstrating a causal link between $PM_{2.5}$ exposure and mortality from cardiopulmonary diseases and lung cancer. That study, using National Health Interview Surveys (1986-2014) with mortality data through 2015, identified robust evidence that long-term $PM_{2.5}$ exposure worsens cardiovascular mortality risks across subgroups of age, sex, race-ethnicity, income, education, and geographic region. The study controlled for individual risk factors and regional and urban versus rural differences. The study found a hazard ratio of 1.12 (95% CI 1.08-1.15) for all-cause mortality, 1.23 (95% CI:1.17-1.29) for cardiopulmonary mortality, and 1.12 (95%CI: 1.00-1.26) for lung cancer mortality. In general, $PM_{2.5}$–mortality associations were consistently positive for all-cause and cardiopulmonary mortality across key modeling choices and across subgroups of sex, age, race-ethnicity, income, education levels, and geographic regions. Importantly, the mean $PM_{2.5}$ concentration in that study was 10.7 μg/m^3 and ranged from 2.5-19.2 μg/m^3.

[10] Vodonos, Alina, Yara Abu Awad, and Joel Schwartz. 2018. "The Concentration-Response between Long-Term PM2.5 Exposure and Mortality; A Meta-Regression Approach." *Environmental Research* 166 (October): 677–89. https://doi.org/10.1016/j.envres.2018.06.021.

[11] "The best available data requirement ... prohibits [an agency] from disregarding available scientific evidence that is in some way better than the evidence [it] relies on.'" Kern Cnty. Farm Bureau v. Allen, 450 F.3d 1072, 1080 (9th Cir. 2006) (quoting Sw. Ctr. for Biological Diversity v. Babbitt, 215 F.3d 58, 60 (D.C. Cir. 2000)). "Essentially, [the agency] 'cannot ignore available ... information.'" San Luis & Delta-Mendota Water Auth. v. Jewell, 747 F.3d 581, 602 (9th Cir. 2014) (quoting Kern Cnty., 450 F.3d at 1080-81 (quoting Conner v. Burford, 848 F.2d 1441, 1454 (9th Cir. 1988)).

[12] Pope, C. Arden, Jacob S. Lefler, Majid Ezzati, Joshua D. Higbee, Julian D. Marshall, Sun-Young Kim, Matthew Bechle, et al. 2019. "Mortality Risk and Fine Particulate Air Pollution in a Large, Representative Cohort of U.S. Adults." Environmental Health Perspectives 127 (7): 077007. https://doi.org/10.1289/EHP4438.

Importantly, other studies ignored by CASAC bolster causality determinations presented in the ISA and support the approach in the PA quantifying human health benefits from improved air quality.[13,14,15,16]

B. EPA's approach is backwards and departs from longstanding legal requirements

The Administrator's proposed decision to retain the primary PM2.5 annual standard is fundamentally at odds with the Clean Air Act's essential purpose and requirements. Ignoring precedent and the statutory directive to set standards at a precautionary level—one "allowing an adequate margin of safety," the Administrator proposes to leave the primary $PM_{2.5}$ standards unrevised because he contends there is no absolute proof or certainty that observed associations between $PM_{2.5}$ and adverse effects at ambient levels are causal. The Administrator proposes not to revise the primary annual standard even though there is coherent and powerful evidence of the most serious harm; and more than ample epidemiological evidence of dire harm, at human exposure levels well below those allowed by the current annual PM2.5 NAAQS; corroborating clinical evidence showing the biological plausibility of those effects; and accountability and similar related studies showing reductions in health effects when PM2.5 levels are reduced. The Proposal ignores or arbitrarily gives inadequate weight to all this evidence, because the Administrator sees no absolute corroboration from clinical and accountability studies, and because he finds purported uncertainty due to "confounding and other potential sources of error and bias," a statement which is not detailed or supported. 85 Fed. Reg. 24,094, 24,119 (Apr. 30, 2020).

The Administrator insists that controlled human exposure studies are the chief evidence for whether or not to revise the standard, *id.* at 24,119-20, and, further, disregards the entire body of epidemiologic evidence due to absence of corroborative effects from controlled human exposure studies conducted at the same levels as levels in these epidemiological studies. *Id.* at 24,120 ("leaves important questions unanswered regarding the degree to which the typical $PM_{2.5}$

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[13] Schwartz, Joel D., Yan Wang, Itai Kloog, Ma'ayan Yitshak-Sade, Francesca Dominici, and Antonella Zanobetti. 2018. "Estimating the Effects of PM2.5 on Life Expectancy Using Causal Modeling Methods." *Environmental Health Perspectives* 126 (12): 127002. https://doi.org/10.1289/EHP3130.

[14] Bowe, Benjamin, Yan Xie, Yan Yan, and Ziyad Al-Aly. 2019. "Burden of Cause-Specific Mortality Associated With PM2.5 Air Pollution in the United States." *JAMA Network Open* 2 (11): e1915834. https://doi.org/10.1001/jamanetworkopen.2019.15834.

[15] Zigler, Corwin M., Christine Choirat, and Francesca Dominici. 2018. "Impact of National Ambient Air Quality Standards Nonattainment Designations on Particulate Pollution and Health." *Epidemiology (Cambridge, Mass.)* 29 (2): 165–74. https://doi.org/10.1097/EDE.0000000000000777. This study was recommended to CASAC and EPA in public comments submitted in two public meetings. See discussion in VIIID.

[16] Wu, X., Braun, D., Schwartz, J., Kioumourtzoglou, M. A., & Dominici, F. (2020). Evaluating the impact of long-term exposure to fine particulate matter on mortality among the elderly. Science Advances, eaba5692.

exposures likely to occur in areas meeting the current standard can cause the mortality or morbidity outcomes reported in epidemiological studies"). The Administrator also invokes unspecified uncertainties as a reason to disregard the entire body of epidemiological evidence, *id.* at 24,119 (associations reported in epidemiological studies "'can reasonably be explained in light of uncontrolled confounding and other potential sources of error and bias'"), and insists on accountability/manipulative causation studies showing "health improvements attributable to reductions in $PM_{2.5}$ in locations meeting the current standards," even though such improvements have been demonstrated in these studies at higher levels of $PM_{2.5}$. *Id.* at 24,120.

The Administrator's insistence on certainty or proof of harm at $PM_{2.5}$ levels below 12 $\mu g/m^3$ as a basis for inaction is unlawful, arbitrary and capricious, and an abuse of discretion. Indeed, it is at odds with law which has been clearly established for 40-some years: the very first case to consider a NAAQS, *Lead Indus. Ass'n v. EPA*, 647 F. 2d 1130 (D.C. Cir. 1980), rejected this approach. The court considered arguments that NAAQS are solely "designed to protect the public from adverse health effects that are clearly harmful", that to revise a NAAQS, there must be a "showing that the effects on which the standards were based are clearly harmful or clearly adverse," and therefore that "EPA [is] to wait until it can conclusively demonstrate that a particular effect is adverse to health before it acts."[17] Rejecting these arguments, the court held that: "requiring EPA to wait until it can conclusively demonstrate that a particular effect is adverse to health before it acts is inconsistent with both the Act's precautionary nature and preventive orientation and the nature of the Administrator's statutory responsibilities." [18] The court continued, in language directly applicable here:

> This court has previously noted that some uncertainty about the health effects of air pollution is inevitable. And we pointed out that "(a)waiting certainty will often allow for only reactive, not preventive regulat(ory action)." Congress apparently shares this view; it specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement….. Congress's directive to the Administrator to allow an 'adequate margin of safety' alone 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.[19]

[17] *Lead Indus. Ass'n v. EPA*, 647 F. 2d 1130, 1151, 1154, 1155 (D.C. Cir. 1980).
[18] *Id.* at 1155.
[19] *Id.* at 1154-55 (internal quotations omitted). *See also id*. at n.48: "Questions involving the environment are particularly prone to uncertainty. Technological man has altered his world in ways never before experienced or anticipated. The health effects of such alterations are often unknown, sometimes unknowable. While a concerned Congress has passed legislation providing for protection of the public health against gross environmental modifications, the regulators entrusted with the enforcement of such laws have not thereby been endowed with a prescience that removes all doubt from their decisionmaking. Rather, speculation, conflicts in evidence, and theoretical extrapolation typify their every action. How

The issue considered in *Lead Industries* was whether a particular effect had to be proven adverse to allow promulgation of a primary NAAQS, but the principle that the Administrator must not and cannot wait for proof or certainty of causation is generally applicable. This is confirmed by the same court's holding in *American Trucking Associations v. EPA.*[20] Petitioners argued there, essentially as the Administrator does here, that EPA could not revise a primary NAAQS based on epidemiological studies because of "the absence of proof of causation — i.e., how particles actually interact with cells and organs to cause sickness and death."[21] The court soundly rejected this argument. First, "[T]he statute itself requires no such proof. The Administrator may regulate air pollutants 'emissions of which, in his judgment, *cause or contribute* to air pollution which may *reasonably be anticipated* to endanger public health or welfare."[22] Second, "[W]ere we to accept petitioners' view, EPA (or any agency) would be powerless to act whenever it first recognizes clear trends of mortality or morbidity in areas dominated by a particular pathogen."[23] The court then found the epidemiological evidence showing "statistically significant relationships between air-borne particulates … and adverse health effects" in "diverse geographic locations with widely varying mixes of air pollution" to "amply justif[y]" the standard for fine particles.[24]

The facts here are even more compelling. Not only are there epidemiological studies of extraordinary statistical power which "show robust statistical relationships between pollution and health effects"[25] in areas with air quality allowed by the current standards,[26] but there is ample evidence of biological plausibility for these effects as well. The Administrator's attempted resurrection of the discredited and rejected insistence on proof of causation provides no basis to justify failure to revise the primary PM2.5 NAAQS. In these respects, the Proposal is unlawful, arbitrary and capricious, and an abuse of discretion.

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else can they act, given a mandate to protect the public health but only a slight or nonexistent database from which to draw? * * * Sometimes, of course, relatively certain proof of danger or harm from such modifications can readily be found. But, more commonly, "reasonable medical concerns" and theory long precede certainty. Yet the statutes and common sense demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable." (emphasis added).

[20] "*ATA I,*" 175 F.3d 1027 (D.C. Cir. 1999), *rev'd on other grounds sub nom.*, *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001).

[21] *Id*. at 1055.

[22] *Id.* at 1055(quoting CAA section 108(a)(1)(A))(emphasis in original).

[23] *Id.* at 1056.

[24] *Id.*

[25] *Id.* at 1055.

[26] *See*, *e.g.*, *Am. Trucking Ass'ns v. EPA*, 283 F. 3d 355, 370 (D.C. Cir. 2002) ("*ATA III*"); *Am.Petroleum Inst. v. EPA*, 655 F.2d 1176, 1185 (D.C. Cir. 1981); *National Ass'n of Mfr's v. EPA*, 750 F. 3d 921, 924 (D.C. Cir. 2014).

C. The Administrator also cannot rely on professed uncertainties.

The Act does not say that the Administrator may act notwithstanding the "inevitable"[27] scientific uncertainties—it says the Administrator *must* act. Thus, "EPA *must* err on the side of caution . . . setting the NAAQS at whatever level it deems necessary and sufficient to protect the public health with an adequate margin of safety, taking into account both the available evidence *and the inevitable scientific uncertainties*."[28] As the D.C. Circuit has held, *en banc*, "EPA should set standards providing a 'reasonable degree of protection … against hazards which research has not yet identified.'"[29] In the face of these explicit directives, the Administrator proposes the exact opposite.[30]

The Administrator's invocation of unspecified uncertainties violates not only these established NAAQS principles, but general administrative law principles as well. "It is a familiar principle that agencies may not 'merely recite the terms 'substantial uncertainty' as a justification for [their] actions'; instead, they 'must explain the evidence which is available, and must offer a rational connection between the facts found and the choice made.'"[31] "The mere invocation of 'substantial uncertainty' is not a justification for the agency's failure to fulfill its statutory mission."[32] The Administrator's nebulous reference to "uncontrolled confounding and other

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[27] *Lead Indust.*, 647 F.2d at 1155.
[28] *ATA III*, 283 F.3d at 378 (emphasis added) ; *see also id.* at 369 ("we have expressly rejected the notion that the Agency must 'establish a measure of the risk to safety it considers adequate to protect public health every time its establishes a NAAQS. *Such a rule would compel EPA to leave hazardous pollutants unregulated unless and until it completely understands every risk they pose, thus thwarting the Clean Air Act's requirement that the Agency err on the side of caution by setting primary NAAQS that 'allow an adequate margin of safety.'* The Act requires EPA to promulgate protective primary NAAQS even where, as here,the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree.'" (emphasis added; internal citations omitted); *Am. Petroleum Inst. v. EPA*, 684 F. 3d 1342, 1353 (D.C. Cir. 2012) (NAAQS create a "duty to err on the side of caution"); *see also American Farm Bur. v. EPA*, 559 F. 3d 512, 533 (D.C. Cir. 2009) ("[T]he agency need not wait for conclusive findings before regulating a pollutant it reasonably believes may pose a significant risk to public health").
[29] *Nat. Res. Def. Council v. EPA*, 824 F. 2d 1146, 1152 (D.C. Cir. 1987) (quoting S. Rep. No. 91-1196, 91st Cong. 2d Sess. (1970)).
[30] In *Mississippi v. EPA*, 744 F. 3d 1334 (D.C. Cir. 2013), the court upheld EPA's decision not to revise the level of the primary ozone NAAQS to an even lower level based on epidemiological studies, and to base the revised level, instead, on results from controlled human exposure studies. 744 F. 3d at 1351-52. That situation is not analogous to the one here, for at least three reasons: (1) the primary standard was in fact revised to be more stringent; (2) the agency invoked the epidemiological evidence as part of a coherent body of evidence supporting the decision to revise (*id.*, at 1347-48); and (3) the agency did not use the controlled human clinical studies to disavow the entire body of epidemiological evidence.
[31] *Mississippi*, 744 F. 3d at 1357, quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983) .
[32] *Murray Energy v. EPA*, 936 F. 3d 597,619 (D.C. Cir. 2019). *See also Wisconsin v. EPA*, 938 F. 3d 303, 318-19 (D.C. Cir. 2019) ("[s]cientific uncertainty, however, does not excuse EPA's failure to align the deadline for eliminating upwind States' significant contributions with the deadline for downwind

potential sources of error and bias," 85 Fed. Reg. at 24,119, is the very type of rote recitation these cases condemn. The Administrator's reference to CASAC's 2019 letter, without any further discussion, specificity or reasoned explanation, likewise is entirely inadequate. *Id*. In all these respects, the Proposal is unlawful, arbitrary and capricious, and an abuse of discretion.

The Administrator thus has it backwards. The law requires action, not insistence on absolute proof. The Administrator's approach is directly at odds with Clean Air Act section 109(d)'s general requirement to act in the face of inevitable uncertainty, and its specific requirement to establish an "adequate margin of safety," in order "to build a buffer against uncertain and unknown dangers to human health."[33] As discussed in greater detail below, the Administrator acted arbitrarily in rejecting the evidence-based framework, erred by ignoring the contrary science and policy conclusions and advice from his own EPA experts and from the dismissed CASAC panel of experts, and erred further in reliance on the advice from the divided chartered CASAC.

IV. EPA's Review of the $PM_{2.5}$ NAAQS Involved Critical Process Failures That Have Compromised the Basis for the Proposal.

In the course of this review, EPA has repeatedly departed from longstanding practices in a manner that marginalizes scientific research on the adverse impacts of particulate pollution. The agency's proposal to retain its existing and inadequate standards for $PM_{2.5}$ is at odds with the scientific record and must be abandoned, not incidentally because of these process lapses.

A. EPA has truncated the review process in ways that have compromised the proposed decision to retain the current standards.

Rather than undertaking a thorough assessment of the current standards and the latest science, as the law requires, EPA has truncated its review in numerous respects. Each of the shortcuts the agency has taken arbitrarily undermined the role of science in its review.

1. EPA drafted its policy assessment before completing a review of the latest scientific research.

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attainment of the NAAQS. 'Questions involving the environment are particularly prone to uncertainty,' but 'the statutes and common sense demand regulatory action to prevent harm, even if the regulator is less than certain.' As a result, 'EPA [cannot] avoid its statutory obligation by noting [scientific] uncertainty ... and concluding that it would therefore be better not to regulate at this time.' It is only when 'the scientific uncertainty is so profound that it precludes EPA from making a reasoned judgment' that it can excuse compliance with a statutory mandate.") (internal citations omitted).

[33] *Mississippi*, 744 F. 3d at 1353 (citing *Lead Industries Ass'n,* 647 F.2d at 1154).

Science and policy considerations were continuously confused throughout the NAAQS review process due to the conflation of review steps that were previously and purposefully distinct. The 2018 Pruitt NAAQS Memo directed EPA to "consider combining its integrated science, risk and exposure, and policy assessment ("PA" or "policy assessment") into a single review."[34] This resulted in the policy assessment being published before the science assessment had been reviewed and finalized, leading to an arbitrary comingling of science and policy. This marks a striking departure from the established precedent of finalizing the science assessment before starting the policy assessment so that the body of science that forms the basis for the review—*i.e.*, the air quality criteria—are fixed before the PA determines what parts of that science are policy relevant and then makes recommendations based on that body of science. As the Independent Particulate Matter Review Panel noted, "[T]he integrity of the process is harmed when policy issues are addressed before the science issues are adequately settled."[35]

The EPA's review documents are intended to be logically sequential, each building on the one before. Producing them concurrently conflicts with principle four of the Pruitt NAAQS memo, the separation of science and policy.[36] Concurrent preparation of the Policy Assessment and Integrated Science Assessment also undermined the CASAC's review and the public-review processes for each of the documents, which are meant to build upon each other.

2. EPA's truncated review process resulted in a failure to accurately reflect the latest scientific knowledge, due to a failure to adequately consider the body of science underlying the review.

Although the information in the ISA and PA compels revision of the primary standard, EPA's review, driven by the Pruitt Memo process described above, was not robust enough to adequately assess that information. The process departed from the 2016 Integrated Review Plan that CASAC approved, which reflected its views of what was needed for a scientifically appropriate review of the PM NAAQS. EPA, "Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter" (Dec. 2016) (EPA-452/R-16-005). That approved plan is shown in the following table:

[34] Memorandum from E. Scott Pruitt, Former Administrator, U.S. Environmental Protection Agency, on Back to Basics for Reviewing the National Ambient Air Quality Standards to EPA Assistant Administrators (May 9, 2018) ("2018 Pruitt NAAQS Memo") at 3, *available at* https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf.

[35] Advice from Independent Particulate Matter Review Panel to Administrator Andrew Wheeler ("IPMRP Advice") (October 22, 2019) at C-51 (Panel chair Frey).

[36] 2018 Pruitt NAAQS Memo, at 10, Principle 4.

Table 1-3. Anticipated schedule for the review of the PM NAAQS.

Stage of Review	Major Milestone	Actual or Target Date
Planning	Literature Search	Ongoing
	Federal Register Call for Information	December 3, 2014
	Workshop on Science/Policy Issues	February 9-11, 2015
	Release Draft IRP for CASAC/public review	April 2016
	CASAC Review Meeting for Draft IRP	May 23, 2016
	Release Final IRP	December 2016
Science Assessment	Release First Draft ISA for CASAC/public review	Fall 2017
	CASAC Review Meeting for First Draft ISA	Winter 2018
	Release Second Draft ISA for CASC/public review	Fall 2018
	CASAC Review Meeting for Second Draft ISA	Winter 2019
	Release Final ISA	Fall 2019
Risk/Exposure Assessments	Release REA Planning Document(s) for CASAC/public review	Fall 2017
	CASAC Review Meeting for REA Planning Document(s)	Winter 2018
	Release First Draft REA(s) for CASAC/Public Review	Fall 2018
	CASAC Review Meeting for First Draft REA(s)	Winter 2019
	Release Second Draft REA(s) for CASAC/Public Review	Fall 2019
	CASAC Review Meeting for Second Draft REA(s)	Winter 2020
	Release Final REA(s)	Fall 2020
Policy Assessment/ Rulemaking	Release First Draft PA for CASAC/public review	Fall 2018
	CASAC Review Meeting on First Draft PA	Winter 2019
	Release Second Draft PA	Fall 2019
	CASAC Review/Public Comment on Second Draft PA	Winter 2020
	Release Final PA	Fall 2020
	Proposed Rulemaking	2021
	Final Rulemaking	2022

CASAC, aided by the additional experts on the PM panel, thus reviewed and agreed to the plan for how the Draft ISA should be developed in 2016 when it reviewed the Integrated Review Plan (IRP) for the current review cycle. CASAC consequently already signed off on the methodological approach for elements of the Draft ISA, such as literature review, causal determination, assessment of at-risk populations and life stages. Notably, the CASAC-approved process required two drafts of the ISA, preparation of a Policy Assessment only after settling the science in a completed ISA, and preparation of a separate risk and exposure assessment.

The agency then negated this settled process, disregarding CASAC's advice embodied in its review and approval of the IRP. Instead, Administrator Pruitt made completion of the PM

NAAQS by December 2020 the sole objective without regard to the need for a robust scientific review process.[37]

Moreover, the agency, without explanation, has ignored its PM review practice of developing for public comment an assessment of studies published after the ISA cutoff date. The agency properly considered such an assessment to be a necessary and appropriate step given the continuing growth of research on fine particles since the 1997 standards. Such a process properly reflects the Act's requirement that air quality criteria "accurately" reflect "the latest scientific knowledge." 42 U.S.C. § 7408(a). The failure to do this on-going assessment violates section 108(a). The failure to acknowledge, much less explain, this change in approach is itself arbitrary—as is the jettisoning of the IRP without acknowledging its existence or CASAC's imprimatur thereof. *See*, *e.g. Physicians for Soc. Responsibility v. EPA*, 956 F.3d 634, 644 (D.C. Cir. 2020).

EPA refused to provide a revised draft of either the science assessment or the policy assessment, despite multiple calls for second drafts—including from the reconstituted CASAC as well as the disbanded Independent Particulate Matter Review Panel (IPMRP). In the April 2019 CASAC review of the draft ISA, CASAC "recommend[ed] development of a Second Draft ISA for CASAC review" due to "the need for substantial revisions of the Draft ISA to provide clearer definitions, and technical details and methods in order to enable meaningful independent scientific review."[38] In response to the CASAC review, Administrator Wheeler wrote that while "the difficulty [of completing the PM NAAQS review by the end of 2020] is not lost on [him]," he has "asked that staff maintain their focus on meeting [the] statutory deadlines…."[39] The final ISA was published without the release of a second draft. Similarly, in the December 2019 review of the draft PA, CASAC recommended that it have "an opportunity to review a revised draft of the PM PA based on the final PM ISA,"[40] as did the IPMRP. EPA refused to give CASAC this opportunity.

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[37] 2018 Pruitt NAAQS Memo, at 2-3.

[38] Letter from Dr. Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee, to Andrew R. Wheeler, Administrator, U.S. Environmental Protection Agency (Apr. 11, 2019) ("CASAC Review of the EPA's *Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018*) ("CASAC Letter"), *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002%20.PDF.

[39] Letter from the Honorable Andrew R. Wheeler, Administrator, US EPA, to Tony Cox, Chair, Clean Air Scientific Advisory Scientific Committee. July 25, 2019, *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/%24File/EPA-CASAC-19-002_Response.pdf.

[40] Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," at 4, December 16, 2019.

Significant prior experience shows that these complex and technical documents often require substantial revisions. Failing to issue second drafts of these documents severely undermines the opportunities for CASAC, public, and other expert comment on EPA's scientific and policy analyses, which are foundational to subsequent regulatory processes. Moreover, and critically, a second draft ISA (as contemplated by the IRP) would have allowed for consideration and inclusion of important additional studies, in keeping with the directives in CAA sections 108(a)(2) and 109(d)(1) to consider the "latest" "useful" science, as part of the "thorough review" of the air quality criteria and existing standards.[41] The truncated review undertaken by EPA, coupled with selective inclusion of post-ISA studies and exclusion of others, has led to a record that does not fully satisfy these requirements—notwithstanding that the record compels revision of the primary standards. In all these respects, the Proposal is unlawful, arbitrary and capricious, and an abuse of discretion.

The Administrator's reasoning for the arbitrary changes and rushing to complete this review by December 2020 is suspect on its face, and his approach leads here to unlawful consequences. The 2018 Pruitt NAAQS Memo was purportedly based on the principle that NAAQS reviews must meet the statutory deadlines, but this explanation, particularly in the context of the PM NAAQS, is implausible.[42] Because the previous revision to the PM NAAQS was finalized in January 2013, the statutory deadline was in January 2018.[43] The Pruitt NAAQS Memo was issued May 9, 2018, which was already clearly beyond the 5-year deadline. The arbitrary December 2020 date in the Pruitt NAAQS Memo is even further beyond that deadline.[44] And, as noted by the IPMRP, *id.*, at C-53, if statutory deadlines were the paramount concern, NAAQS for carbon monoxide, oxides of nitrogen, and oxides of sulfur were considerably further behind the statutory deadline and logically deserved to be prioritized.

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https://yosemite.epa.gov/sab/sabproduct.nsf/E2F6C71737201612852584D20069DFB1/$File/EPA-CASAC-20-001.pdf. ("CASAC PA Review")

[41] 42 U.S.C. § 7408(a)(2) and § 7409(d)(1).

[42] Memorandum from E. Scott Pruitt, Former Administrator, U.S. Environmental Protection Agency, on Back to Basics for Reviewing the National Ambient Air Quality Standards to EPA Assistant Administrators (May 9, 2018) ("2018 Pruitt NAAQS Memo"), *available at* https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf.

[43] National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3,085 (Jan. 15, 2013).

[44] *Id.*

More basically, the deadline is not a valid basis for substantively compromising the review. The statute still requires any decision to be based on the air quality criteria, which in turn are to be "useful" and to "accurately reflect the latest scientific knowledge." 42 U.S.C. § 7408(a)(2). The CASAC-approved IRP indicates what is necessary to properly fulfill those requirements. In particular, a second draft ISA is necessary not only to assess the science but also to augment the initial draft with further science emerging from the CASAC review and public comment process.

B. CASAC failed to conduct a meaningful scientific review of the ISA and PA.

1. EPA banned scientists from serving on committees (including CASAC) if they receive EPA grants, an unlawful, arbitrary and capricious policy

The Administrator's reliance on certain CASAC recommendations during this NAAQS review is unlawful and arbitrary because the Agency illegally limited the pool of potential appointees when selecting most of the members based on a directive issued by former EPA Administrator E. Scott Pruitt: "Strengthening and Improving Membership on EPA Federal Advisory Committees," U.S. Environmental Protection Agency, October 31, 2017 ("Pruitt directive"). That policy was rejected as arbitrary and capricious by both the D.C. Circuit and the Southern District of New York. *Physicians for Soc. Responsibility v. Wheeler*, 956 F.3d 634 (D.C. Cir. 2020); *Nat. Res. Def. Council v. EPA*, No. 19-cv-05174, 2020 WL 615072 (S.D.N.Y. Feb. 20, 2020) ("NRDC"). *See also Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020) (ruling the policy is judicially reviewable and remanding to the District of Massachusetts for further proceedings).

In the October 2017 directive, Administrator Pruitt announced that EPA would no longer allow scientists who have received grants from the agency to serve on its scientific committees. EPA grants are awarded through a competitive process and, therefore, researchers who receive those grants are often leading experts in their fields. As the D.C. Circuit recognized, this directive represented "a major break from the agency's prior policy, under which grantees regularly served on advisory committees." *Physicians for Soc. Responsibility,* 956 F.3d at 645.

The Southern District of New York declared EPA's exclusion of these experts arbitrary and capricious because, among other things, EPA failed to explain "why an outright ban on EPA grant recipients would improve the existing policies that required demanding and continuous conflict of interest reviews[.]" *Nat. Res. Def. Council*, No. 19-cv-05174, 2020 WL 615072, at *8 (Feb. 10, 2020) . The D.C. Circuit faulted EPA because it "nowhere confront[ed] the possibility that excluding grant recipients—that is, individuals who EPA has independently deemed qualified enough to receive competitive funding—from advisory committees might exclude" the candidates who are "'the most qualified, knowledgeable, and experienced[.]'" *Physicians for*

Soc. Responsibility, 956 F.3d at 647. The Southern District issued an order vacating the Pruitt directive on April 15, 2020, pronouncing these flaws "serious." *Nat. Res. Def. Council v. EPA*, No. 19-cv-05174, 2020 WL 2769491 (S.D.N.Y. Apr. 15, 2020). EPA has chosen not to appeal.[45] Accordingly, the Pruitt directive is void.

Because the CASAC advising EPA on this NAAQS review was illegally and arbitrarily constituted, EPA cannot lawfully rely on the advice of that CASAC for the proposed or final action in this matter. Due to the Pruitt directive, numerous scientists were illegally barred from even being considered for CASAC membership. Accordingly, CASAC's recommendations—on which the proposed action at issue here heavily relies—are legally void and the Administrator cannot lawfully rely on them.

The exclusion of scientists from CASAC based on the Pruitt directive thus rendered the decision-making process arbitrary. It was arbitrary for EPA both to take and to rely on advice from the illegally and arbitrarily formed CASAC, as described above. Further, had the Agency adhered to its longstanding practice, the pool of potential CASAC members would have included researchers with more expertise and experience with CASAC reviews. As the D.C. Circuit noted, "[t]he Administrator's failure to address [Office of Government Ethics] and EPA's contrary conclusions is 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." *Physicians for Soc. Responsibility,* 956 F.3d at 647. Instead, the Agency relied on a policy that was based on specious concerns about independence and conflicts of interest to hinder the committees' work. The decision criteria relied upon in the policy were arbitrary, unlawful, and unrelated to expertise. It is worth noting EPA had expressed no concerns about members who work for or are funded by industries or government entities subject to EPA regulation. Indeed, members from industry or government comprised the majority of the CASAC's membership during this review.

In summary, EPA undermined its own ability to find and appoint qualified scientists with the necessary expertise to the CASAC for the purpose of conducting the NAAQS review. Indeed, before it was disbanded entirely, a number of scientists were removed from CASAC's particulate-matter panel as a result of the directive.[46] A number of scientists nominated to CASAC and Administrator Wheeler's non-member pool of particulate-matter experts, moreover,

[45] Press Release, U.S. 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.

[46] Declarations of Peter Adams, Joel Kaufman, Rob McConnell, and Christopher Zarba (attached) (discussing removals from CASAC and its particulate-matter panel as a result of the directive).

were also ineligible as a result of the directive.[47] The directive required EPA to exclude many of the most qualified scientists from participating in the NAAQS review and frustrated the external review process, rendering the process and its outcome illegal and arbitrary.

2. EPA's Actions Denied the Agency the Very Expertise the Statute Demands EPA to Rely Upon in Setting the NAAQS

For four decades, the chartered seven-member CASAC has been augmented with additional experts to have the breadth, depth, and diversity of expertise needed to review multidisciplinary scientific issues relevant to each of the criteria pollutants regulated under the NAAQS.[48] That expert panel has been in place to fulfill the statute's requirement that the NAAQS reflect the latest scientific knowledge. The panel's intended role in the initial stages of this proposal, was reflected in the Independent Review Plan approved by CASAC and by the agency, and the panel selection was by open and lawful process.[49]

On October 10, 2018, without explanation, EPA Administrator Wheeler arbitrarily disbanded the Particulate Matter Review Panel, a group of independent experts on particulate pollution and health selected by the chartered CASAC to inform the EPA's review of the ambient particulate matter standard. The panel was actively participating in this review at the time of its unlawful disbanding.

[47] Compilation of EPA Grant Information regarding Nominees to CASAC and Administrator Wheeler's Expert Pool (attached) (documenting the ineligibility of three CASAC nominees—Howard Kipen, Rob McConnell, and Armistead Russell—and five expert-pool nominees—Peter DeCarlo, David Eaton, Joel Kaufman, Armistead Russell, and Ivan Rusyn—as a result of their EPA grants and the directive); *see also* Declaration of Edward Avol (attached) (noting that the directive had required him to choose between research funding and public service on the EPA's advisory committees, despite his previous work on numerous CASAC expert panels).

[48] CASAC's charter provides it with the authority to convene such expert panels. That charter states: "EPA, or CASAC with the Agency's approval, may form subcommittees or workgroups for any purpose consistent with this charter."" Of course, the panel is not CASAC, and does not itself make recommendations to the agency. As the CASAC charter states, "[s]uch subcommittees or workgroups may not work independently of the chartered committee and must report their recommendations and advice to the chartered CASAC for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered committee, nor can they report directly to the EPA." United States Environmental Protection Agency Charter, Clean Air Scientific Advisory Committee, Filed with Congress, June 5, 2019, https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal% 20Charter%203.21.19%20-%20final.pdf. Additional experts have been appointed to review panels that interact with members of the chartered CASAC for all reviews since the late 1970s. Over time, the chartered CASAC has typically been augmented with 12 or more additional experts in a given review cycle for a given criteria pollutant. The average number of experts among 20 such panels for which membership data is available is 14, and the average size of the review panels is 20 members, inclusive of participating CASAC members.

[49] *See* Request for Nominations, 80 Fed. Reg. 6,086 (Feb. 4, 2015).

Members of the disbanded expert panel have since continued to offer the Agency their expertise, in oral and written comments, despite having been summarily dismissed by the Administrator, in the interest of public health and the environment. That group of experts, now called the Independent Particulate Matter Review Panel (IPMRP or Panel), reconvened to ensure independent science advice reaches EPA decision makers. The IPMRP submitted comprehensive comments on both the ISA and the PA, as well as follow up comments to the Administrator and to the chartered CASAC.[50]

The agency has neither provided an explanation for disbanding the particulate matter panel, nor has it even acknowledged the IPMRP comments and advice in the proposal. These omissions constitute clear legal error and are arbitrary. In order that this review "accurately reflect" the relevant body of science, and a "thorough review" of that science, see CAA section 108(a)(2) and 109(d)(1), the agency must consider the IPMRP advice, and indeed accord it considerable weight, and ultimately, either follow its advice or provide a reasoned explanation for any differences with that advice.

The improper dismissal has drastic consequences. As noted below, the chartered CASAC, by its own admission, lacks the expertise to review the body of science underlying this review, and requested expert assistance from this very Panel.[51] This has resulted in a CASAC lacking the requisite expertise to undertake a complete and thorough review of the underlying body of science, despite having had at the outset, an expert panel with precisely the expertise required. Indeed, such expertise is the reason EPA's longstanding practice has been to ensure the availability of a review panel. And it is why this specific group of experts was chosen in the first place. And it is why the reconstituted CASAC asked that "EPA reappoint the previous CASAC PM panel."[52] The only credible way to provide a "thorough review" that "accurately reflect[s] the latest scientific knowledge" – as required by the Clean Air Act, 42 U.S.C. §§ 7409(d)(1), 7408(a)(2) – is to engage scientists who are active at the leading edge of scientific work in disciplines and areas related to the subject matter of a review, as described in the February 4, 2015 Federal Register request for nominations, 80 Fed. Reg. 6,086, and as illustrated by the history of CASAC Review Panels.

[50] See comments of IPMRP, December 10, 2018; "Advice from Independent Particulate Matter Review Panel to Administrator Andrew Wheeler" ("IPMRP Advice") (October 22, 2019),

[51] Louis Anthony Cox et al., "CASAC Review of the EPA's *Integrated Science Assessment for Particulate Matter (External Review Draft - October 2018)*," Environmental Protection Agency, April 11, 2019, *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/%24File/EPA-CASAC-19-002+.pdf

[52] *Id.*

3. By its own admission, CASAC lacked the requisite expertise, including in epidemiology, to advise the Administrator on the PM NAAQS

Congress established CASAC to be an independent body providing expert scientific advice to EPA on NAAQS decisions. 42 U.S.C. § 7409(d). Here, however, even the members appointed by EPA to the reconstituted CASAC admitted that they lacked the scientific expertise to provide such advice, as a result of the disbanding of the Panel. They so stated in comments to EPA dated April 11, 2019:

> Additional expertise is needed for the Clean Air Scientific Advisory Committee (CASAC) to provide a thorough review of the particulate matter (PM) National Ambient Air Quality Standards (NAAQS) documents. The breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals. For example, the chartered CASAC has found it difficult to achieve consensus in some areas (summarized below), and to do so likely requires further scientific expertise from, and discussion with, epidemiologists and additional experts in human clinical studies and toxicology. Some of the proposed changes in causality determinations in the Draft ISA, for example changing the causality designation of long-term exposure to ultrafine particles (UFP) on nervous system outcomes from "inadequate" to "likely," are driven primarily by animal toxicology studies. Therefore, additional expertise is needed in comparative toxicology, dosimetry, and extrapolation of findings in animals to humans.
>
> Over the past 30 years, the CASAC's advice to the EPA on NAAQS reviews has been assisted by expert review panels that supplement and expand the scientific expertise brought to bear. Such a review panel was appointed by the EPA for the current PM review. However, the panel was disbanded by the EPA prior to the release of the Draft ISA.[53]

[53] Louis Anthony Cox, et al., "CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft - October 2018)," Environmental Protection Agency, April 11, 2019 ("CASAC Letter"), *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/%24File/EPA-CASAC-19-002+.pdf.

As well as conceding that it needed additional expertise in a range of fields pertaining particularly to the primary standard—"biological mechanisms of causation, causal inference, multi-stressor interactions, and potentially others such as: epidemiology, human clinical studies; comparative toxicology, dosimetry, and extrapolation of findings in animals to humans; characterization of sampling errors and biases from continuous ambient PM measurements and satellite remote sensing aerosol optical depth (AOD) analysis; errors and biases in dispersion modeling and photochemical grid modeling; errors-in-variables methods and effects of exposure (and covariate) estimation errors on epidemiologic study results; epidemiology of low-dose causal concentration-response functions"—CASAC also acknowledged it needed more expertise in fields pertaining to the secondary standard—"effects of PM on visibility impairment, climate, and materials."[54]

Given that CASAC, by its own admission, lacked the expertise to consider the breadth and diversity of the evidence, EPA's reliance on the non-consensus advice of CASAC in the proposal at issue here is arbitrary. CASAC was simply not equipped to provide expert advice to the Administrator on the key scientific and technical issues, and therefore its advice warranted no deference from the Administrator.

For the external review of the ISA, CASAC did not have the necessary expertise because EPA provided no other experts for the committee to rely on during its deliberations. As the CASAC noted in its review of the PM ISA, "[o]ver the past 30 years, the CASAC's advice to the EPA on NAAQS reviews has been assisted by expert review panels that supplement and expand the scientific expertise brought to bear."[55] Recognizing its own deficiencies, the CASAC, in a letter to the Administrator, appealed to EPA to reinstate the PM Panel or appoint a panel with similar expertise, to aid in its review of the NAAQS documents.[56] CASAC made this recommendation (along with requesting a second draft of the ISA for review) because of "[t]he need for substantial revisions to the Draft ISA to provide clearer definitions, and technical details and methods in order to enable meaningful independent scientific review."[57] Without these steps, the CASAC was apparently struggling or unable to provide a meaningful independent scientific review.

The CASAC's lack of expertise was also exacerbated by the fact that only six CASAC members participated in the review of the PM Policy Assessment, as one CASAC member left the committee during the NAAQS review process. Therefore, when reviewing the PM Policy Assessment document, the CASAC had fewer members (and less expertise) than required by the Clean Air Act, which calls for "an independent scientific review committee composed of seven

[54] *Id.*
[55] CASAC Letter, at 1.
[56] *Id.* at 2.
[57] *Id.*

members." 42 U.S.C § 109(d)(2)(A). Multiple members of the CASAC stated their desire to have additional expert help. The CASAC consensus letter asked for restoration of the expert Panel to provide that assistance.[58] At a CASAC meeting, at least one member of the CASAC called the process dysfunctional, and stated during the meeting that he was proceeding under protest, due to the lack of access to experts.[59] In all these respects—the inadequate composition of CASAC, the lack of critical expertise, and EPA's reliance on advice from this irremediably flawed CASAC—the Proposal is unlawful, arbitrary and capricious, and an abuse of discretion.[60]

The composition of the CASAC, as appointed by the EPA Administrator, further contributed to the CASAC's inability to conduct a meaningful scientific review. As noted in the preceding section, this particular CASAC lacked balanced representation, which significantly impaired its ability to conduct a meaningful scientific review of the PM science and policy documents. Five of the seven CASAC members appointed to review the ISA were from federal, state, or local governments, and four of the six CASAC members involved in the review of the PM policy assessment were from state or local governments. This severely limited the CASAC's representation of diverse perspectives and expertise. The unbalanced composition of the CASAC and the dearth of academic research scientists hindered the committee's ability to conduct the "thorough" review mandated by the Act. 42 U.S.C. § 7409(d)(1).

In addition, most of the members of this particular CASAC lacked previous experience in serving on CASAC review panels. These members lacked a reference point[61] and a full understanding of their untenable position and the difficult circumstances EPA created for this NAAQS review. Indeed, Dr. Frampton, the only academic scientist to participate in this review and a CASAC member with previous experience participating in a CASAC review, was particularly outspoken about the problematic process and lack of expertise in this CASAC. *See*, *e.g.*, CASAC Letter, at A-81; December 10, 2018 CASAC letter at B-29.

[58] CASAC Letter, at 2.

[59] Summary Minutes of the U.S. Environmental Protection Agency (EPA) Chartered Clean Air Scientific Advisory Committee (CASAC) Public Meeting on Particulate Matter, at 4. Oct. 24-25, 2019.

[60] As stated in the comment from the International Society for Environmental Epidemiology, a society comprised of eminent researchers who study environmental causes of ill-health, "The current CASAC is unqualified to interpret epidemiologic studies given that it lacks adequate depth and diversity of epidemiologic expertise. The myriad of changes to the NAAQS review process are collectively harmful to the quality, credibility, and integrity of the scientific review process and to the CASAC as an advisory body." Comment of June 17, 2020 p. 4.

[61] For example, the references to and descriptions of Greven (2011), not realizing that EPA had comprehensively analyzed that study in the previous review, and that their reading of the study was at odds with the views of Dr. Greven herself. Further, CASAC demonstrated an inability to comprehend how long-term measurements in short-term epidemiologic studies could be relevant to the level of the annual standard, not realizing that this was EPA's methodology in the last review, and that the D.C. Circuit had remanded a previous PM NAAQS for failing to analyze this very feature. *See Am. Farm Bureau*, 559 F. 3d 512, 522-23 (D.C. Cir. 2009). Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," at 7-8 and A-2, December 16, 2019.

The Administrator's late appointment of a "pool" of experts after the CASAC review of the ISA does not rectify these failings. Appointment by the Administrator, rather than via the customary review process with SAB vetting and public participation, is an inadequate process and leads to at least the appearance of bias. And due to the Pruitt directive, eminent scientists were illegally barred from consideration for inclusion in the pool.[62]

While Administrator Wheeler has claimed the pool he ultimately selected addressed "CASAC's request for additional expertise[,]" this was not the case. [63] According to a report quoting one of CASAC's members in the wake of the Administrator's announcement, everyone named to the pool also "lacked 'sufficient expertise and experience' in epidemiology"—an area in which CASAC needed significant help.[64] Though an EPA roster identified Dr. Frederick Lipfert as an expert on "air quality" and "epidemiology," for example, a press report later quoted him as saying: "'I'm an amateur epidemiologist at best[.]'"[65] Another member of the pool, Dr. David Parrish, repeatedly stated in his responses to CASAC's questions that he had "no relevant expertise in evaluating exposure and risk," "no relevant expertise in evaluating public health implications," "no relevant epidemiological expertise," and "no relevant health effects expertise[.]"[66] The Administrator's decision to appoint pool members lacking relevant expertise was arbitrary and unlawful, particularly given the fact that candidates with relevant expertise had been included on the list of nominees.[67]

Six of the pool's twelve original members, moreover, were reportedly nominated by or affiliated with groups that have opposed the strengthening of NAAQS in the past.[68] As a report on the pool's members explained:

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[62] *See* Compilation of EPA Grant Information regarding Nominees to CASAC and Administrator Wheeler's Expert Pool (attached) (documenting the ineligibility of five expert-pool nominees—Peter DeCarlo, David Eaton, Joel Kaufman, Armistead Russell, and Ivan Rusyn—as a result of their EPA grants and the directive).

[63] EPA Press Office, Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts (Sept. 13, 2019) (attached).

[64] Sean Reilly, Documents Expose Ties Among EPA Panel's Experts, E&E News (Feb. 7, 2020) (attached), *available at* https://www.eenews.net/stories/1062289617.

[65] *Id.* (noting that Dr. Lipfert had nominated himself for the expert pool, and that his "educational background, which includes a doctorate, is in engineering and environmental studies"); List of Nominees for CASAC PM and Ozone Consultants (Aug. 2019) (attached).

[66] Responses to CASAC Questions on the Ozone PA from Consultant Dr. David Parrish at 5-6, 9-10 (attached); Documents Expose Ties Among EPA Panel's Experts, E&E News (Feb. 7, 2020).

[67] Documents Expose Ties Among EPA Panel's Experts, E&E News (Feb. 7, 2020) (noting that the EPA's own "roster shows that Wheeler passed over … academic specialists in epidemiology in appointing the experts"); List of Nominees for CASAC PM and Ozone Consultants (Aug. 2019).

[68] *Id.*

> Two of Wheeler's … picks work for well-known industry consulting firms that are representing clients with a stake in the reviews. … [B]oth were nominated by the National Rural Electric Cooperative Association, which opposed EPA's 2015 cut to the national ground-level ozone standard[.] … Another two—one of whom has since quit—were endorsed by the National Cattlemen's Beef Association, which unsuccessfully fought EPA's 2012 tightening of the annual limit on soot concentrations. … Yet another, the self-described amateur epidemiologist, is also on the advisory board of a conservative group known as the American Council on Science and Health. In comments to CASAC last fall, a trustee for the council disputed the long-established connection between soot exposure and early death. … [And] [a]nother expert working with the committee is … an independent consultant nominated by the Chicago-based Truck and Engine Manufacturers Association, which also opposed EPA's 2015 decision to trim the ozone threshold.[69]

This report raises questions about whether a number of members of the pool could be relied upon to provide wholly objective scientific advice.

Even if Administrator Wheeler had populated his pool with the experts CASAC needed to complete its review, the limitations he placed on the pool's members would have made it difficult for them to offer meaningful contributions to the process. While members of review panels typically participate in CASAC's meetings, which are public, Administrator Wheeler's pool was not allowed to join the committee's meetings—or to speak directly, even, with the committee's members. As one of CASAC's members has said, according to a recent report, the Administrator's requirement that the pool's members only communicate with the committee in writing "'adversely affect[ed]' CASAC's ability to advise EPA[.]"[70] The Administrator's "hurry-up schedule" further prevented the pool's members from offering useful comments. As a professor at Texas A&M University reportedly explained after resigning from the pool, "'I simply did not have as much time to devote to the tasks as the tasks would have required[.]'"[71]

All told, the pool of consultants selected by Administrator Wheeler failed to remedy the arbitrary and unlawful deficiencies in CASAC's review. Instead, the pool made the Administrator's reliance on CASAC's advice all the more arbitrary, for even with the consultants, CASAC lacked the necessary expertise to comment on the standards.

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[69] Documents Expose Ties Among EPA Panel's Experts, E&E News (Feb. 7, 2020).
[70] *Id.*
[71] *Id.* (quoting Professor Brent Auvermann).

EPA has failed to recognize and consider the impact of these arbitrary decisions on the CASAC's ability to perform its duties and on the quality of the recommendations produced by the CASAC. Rushing through the external review process, without the typical subject matter experts and a shorthanded CASAC, was particularly egregious and undermined the CASAC's ability to conduct the required review, make recommendations, and advise the Administrator, as required by the CAA. The above factors and "exceptional nature" of this NAAQS review indicate that the current CASAC was simply unable to fulfill its role in this process under these challenging circumstances, and the Administrator's reliance on this broken process is arbitrary and unlawful.[72]

4. CASAC lacked necessary expertise to conduct the review of both the primary and secondary standards

The range and depth of expertise relating to both health and welfare effects of PM of the members of the now-disbanded IPMRP, discussed below, are substantially greater than that represented by the current CASAC committee. In fact, more than a year ago, the CASAC recommended that:

> [T]he EPA reappoint the previous CASAC PM panel (or appoint a panel with similar expertise) as well as adding expertise in biological mechanisms of causation, causal inference, … and potentially others such as: characterization of sampling errors and biases from continuous ambient PM measurements and satellite remote sensing aerosol optical depth (AOD) analysis; errors and biases in dispersion modeling and photochemical grid modeling; … and effects of PM on visibility impairment, climate, and materials. The panel should be appointed in time to review the Second Draft ISA.[73]

In the April 2019, consensus comments on the ISA, the CASAC expressed to EPA's Administrator that:

> It would be helpful for the CASAC to have ready access to an expert that studies the effects of PM on visibility impairment, climate, and materials. This would allow for additional insight into the nonecological welfare effects and better inform our recommendations on the appropriate level for the secondary PM standard.[74]

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[72] Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," at 1, December 16, 2019. https://yosemite.epa.gov/sab/sabproduct.nsf/E2F6C71737201612852584D20069DFB1/$File/EPA-CASAC-20-001.pdf.
[73] *Id.* at 25; EPA's *Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)"* cover letter at 2.
[74] CASAC Letter, at 25.

Three of the current CASAC committee members expanded on these consensus concerns and recommendations in their individual April 2019, review comments. The following are the concerns and recommendations from those individuals:

- *Current CASAC member Dr. James Boylan*: "I recommend that EPA reconvene the PM Review Panel. I believe that a PM Review Panel would provide the 7-member chartered CASAC with additional insight and expertise to allow for a more thorough and in-depth review of the relevant science and policy documents. My experience on the most recent SO_2 Review Panel has shown me the importance and value of having multiple independent experts (who are at the leading edge of research in their respective fields) thoroughly reviewing each chapter."[75]

- *Current CASAC member Dr. Mark W. Frampton:* **"Need to re-appoint the CASAC PM review panel.** Prior to the release of this draft PM ISA, and without consulting CASAC, EPA disbanded the expert PM review panel that had been previously appointed to assist CASAC in this important review. Over the past 30 years, NAAQS document reviews by CASAC have been assisted by expert review panels that supplement and expand the scientific expertise brought to bear. The seven chartered CASAC members by themselves do not have the breadth and depth of knowledge or expertise in many areas that are necessary to adequately advise the EPA, and to meet the statutory requirement for a thorough and accurate review. . . . In order to provide the needed expertise in the review process, EPA should immediately re-appoint the PM review panel, and convene an

[75] *Id.* at A-2. Additionally, Dr. Boylan expressed similar concerns in his individual comments that were one of the Enclosures to the CASAC's December 10, 2018, letter at B-2 ("The CASAC review letter on EPA's Draft ISA submitted to the EPA Administrator on April 11, 2019 recommended the development of a Second Draft ISA for CASAC review and the reappointment of the previous CASAC PM panel (or appoint a panel with similar expertise) in time to review the Second Draft ISA. Instead, EPA has provided CASAC with a pool of consultants that can respond to written questions from the CASAC. Although the pool of consultants has provided additional insight and useful information, they do not serve the same role as the former PM review panel since there are no deliberations and only written answers to specific questions. I feel that the traditional review process (with pollutant specific review panels) is significantly more informative to CASAC's recommendations since it allows verbal discussions and deliberations among experts with differing backgrounds and opinions resulting in a more comprehensive examination of controversial topics. The purpose of the PA is to bridge the gap between EPA's scientific assessments and the judgement required by the EPA Administrator when determining whether to retain or revise the NAAQS. It is unusual to review a draft PA when the ISA had not been finalized. Also, it is unusual to include the REA as part of the PA rather than a stand-alone document that is reviewed prior to the release of the draft PA. I feel that a second draft of the PA (with an updated REA) should be reviewed by the CASAC after the final ISA is released.")

additional CASAC public meeting to review and discuss the panel's comments, before CASAC finalizes its advice on the current draft ISA."[76]

- *CASAC Member Dr. Timothy E. Lewis*: "It would be helpful for the PM CASAC seven-member panel to have access to a much larger review panel that would allow for additional input into the non-ecological welfare effects and better inform our recommendations on the appropriate level for a secondary standard."[77]

Despite EPA's awareness of the fact that CASAC lacked the knowledge to provide EPA with the scientific advice that Congress intended, EPA failed to provide the committee with the experts required for an objective evaluation of the scientific issues raised. As the D.C. Circuit has held:

> Congress expected that CASAC's central role would be one of scientific analysis, explaining that CASAC's "main function" was "to assess the health and environmental effects of ambient air pollution." ... CASAC would "provide an outside mechanism for

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[76] *Id.* at A-81 (emphasis added). Additionally, Dr. Frampton expressed similar concerns in his individual comments that were part of December 10, 2018 CASAC letter at B-29 ("In response to a CASAC request in its April 11 letter to the Administrator, EPA has appointed a panel of twelve expert consultants as a resource in the review of this PM PA, as well as for the ozone review. Those panel members have already provided helpful and insightful responses to specific questions posed by the chartered CASAC members. However, CASAC had stated in its April 11 letter, "Additional expertise is needed for the Clean Air Scientific Advisory Committee (CASAC) to provide a thorough review of the particulate matter (PM) National Ambient Air Quality Standards (NAAQS) documents. The breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals."
CASAC recommended that "…the EPA reappoint the previous CASAC PM panel (or appoint a panel with similar expertise)…". EPA has not done so. Instead, it selected a pool of 12 in a process again fraught with arbitrariness. The panel of 12 consultants appointed by EPA does not have the breadth or depth of expertise that was represented on the original (dismissed) PM panel, and moreover does not include additional areas of expertise requested. The newly appointed panel of consultants does not include sufficient expertise and experience in air pollution epidemiology research. This is a scientific discipline that is obviously of key importance in the review of the PM standards. None of the current chartered CASAC members are experts in air pollution epidemiology. In addition, the restrictive process for interacting with the newly appointed consultants, which was imposed by EPA without consultation with CASAC, prevents open and frank discussions that are part of the process of achieving consensus. These limitations adversely affect the ability of CASAC to provide the EPA with the best and most relevant advice on the adequacy of the current NAAQS.

We note the difficulty and limitation in providing cogent and insightful advice on this PA document, given that the ISA has yet to be finalized, and the CASAC advice for revisions to the ISA, that were made in the CASAC letter to the Administrator (April 11, 2019), have yet to be addressed. Thus CASAC is attempting to review policy assessment and planning that is based on an incomplete scientific review.")
[77] *Id.* at A-150. Notably Mr. Lewis' comments were brief, and contained in less than 1.5 pages.

> evaluating whether any pollutant may reasonably be anticipated to endanger public health or environment, for evaluating the scientific and medical data which might bear on this question, and for reviewing gaps in the available data and recommending additional needs for research." ... Given these functions, Congress expected that CASAC members would "be selected on the basis of their special expertise" in fields such as "environmental toxicology, epidemiology and/or clinical medicine."[78]

Thus, EPA flouted the Act's requirements as the Committee members appointed by the Administrator lacked the knowledge, breadth, and depth to advise EPA. EPA also failed to provide adequate time for the existing CASAC's review, contrary to the CASAC's request. Furthermore, it should be noted that all of the current CASAC members who offered comments on secondary standards specifically recommended that added expertise on PM welfare effects was needed. For the reasons given above, EPA's proceeding in this way and relying on CASAC's advice is both unlawful and arbitrary.

C. Additional process concerns

The particulate matter review is being speedily finalized during a global pandemic caused by a respiratory virus, which raises serious concerns about the adequacy of the opportunity for public comment and other issues with statutory requirements under the Clean Air Act. That is particularly of concern because the very respiratory health experts who are most relevant and best situated to provide detailed comments are, necessarily, currently preoccupied with the COVID-19 crisis. Notwithstanding the extent of the current crisis, EPA has only given the public a 60-day comment period, denying requests for an extension of time. This would be a remarkably short comment period for such a consequential, highly technical and scientific rulemaking, even in the absence of a deadly pandemic. Further the closure of the docket room (not to mention the closure of public reading areas, like libraries and schools that afford internet access to those who do not have it at home), coupled with the requirement that comments be submitted electronically (both changes necessitated by the pandemic) restrict opportunities for public input, potentially silencing important feedback. Pushing through this incredibly important review despite the current circumstances and changes to the process that further restrict public input is unacceptable, and must be remedied before the rule is finalized.

D. These arbitrary and unlawful process failures render the proposed decision arbitrary and unlawful

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[78] *Mississippi v. EPA*, 744 F.3d 1344, 1354 (D.C. Cir. 2013) (citations omitted).

For the reasons given above, each of these process failures was arbitrary. Each alone thus renders the overall process and the proposed outcome—unchanged standards—arbitrary and unlawful. Taken in combination, their arbitrariness builds on one another. For example, EPA's rushed process may have deprived even a lawfully constituted CASAC of adequate time to provide expert advice. The inexpert CASAC, even assisted by the ad hoc consultant pool, failed to remedy these issues. Thus, together, they result in an arbitrary and unlawful proposal.

V. EPA's Proposal is Unlawful Because the Latest Scientific Knowledge Shows the Current Standard Is Not Requisite to Protect Public Health Within an Adequate Margin Of Safety

A. Scientific evidence from animal studies and controlled human exposure studies available by the ISA cut-off date of January 2018

Notwithstanding the Administrator's arbitrary preference for animal and controlled human studies over the massive epidemiological record (see discussion below in sections VI and VII), as shown in the ISA, both animal toxicological and controlled human exposure (CHE) studies using concentrated ambient particle (CAP) exposures provide evidence of a direct effect of PM exposure on various health effects (ISA at ES-22). This evidence base demonstrates a coherence of effects. Specifically, the ISA notes new evidence of adverse health effects for a number of endpoints:

> *Short-term $PM_{2.5}$ exposure and subclinical effects underlying asthma exacerbation:*
> As noted in the ISA, "several studies conducted in animal models of allergic airway disease provide evidence that exposure to PM2.5 CAPs and DEP exacerbates allergic responses. In addition, one study found that PM2.5 CAPs exposure resulted in an inhibition of allergic responses. These disparate findings may be due to source-related differences in the composition of PM2.5 CAPs from different locations." (ISA at 5-46).
>
> *Subclinical Effects Underlying Exacerbation of Chronic Obstructive Pulmonary Disease (COPD):*
> In the 2009 PM ISA, Gong et al. (2004a) and Gong et al. (2005) found a decrease in columnar epithelia cells following short-term exposure to PM2.5. Those studies also investigated PM2.5-induced health effects in adults with COPD and found a decrease in columnar epithelia cells ($p < 0.01$) following short-term exposure to PM2.5. This effect was more pronounced in healthy subjects than in those with COPD.
>
> *Lung function:*
> The 2009 PM ISA reported several animal toxicological studies that measured pulmonary function following single or multiday exposure to $PM_{2.5}$ CAPs. Table 5-14 of the ISA details recent animal studies identifying lung function impacts from $PM_{2.5}$, including changes in peak respiratory flow, minute volume, breathing frequency, inspiratory and expiratory time, expiratory flows, and tidal volume.

Asthma:
A 2016 study evaluated the effects of $PM_{2.5}$ on the development of asthma in mice and found evidence that $PM_{2.5}$ can induce an immune phenotype in the absence of an allergen. As noted in the ISA at page 5-188, that study also assessed airway responsiveness to methacholine using whole-body plethysmography to measure Penh. Methacholine is a muscarinic receptor agonist that elicits bronchoconstriction and is used to evaluate airway hyperresponsiveness, a hallmark of asthma.

Respiratory Effects in Healthy Populations:
The 2009 PM ISA provided limited evidence that exposure to $PM_{2.5}$ resulted in subclinical or inflammatory effects in healthy populations. Since then, a number of controlled human exposure studies have observed impacts on small numbers of healthy nonsmokers (Table 5-13 of ISA).

Arrhythmia and Conduction Abnormalities:
As noted at ISA page 6-38, there is some evidence from CHE studies that short-term exposure to PM2.5 can result in abnormal electrical activity in the heart

Changes in Blood Pressure:
Overall, recent CHE studies provide some evidence that short-term $PM_{2.5}$ exposure can result in changes in blood pressure following CAPS but not DE exposure (ISA at 6-57).

Systemic inflammation:
Recent CHE studies show some evidence that short-term $PM_{2.5}$ exposure can result in systemic inflammation (ISA at 6-89).

Vascular function:
Recent CHE studies do show evidence of a $PM_{2.5}$ effect on vascular function. In contrast to the results reported in a couple of studies from the previous review, all of the current studies generally report some effect of $PM_{2.5}$ ambient particles or DE particles on measures of blood flow (ISA at 6-106).

Evaluating this evidence, the IPMRP noted that the additional evidence provided by animal toxicological and controlled human exposure studies “support and strengthen” the available evidence base demonstrating harm, and that the animal study evidence particularly “supports biologic plausibility for PM effects on the cardiovascular, respiratory, and nervous systems, as well as for cancer effects.”[79] The IPMRP also notes that, when considered in tandem with the

[79] Advice from the Independent Particulate Matter Review Panel (formerly EPA CASAC 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)

available observational epidemiology evidence analyzing different locations, study designs, and statistical approaches, "coherent results from animal toxicological and controlled human exposure studies, provide clear and compelling scientific evidence that the current $PM_{2.5}$ standards are not adequate to protect human health."[80]

B. Scientific evidence from accountability studies available by the ISA cut-off date of January 2018

The Administrator and certain CASAC members seem to regard accountability studies as the quintessential decision tool, discounting epidemiologic evidence. As discussed in the following section, and further in section VII.D below, as it happens, the accountability/intervention literature, though still emerging, offers strong support for the need to revise the standards. EPA's 2019 Integrated Science Assessment and 2020 Policy Assessments did address studies that used causal analysis, including quasi-experimental designs, as well as epidemiology studies that addressed time periods during which $PM_{2.5}$ concentrations declined over time. Some of these are classified as intervention or accountability studies. These assessments are presented in Sections 11.1.2.1 and 11.2.2.4 of the ISA. Section 11.1.2.1, *Examination of $PM_{2.5}$-Mortality Relationship through Causal Modeling Methods* examined two causal inference studies focused on daily mortality that used propensity scores and sensitivity analyses using an approach similar to Granger causality (Schwartz et al. 2015 ; Schwartz et al. 2017).[81] They also assessed the quasi-experimental accountability study noted above (Yorfuji et al. 2016). The ISA concluded:

> Although the studies to date that have used causal modeling statistical approaches are limited to two locations, overall the studies provide additional support for the relationship between short-term $PM_{2.5}$ exposure and mortality described in previous and recent studies, including those highlighted in Figure 11-1. Additionally, the study by Yorifuji et al. (2016) demonstrates that improvements in air quality, including reductions in $PM_{2.5}$ concentrations, contribute to public health benefits such as reductions in daily mortality.[82]

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https://yosemite.epa.gov/sab/sabproduct.nsf/81DF85B5460CC14F8525849B0043144B/%24File/Independent+Particulate+Matter+Review+Panel+Letter+on+Draft+PA.pdf

[80] We discuss in greater detail below in section VII.C that the animal and controlled human studies were conducted at levels which properly should be regarded as policy-relevant, and which EPA itself has regarded as policy-relevant in past reviews.

[81] See also discussion of the causal methods used in these and related studies in comments submitted by Dr. Joel Schwartz (2020).

[82] 2019 Integrated Science Assessment, p. 11-13.

ISA Section 11.2.2.4 *Studies with Analyses that Inform Causal Inference* assessed long-term studies, including the Pun et al. (2017), Greven et al. (2011) and Janes (2007) discussed above. The ISA also assessed Wang et al. (2016), and Cox and Popkin (2014). Wang et al. (2016) applied a differences in differences approach to the entire population of New Jersey, using a fine scale of geographic control, based on census level deaths over a six-year period (Wang et al. 2016). This study reported a causal estimate of a 1.5% increase in annual deaths for each 1 µg/m3 increase in $PM_{2.5}$. Cox and Popkin (2014) used Granger and other causal inference approaches to examine reductions in $PM_{2.5}$ and mortality in 15 U.S. states between 2000 and 2010. They found evidence of an effect in a small number of counties. The ISA concludes that "[i]nference from this study is limited by a lack of individual-level data; it is an ecologic study relying on county-level mortality rates, with no control for potential confounders other than age, making it difficult to adequately interpret the results." (2019 Integrated Science Assessment , p.11-79-80)

EPA should also consider several other relevant PM studies that used the differences in differences approach, which Dr. Joel Schwartz summarizes in his comments on the proposal (Schwartz 2020).[83] Dr. Schwartz notes that because studies using this quasi-experimental approach focus on changes in exposure and changes in outcomes, they are a form "of accountability studies demonstrating that *changes* in $PM_{2.5}$ produce *changes* in death rates, which the Administrator and some CASAC members believe is necessary." (Schwartz 2020, p.8). Kioumourtzoglou et al. (2015a) confirmed a causal association between $PM_{2.5}$ and annual death rates, and a follow-up (2016) Kioumourtzoglou et al. (2016) found changes in annual exposures to $PM_{2.5}$ were associated with changes in rates of hospital admissions for neurological conditions. In introducing these and more recent causal inference studies, Dr. Schwartz takes exception to the Administrator's assertion regarding a lack of such studies:

> Contrary to EPA's assertion, there are multiple publications using causal modeling methods to assess both the effects of short-term and long-term

[83] In addition to Wang et al. 2016, Schwartz (2020) discusses four differences in differences studies that were published in time to be discussed in the ISA. The two Zanobetti studies used PM_{10} as the indicator. Zanobetti A, Schwartz J. 2007. Particulate air pollution, progression, and survival after myocardial infarction. Environmental health perspectives 115:769-775. This study used PM_{10} data, not $PM_{2.5}$. Zanobetti A, Bind MA, Schwartz J. 2008. Particulate air pollution and survival in a COPD cohort. Environ Health 7:48. Janke K PC, Henderson J. 2009. Do current levels of air pollution kill? The impact of air pollution on population mortality in England. Health Economics. This study used PM_{10} data, not $PM_{2.5}$. Kioumourtzoglou MA, Austin E, Koutrakis P, Dominici F, Schwartz J, Zanobetti A. 2015a. $PM_{2.5}$ and survival among older adults: Effect modification by particulate composition. Epidemiology. Kioumourtzoglou MA, Schwartz JD, Weisskopf MG, Melly SJ, Wang Y, Dominici F, et al. 2016. Long-term pm exposure and neurological hospital admissions in the northeastern united states. Environ Health Perspect. 124(1): 23–29 (final publication as published in EHP- Schwartz 2020 lists as 2015b – online version).

> exposure to $PM_{2.5}$ on death rates and other serious events. Moreover, the similarities in their findings to studies using conventional approaches suggests that there was no confounding in those studies as well. These are also consistent with studies that have examined changes in exposure and related them to changes in death rates, as described below.[84]

While not grouping intervention or accountability studies in a single section, the ISA summarized Studies of Temporal trends and Life Expectancy in Section 11.2.2.5 pages. The PA highlights two of these retrospective studies ((Pope et al. 2009) and (Correia et al. (2013)) that found statistically significant associations between declining ambient $PM_{2.5}$ levels and increasing life expectancy over two time periods. The second study compared levels in 2000 (13.2 µg/m^3) with that in 2007 (11.6 µg/m^3) in 545 U.S. counties. The results were significant despite involving a smaller drop in $PM_{2.5}$ concentrations than had occurred in the 2009 study or than has occurred between 2000 and 2017. Current national average annual levels are close to 8 µg/m^3 (2020 Policy Assessment, p. 2-29).

The ISA also examined the first studies to relate declining concentrations of long-term $PM_{2.5}$ to beneficial respiratory health effects (2019 Integrated Science Assessment, p. 5-208-210). The populations included children living in several Southern California communities in which air programs produced significant reductions in fine particles and other pollutants, Berhane et al. (2016) and Gauderman et al. (2015). The ISA concluded that these studies "observed a consistent relationship between decreasing $PM_{2.5}$ concentrations and improved respiratory health. These results provide corroborating evidence of an association between $PM_{2.5}$ and lung development (Section 5.2.2) and bronchitis (Section 5.2.5)." (2019 Integrated Science Assessment, p. 5-211).

The PA included the life extension studies summarized above and these children's intervention studies in Table 3-3 as recent evidence examining health impacts of long-term reductions in ambient $PM_{2.5}$ concentrations. The IPMRP report found that "the accountability studies listed in Table 3-3 of the [then] draft PA are useful in supporting causality determinations of adverse effects of $PM_{2.5}$ at annual levels close to, and overlapping with the current standard. Thus, they provide important insights related to risk reduction." (IPMRP Advice, p. B-24).

In developing their conclusion that the current scientific evidence calls into question the adequacy of the public health protection afforded by the current $PM_{2.5}$ standards, the PA stated:

> Consistent findings from the broad body of epidemiologic studies are also supported by an emerging body of studies employing "causal inference" or quasi-experimental statistical approaches to further inform the causal nature of the

[84] Comment submitted by J. Schwartz (June 9, 2020).

> relationship between long- or short-term term $PM_{2.5}$ exposure and mortality (U.S. EPA, 2019, sections 11.1.2.1, 11.2.2.4). These studies are summarized above in section 3.2.1.1. . . . Other recent studies additionally report that declines in ambient $PM_{2.5}$ concentrations over a period of years have been associated with decreases in mortality rates and increases in life expectancy, improvements in respiratory development, and decreased incidence of respiratory disease in children, further supporting the robustness of $PM_{2.5}$ health effect associations reported in the epidemiologic evidence (summarized in sections 3.2.1 to 3.2.3)

2020 Policy Assessment, p. 3-103.

The PA also notes an extended analysis of the Harvard Six Cities cohort (Laden et al. 2006) assessed in the previous PM review (2020 Policy Assessment, p. 3-19). The summary in EPA's previous PA reported that this study "found that as cities cleaned up their air, locations with the largest reductions in $PM_{2.5}$ saw the largest improvements in reduced mortality rates, while those with the smallest decreases in $PM_{2.5}$ concentrations saw the smallest improvements." (2011 Policy Assessment, p. 2-20).

The ISA and PA excluded intervention or accountability studies that did not measure $PM_{2.5}$ directly. Yet, some older studies do provide useful insights with respect to interventions that would be expected to result in marked reductions in fine particles and/or components. A prominent example are studies by Pope et al. (1992),[85] who noted a marked drop in mortality in Utah during a year-long strike that closed a steel mill that was the dominant source of air pollution. When operations resumed, mortality returned to its previous levels. Although particles were measured as PM_{10}, fine particles would be a significant contributor to the total, particularly during stagnations. As noted by Schwartz (2020), "this did not happen in control locations, where there was no change in pollution from a strike, which also makes this a difference in differences analysis."

Schwartz 2020 also summarizes a large-scale natural experiment that occurred during a copper smelter strike between July 1967 and early April 1968 (Pope et al. 2007a).[86] Earlier work had established that the strike resulted in a 2.5 $\mu g/m^3$ reduction of sulfates, a major component of fine particles in the region. As Pope noted, the reductions of total fine particle mass would have been somewhat larger, as smelter operations also emit metals and other co-pollutants (Pope et al. 2007b). Pope et al. (2007a) examined how mortality rates changed in response to the change in

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[85] Pope CA, 3rd, Schwartz J, Ransom MR. 1992. Daily Mortality and PM_{10} Pollution in Utah Valley. *Archives of Environmental Health* 47:211-217.

[86] Pope CA III, Rodermund DL, Gee MM. 2007a Mortality effects of a copper smelter strike and reduced ambient sulfate particulate matter air pollution. *Environmental Health Perspectives* 2007;115:679-683. Pope CA III. 2007b) Mortality from copper smelter emissions: Pope responds (Authors' reply to letter of TJ Grahame). *Environmental Health Perspectives* 2007;115:A439-A440.

particle concentrations. After controlling for time trends, mortality counts in bordering states, (which as Schwartz (2020) notes is a form of a differences-in-differences causal approach) and influenza/pneumonia deaths, the researchers found that the decrease in particle concentrations resulted in a 2.5% decrease in the number of deaths in the four-state region. Schwartz concludes that based on the causal analysis of the intervention, this unambiguously establishes particles as a cause of early death.

EPA discussed these studies in past reviews but did not reconsider them here. Both studies provide important supporting evidence of the benefits of fine particle reductions. The smelter strike study is particularly relevant to the suggestion by the Administrator that no study has examined an intervention that began with levels below the current standard.[87] 85 Fed. Reg. at 24,120. An examination of the sulfate and visibility data in the Southwest during that period found urban and rural areas in the region to be far cleaner than in the Eastern United States (Trijonis 1979).[88] EPA can and should determine whether it is or is not an example of an intervention that begins and ends below the current annual standards.

In summary, our examination of the studies using causal methods, and/or interventions or accountability studies that were considered in the ISA and PA, as well as two additional earlier accountability studies from past reviews, finds more studies that contradict rather than support the assertion made by some CASAC members regarding the lack of studies that find reductions in fine particles produce health benefits. EPA authors of the final PA considered the two recent secondary reviews of accountability studies recommended by CASAC and found them wanting in terms of studies that actually assessed $PM_{2.5}$ interventions. As explained in section VII below, one of these reviews simply rejected "indirect" cohort studies that found reductions in pollution over time were associated with health benefits. Based on comments from the authors, CASAC misinterpreted the relevance of several studies that they suggest showed no benefits of $PM_{2.5}$ reductions over time.

Yet, as noted in the PA and in these comments, as of early 2018, the majority of epidemiology studies using causal inference and/or examining $PM_{2.5}$ reductions over time, including indirect cohort, interventions, and accountability approaches, have found improved health with $PM_{2.5}$ reductions, even when addressing a number of potential confounders. Based on the EPA's assessment of the newer intervention, causal inference, and related studies that were included in the ISA, the Policy Assessment concluded that the studies in these areas served to strengthen the conclusions from the last review and add to the weight of evidence that the current standards should be strengthened.

[87] As noted above, reliance on such absence as a basis for not revising the annual primary standard is a legal error. We note here that it may also be a misstatement of fact.
[88] Trijonis J. Visibility in the southwest—an exploration of the historical database. Atmos Environ. 1979;13:833–843. [Google Scholar].

Given the concordance of the IPMRP, EPA's own expert assessments of the evidence relevant to these studies, as well as the problems identified with CASACs assessments discussed above, reliance by the Administrator on the CASAC letter's suggestion of a "lack of consistent support from newer intervention and accountability studies" (Cox Dec. 16, 2019, Letter, p. 9) would be arbitrary and capricious, and an abuse of discretion.

In fact, neither the CASAC letter nor EPA has actually examined the newest intervention and accountability studies published since January 2018, including those using causal inference methods, some of which are over two years old. As discussed in the next subsection, a number of important recent accountability studies undermine the assertions made by CASAC and the Administrator. We discuss in section VII.D.3 below the more recent accountability study literature, which also strongly indicates that reductions in $PM_{2.5}$ result in corresponding reductions in health effects.

For all these reasons, and the further reasons stated in section VII.D, the Administrator's proposed reading of the accountability/intervention evidence is contrary to the evidence of record. The proposal's reliance on these errors by CASAC; the proposal's failure to explain its inconsistency with EPA's prior review, discussed above; and the proposal's failure to examine the newest intervention and accountability studies published since January 2018 make clear the proposal is unlawful, arbitrary and capricious and an abuse of discretion.

C . The Administrator's reliance on certain CASAC recommendations is unwarranted and unreasonable in light of the scientific evidence

The range and depth of expertise relating to both health and welfare effects of PM on the now-disbanded IPMRP, as discussed above, are substantially greater than that represented by the current CASAC. In fact, as already described, current CASAC recommended that EPA make changes to appoint members with appropriate expertise, including requests to reappoint the previous CASAC PM review panel.

Despite EPA's awareness of the fact that CASAC lacked the knowledge or expert advisors needed to "appraise the adequacy and basis of existing, new, or revised national ambient air quality standards,"[89] EPA failed to provide the committee with the experts needed for the type of in-depth, rigorously technical evaluation of the scientific issues raised—that is, to provide the "thorough" review mandated by the Clean Air Act. 42 U.S.C. § 7409(d)(1). Thus, EPA flouted the Act's requirements. EPA also failed to provide adequate time for CASAC's review, contrary to the CASAC's request. Furthermore, it should be noted that all of the current CASAC members

[89] *Id.* § 7409(d)(2)(A).

who offered comments on secondary standards specifically recommended that added expertise on PM welfare effects was needed.

Individuals on CASAC and those informing CASAC have offered comments that undermine reliance on "the latest scientific knowledge"—which is what the Clean Air Act demands. Because this input is biased, lacks scientific rationale, departs from prior CASAC practice, is incomplete, and internally inconsistent, CASAC deliberations were not based on the latest scientific knowledge.

1. Dr. Cox

In his independent comments submitted as part of the December 16, 2019 letter to EPA reviewing the draft Policy Assessment, Dr. Cox misleadingly asserts that "the scientific information and conclusions presented in the draft PA are not clear in meaning, transparent in derivation, scientifically valid, empirically validated, or trustworthy as guides to policy."[90] As explained by EPA in the ISA (section P.3.2, Evaluation of the Evidence), the scientific information reviewed and synthesized within the ISA and PA must meet specific criteria to ensure the validity of scientific conclusions made in these documents.[91] Dr. Cox makes an unfounded and sweeping assertion about the information in the PA without identifying any credible transparency or validation problems with the underlying studies informing EPA's assessments. Furthermore, App. B to the Policy Assessment documents each major epidemiological study design, statistical methodology, and method for controlling for potential confounding. All of the material in this Appendix, of course, comes from the ISA, pointing to Dr. Cox's mistaken reference to lack of transparency.

EPA's reliance on technical opinions of Dr. Cox was arbitrary and capricious. Dr. Cox disagrees with the longstanding EPA and CASAC interpretation of causal issues that are in accordance with the latest scientific knowledge and expert consensus, and he does not seem to understand EPA's thorough analysis to arrive at its causal determinations.[92] The causal determinations made by EPA are based on thousands of studies that collectively satisfy and exceed causal criteria in epidemiology and demonstrate significant harms of air pollution to public health (not merely correlational associations).

[90] Page B-10 of Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," December 16, 2019.
[91] ISA at P-17 to P-20.
[92] *See* ISA, ES-9 to ES-11 (Dec. 2019) (Table ES-1, summarizing causality determinations in the 2009 and current ISAs).

Of course, associations and causation are not synonymous. However, Dr. Cox denies the coherence of the epidemiological and supporting experimental evidence. As the IPMRP found, "[t]he epidemiological 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."[93] Studies conducted in both the follow-up evaluations of the ACS and Six Cities cohorts, plus studies conducted in other cohorts demonstrate consistent, positive associations between long-term $PM_{2.5}$ exposure and mortality across various demographic groups (e.g. age, sex, occupation), spatial and temporal extents, exposure assessment metrics, and statistical techniques.[94] Consistency of results based on multiple studies that employ multi-pollutant models, among which there are differences in underlying factors such as the relative ambient mixtures of co-pollutants, population demographics, climatic zones, and distributions of housing characteristics support the robustness of that evidence.[95] These associations across different areas, populations, study designs, statistical methodologies, health outcomes, and approaches for controlling for potential confounding, simply cannot be attributed to residual confounding. As the Policy Assessment found, "'[s]ensitivity analyses indicate that adding covariates to control for potential confounders can either increase or decrease the magnitude of PM2.5 effect estimates, depending on the covariate, and that none of the covariates examined can fully explain the association with mortality." Policy Assessment at 3-102.

EPA's expert staff, and even the proposal itself, maintain the causality determinations of the ISA.[96] Indeed, the Administrator proposes to retain the existing standard, an action inexplicable if his judgment is that observed associations are not causal.

Dr. Cox also states that "[a]lthough consistent with the approach taken in previous NAAQS reviews and advocated by the previous CASAC, the approach, predictions, and conclusions presented in the PA lack scientific validity."[97] Here, Dr. Cox acknowledges the history and sound approach applied to interpretation of scientific information in past NAAQS reviews, but argues for a radical departure from proven EPA and CASAC practice under the guise of improving "scientific validity." Nowhere does Dr. Cox identify specific validity concerns with a level of detail to allow for a nuanced and targeted interpretation of his advice.

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93 IPMRP Advice at B-21.
94 *See generally* ISA at 11-66 to 11-77, 11-80 (Sections 11.2.2.1, 11.2.5).
95 *See generally* IPMRP Advice at B-28.
96 EPA, Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter at 3-18, 4-6, 5-10 (Jan. 2020) (summarizing causality determinations); 85 Fed. Reg. 24,094, 24,100 (Apr. 30, 2020).
97 CASAC PA Review at B-13.

Dr. Cox believes that the PA provides "no valid scientific information" about the health impacts of changes in air pollution levels,[98] despite the robust documentation of causal effects provided in the ISA and other published analyses demonstrating human health improvements from improved air quality in the United States.[99] The Administrator mistakenly suggests that evidence is lacking as to whether changes in $PM_{2.5}$ cause changes in deaths or other adverse events and suggested such evidence is lacking. 85 Fed. Reg. 24,120. But EPA's own preamble states that "Pope et al. (2009) conducted a cross-sectional analysis using air quality data from 51 metropolitan areas across the U.S. beginning in the 1970s through the early 2000s, and found that a 10 ug/m3 decrease in long-term PM2.5 concentration was associated with a 0.61-year increase in life expectancy." 85 Fed. Reg. 24,106. The preamble further notes that "[a]dditional studies conducted in the U.S. or Europe similarly report that reductions in ambient PM2.5 are associated with improvements in longevity." (citing ISA section 11.2.2.5). Laden et al. specifically examined changes in PM2.5 concentrations in two follow-up periods in the Harvard Six City Study and changes in mortality rates, and reported an association, with almost the same effect size as in the original study.[100] And a more recent study of Abu Awad et al. examined the change in PM2.5 exposure due to moving residential location and changes in mortality experienced among people moving from the same neighborhood. This study also found a strong effect of higher levels of PM2.5 on mortality.[101] See the further discussion of the accountability/intervention/manipulative causation literature in section VII.D below.

Dr. Cox's views do not reflect the latest scientific knowledge in the area in which he is offering his expertise, but rather are dangerously out of step with the prior CASAC,[102] consensus among EPA scientists and experts in the field that improvements in air quality deliver profound health benefits to the American people and that there is no safe level of $PM_{2.5}$ exposure. While Dr. Cox has attempted to undermine the robust and still-growing epidemiology evidence base for the $PM_{2.5}$-mortality relationship, other CASAC members have noted rightly that the "causal

[98] Page B-19 of Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," December 16, 2019.
[99] Zigler, Corwin M., Christine Choirat, and Francesca Dominici. 2018. "Impact of National Ambient Air Quality Standards Nonattainment Designations on Particulate Pollution and Health." *Epidemiology (Cambridge, Mass.)* 29 (2): 165–74. https://doi.org/10.1097/EDE.0000000000000777.
[100] Laden F, Schwartz J, Speizer FE, Dockery DW. Reduction in fine particulate air pollution and mortality: Extended follow-up of the Harvard Six Cities study. *Am J Respir Crit Care Med*. 2006;173(6):667-672. doi:10.1164/rccm.200503-443OC.
[101] Awad, Yara Abu, Qian Di, Yan Wang, et al. 2918, "Change in $PM_{2.5}$ exposure and mortality among Medicare recipients: Combining a semi-randomized approach and inverse probability weights in a low exposure population." Environ Epidemiol. 2019;3(4):e054. doi:10.1097/EE9.0000000000000054.
[102] CASAC Review of Quantitative Health Risk Assessment for Particulate Matter – Second External Review Draft (February 2010). https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/BC4F6E77B6385155852577070002F09F/$File/EPA-CASAC-10-008-unsigned.pdf.

relationship between $PM_{2.5}$ exposure and mortality is robust, diverse, and convincing."[103] To the extent EPA's proposal relies on Dr. Cox's views, it violates the statute and exemplifies arbitrary and capricious decision-making. Furthermore, Dr. Cox criticizes the transparency of conclusions made in the PA,[104] but the risk modeling results in the PA are based on dose-response data that EPA analyzed using its open-source Benefits Mapping and Analysis (BenMAP) program.[105] The conclusion that lowering the PM NAAQS would deliver substantial health benefits is clear.

Moreover, placing sole reliance on the manipulative causation approach that Dr. Cox recommends in his comments on the PA runs counter to the Clean Air Act section 108(a)(2) requirement to consider all of the latest scientific evidence and would eliminate most studies that past and more qualified CASACs and PM panels have recommended as relevant to decisions on the standards. And nothing in the Clean Air Act requires following an approach that looks solely at the effects of PM alone, without regard to how it may interact with other factors. To the contrary, the statutory text governing the ISA itself shows that it's not just the effects of PM alone that matter. The Act says that, to the extent practicable, the ISA shall include information on types of air pollution that "may interact with" the criteria pollutant "to produce an adverse effect on public health or welfare." 42 U.S.C. § 7408(a)(2)(b). And the Act says that, to the extent practicable, the ISA shall include information on factors that "may alter the effects on public health or welfare" of the criteria pollutant. *Id.* § 7408(a)(2)(A). Adverse effects are what the NAAQS must prevent, and the Act indicates that it contemplates that those effects can be produced by the pollutant at issue in conjunction with other pollutants and other factors.

Dr. Lange, another CASAC member, echoes Dr. Cox's advocacy for this approach in her comments, and mistakenly decries a "lack of methods demonstrating manipulative causality" and contends that it is "very difficult to predict whether changing the standard will have any impact

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[103] Clean Air Sci. Advisory Comm., EPA-CASAC-19-002, CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018), at 3 (Apr. 11, 2019), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf.

[104] Page B-25 of Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," December 16, 2019 ("The PA's derivations of conclusions from evidence presented are not clear, explicit, and independently verifiable/checkable (i.e., they are not transparent)").

[105] U.S. Environmental Protection Agency. 2014. "Environmental Benefits Mapping and Analysis Program - Community Edition (BenMAP-CE)." Collections and Lists. US EPA. March 14, 2014. https://www.epa.gov/benmap.
Sacks, Jason D., Jennifer M. Lloyd, Yun Zhu, Jim Anderton, Carey J. Jang, Bryan Hubbell, and Neal Fann. 2018. "The Environmental Benefits Mapping and Analysis Program – Community Edition (BenMAP–CE): A Tool to Estimate the Health and Economic Benefits of Reducing Air Pollution." Environmental Modelling & Software 104 (June): 118–29. https://doi.org/10.1016/j.envsoft.2018.02.009.

on public health."[106] As noted in Cox (2018), the "concept of *manipulative causation* differs from the more familiar concepts of associational and attributive causation most widely used in epidemiology."[107] The seven new criteria proposed in that article (without any co-authors) have not been evaluated and are based on "modern literature on causal discovery and inference principles and algorithms for drawing limited but useful causal conclusions from observational data." Ironically, a proper reading of this evidence indicates that it supports the epidemiological evidence and hence revision of the standards to provide requisite protection.[108] On this point, in March 27, 2019 comments to CASAC, former CASAC member Dr. Jonathan Samet noted that this approach is not consistent with the best available scientific evidence: "To date, using Google Scholar, I find few citations by others, the hallmark of peer recognition and of scientific significance. These papers have had insufficient time to be considered by the scientific community in-depth. The approach and underlying methods proposed by CASAC cannot be considered the current state-of-practice. Papers by others are cited, but publication dates are also recent. These references point to future directions around estimation of effects, but cannot be considered as redefining the state-of-practice."[109] See also section VII.D below for a detailed discussion of the manipulative causality literature and how it supports revision of the primary standard.

2. Dr. Lange

CASAC member Dr. Lange misinterprets the underlying scientific information in the ISA and the implications of newly available information synthesized in the PA.

The evidence base directly contradicts unfounded claims made by Dr. Lange about supposed deficiencies of the scientific evidence.[110] The literature that Dr. Lange cites in major point #5 of her comments is outdated and does not reflect the best available scientific evidence that is

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[106] Page B-41 of Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," December 16, 2019.
[107] Cox, Louis Anthony. 2018. "Modernizing the Bradford Hill Criteria for Assessing Causal Relationships in Observational Data." Crit Rev Toxicol. 2018 Sep;48(8):682-712. doi: 10.1080/10408444.2018.1518404.
[108] *See* IPMRP Advice at B-24; Policy Assessment at 3-103; see also the detailed discussion of the manipulative causation literature below.
[109] Written Comments from Jonathan Samet, Colorado School of Public Health. https://yosemite.epa.gov/sab/sabproduct.nsf/B0605B2191E1B1F3852583CA005E759B/$File/Comments+Concerning+EPA%E2%80%99S+ISA+for+Particulate+Matter_Samet_03.27.19.pdf
[110] Clean Air Sci, Advisory Comm., Preliminary Comments from CASAC Members on the PM Policy Assessment (Oct. 21, 2019), https://yosemite.epa.gov/sab/sabproduct.nsf//01A6E0DE6D9865AC8525849A003EFD8D/$File/Preliminary+CASAC+PM+PA+Comments-102119.pdf.

described in the ISA, which identified "consistent evidence of positive associations between long-term $PM_{2.5}$ exposures and mortality."[111] In terms of hazard identification in the PA, Dr. Lange claims that it:

> … has not substantively changed since the last assessment. Most of the causality designations are the same, and the ones that have been upgraded from *suggestive* to *likely* are those that CASAC expressed concerns with. Even if there was more certainty in those new endpoints, they don't provide evidence that risks are occurring at lower concentrations. In the last review the EPA already expressed their greatest degree of certainty in the association between PM2.5 concentrations and mortality and CVD, so the certainty for those key endpoints by definition cannot be greater in this review.[112]

Dr. Lange also oversimplifies the concept of "certainty" and conflates the degree of certainty presented in the causal determinations of the ISA with the confidence intervals presented in the health impact estimates within the PA (e.g., see confidence intervals in Table 3-8 of the PA, Estimated delta and percent reduction in $PM_{2.5}$-associated mortality for the current and potential alternative annual standards in the 30 study areas where the annual standard is controlling). Quantitative uncertainty estimates expressed in these confidence intervals are distinct from the qualitative statements made in the causal determinations of the ISA.

In further refutation of Dr. Lange's claims, the ISA notes that "concentration-response relationships remain linear over the distribution of ambient $PM_{2.5}$ concentrations with no evidence of a threshold" and overall reduced uncertainty in establishing this relationship. Dr. Lange claims that, in the PA, "consideration needs to be made for the problems with epidemiology studies"; indeed, this consideration has already been made in the ISA, which notes that studies "consistently report positive associations with mortality across different geographic locations, populations, and analytic approaches." Regardless of remaining uncertainties within the epidemiology literature, which have been reduced since the 2009 PM ISA, see IPMRP Advice at B-21 to 22, robust evidence clearly demonstrates that the current standards are not adequately protective of health. That conclusion is supported by the IPMRP who have called for stronger annual and daily standards for PM2.5.[113]

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[111] U.S. Envtl. Prot. Agency, EPA/EPA/600/R-18/179, Integrated Science Assessment (ISA) For Particulate Matter (External Review Draft), at 3-19 (2018), https://yosemite.epa.gov/sab/sabproduct.nsf/0/932D1DF8C2A9043F852581000048170D/$File/PM-1STERD-OCT2018.PDF.

[112] Page B-41 of Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," December 16, 2019.

[113] Independent Particulate Matter Review Panel (2020). "The Need for a Tighter Particulate-Matter Air-Quality Standard." *New England Journal of Medicine*, N https://doi.org/10.1056/NEJMsb2011009.

In terms of dose-response, Dr. Lange incorrectly states that there is “nothing changed” in the dose-response curve for major hazards.[114] The claim by CASAC members that “nothing changed” is also recounted by EPA in the PA in a section quoted by the Administrator in his proposed decision.[115]

Dr. Lange narrowly considers the dose-response methods applied by EPA to develop quantitative health projections in the PA, and she and certain other CASAC members ignore new evidence[116] of heightened risks and a steeper dose-response curve at low $PM_{2.5}$ levels. EPA itself notes in the PA that “There is a long-standing body of strong health evidence demonstrating relationships between long- or short-term $PM_{2.5}$ exposures and a variety of outcomes, including mortality and serious morbidity effects. Studies published since the last review have reduced key uncertainties and broadened our understanding of the health effects that can result from exposures to $PM_{2.5}$. Recent U.S. and Canadian epidemiologic studies provide support for generally positive and statistically significant health effect associations across a broad range of ambient PM2.5 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 PM2.5 standards.”[117] The contention that new scientific information has not been presented in the ISA or applied in the PA is incorrect. *See Mississippi*, 744 F.3d at 1344 (noting that “as the contours and texture of scientific knowledge change, the epistemological posture of EPA’s NAAQS

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[114] Page B-41 of Clean Air Scientific Advisory Committee. 2019. “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) (EPA-CASAC-20-001),” December 16, 2019.

[115] 3-98 of U.S. Environmental Protection Agency. 2020. “Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter.” https://www.epa.gov/sites/production/files/2020-01/documents/final_policy_assessment_for_the_review_of_the_pm_naaqs_01-2020.pdf (“These members of the CASAC additionally contend that recent epidemiologic studies reporting positive associations at lower estimated exposure concentrations mainly confirm what was anticipated or already assumed in setting the 2012 NAAQS, and that such studies do not provide new information calling into question the existing standard. Thus, they advise that, ‘while the data on associations should certainly be carefully considered, this data should not be interpreted more strongly than warranted based on its methodological limitations.’”); 85 Fed Reg. at 24,119.

[116] Pappin, Amanda J., Tanya Christidis, Lauren L. Pinault, Dan L. Crouse, Jeffrey R. Brook, Anders Erickson, Perry Hystad, et al. 2019. “Examining the Shape of the Association between Low Levels of Fine Particulate Matter and Mortality across Three Cycles of the Canadian Census Health and Environment Cohort.” *Environmental Health Perspectives* 127 (10): 107008. https://doi.org/10.1289/EHP5204.

[117] Page 3-106 of U.S. Environmental Protection Agency. 2020. “Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter.” https://www.epa.gov/sites/production/files/2020-01/documents/final_policy_assessment_for_the_review_of_the_pm_naaqs_01-2020.pdf.

review necessarily changes as well; additional certainty about what was merely a thesis might very well support a determination that the line marked by the term 'requisite' has shifted").

Dr. Lange claims that "the EPA Administrator is making a decision (and the CASAC is making a recommendation) based on the data and analyses as they stand today."[118]

EPA expert staff considered CASAC comments and recommendations and responded to them with changes (e.g. removing the mention of "accountability" in Table 3-2). They did add more on uncertainties regarding the risk assessment, but disagreed with the causality arguments made by Dr. Cox, instead affirming that the standards were wanting and should be revised. PA at 3-106-107. Administrator Wheeler's proposal contradicts the conclusion made in the PA that "the available scientific evidence, air quality analyses, and the risk assessment, as summarized above, can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the combination of the current annual and 24-hour primary PM2.5 standards."[119] The IPMRP agreed with these views of the EPA expert staff. IPMRP Advice at B 20-22. The IPMRP also found that arguments for keeping the current standard are unjustified, indeed, "specious." *Id.* at B-23 -25.

Dr. Lange's mistaken assertion that "nothing changed" since the last review is telling in that it is directly and thoroughly contradicted by the information presented in the ISA and the PA. Her assertion demonstrates the CASAC's inability to fairly interpret and consider the evidence presented in these assessments before making recommendations to the Administrator. We address this mistaken assertion in detail later in these comments.

Later in her comments, Dr. Lange confuses statistical significance with policy relevance in another statement of her comments by writing: "Just taking into account the uncertainty quantified by the 95% CIs of the C-R functions, the risk estimates between the current standard and the alternative standards overlap, showing that there does not seem to be an expectation of a statistically significant decrease in risk with a decrease of the $PM_{2.5}$ annual standard."[120] The quantitative risk estimates provided in the PA include confidence intervals that are based on the

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[118] Page B-40 of Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," December 16, 2019.

[119] Page 3-106 of U.S. Environmental Protection Agency. 2020. "Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter." https://www.epa.gov/sites/production/files/2020-01/documents/final_policy_assessment_for_the_review_of_the_pm_naaqs_01-2020.pdf.

[120] Page B-40 of Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," December 16, 2019.

underlying epidemiology studies analyzed through BenMAP. Dr. Lange appears to believe that, although the central estimates of these risk estimates under alternate standards vary substantially, the 95% confidence intervals (which convey statistical significance) should outweigh these central estimates. That approach is not consistent with the conclusion made in the PA that lowering the NAAQS would achieve "reductions in estimated IHD mortality risk across the 30 study areas"[121], a finding consistent with the best available epidemiologic evidence.[122]

Dr. Lange contends that, because "[m]ost of the exposure data being measured or modeled in the epidemiology studies is from the early 2000s with no data later than 2013" that "the impact of lowering the standard in 2012 hasn't been assessed or captured in these studies."[123] It is unclear why the information presented by EPA in the ISA (e.g., in Figure 11-17, Associations between long-term $PM_{2.5}$ exposure and total (nonaccidental) mortality in the American Cancer Society cohort) is not timely enough for Dr. Lange. No evidence is presented in the ISA indicating that the health harms of $PM_{2.5}$ have lessened since 2013, and in fact newly published studies indicate added risk of effects in areas with air quality distributions allowed by the current NAAQS. More fundamentally, Dr. Lange's question, echoed by the Administrator, reflects a fundamental legal error. The NAAQS provisions of the Act do not require the Administrator to have conclusive proof of harm before taking action, as already described. And, as shown below, there is ample evidence that reducing $PM_{2.5}$ exposures reduces risk, and the IPMRP and the Policy Assessment so interpret the accountability/manipulative causation literature. The new Domenici study from June, 2020 confirms these conclusions.

i. Enstrom et al. (2017)

A study by James Enstrom, referenced in the ISA and relied upon by at least one CASAC member,[124] Dr. Lange, provides no support for the proposal to retain the annual and 24-hour $PM_{2.5}$ NAAQS.[125] The study suffers from multiple problems and it is inconsistent with the overwhelming body of peer-reviewed literature on the health hazards of $PM_{2.5}$.

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[121] Page 3-93 of U.S. Environmental Protection Agency. 2020. "Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter." https://www.epa.gov/sites/production/files/2020-01/documents/final_policy_assessment_for_the_review_of_the_pm_naaqs_01-2020.pdf.

[122] Shi, Liuhua, Antonella Zanobetti, Itai Kloog, Brent A. Coull, Petros Koutrakis, Steven J. Melly, and Joel D. Schwartz. 2016. "Low-Concentration PM2.5 and Mortality: Estimating Acute and Chronic Effects in a Population-Based Study." *Environmental Health Perspectives* 124 (1): 46–52. https://doi.org/10.1289/ehp.1409111.

[123] Page B-41 of Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," December 16, 2019.

[124] The inclusion of this study further cuts against the assertions of certain CASAC members that the ISA did not include negative studies.

[125] Letter from Dr. Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee, to Andrew R. Wheeler, Administrator, U.S. Environmental Protection Agency (April 11, 2019), "CASAC Review of

The draft and final Integrated Science Assessment for Particulate Matter reference Enstrom's study.[126] Notably, Enstrom's study is the *only* study using ACS data included in the ISA that concludes there is a "null association" between county-level averages of $PM_{2.5}$ and deaths.[127] The ISA then notes that "[i]nconsistencies in the results could be due to the use of 85 counties in [Enstrom's 2017 reanalysis] and 50 metropolitan statistical areas in the original [1995] ACS analysis."[128] EPA cites a litany of other studies that "were consistent with previous results from the ACS cohort . . . and provide evidence of positive associations for cause of death that had not previously been evaluated."[129]

In his study, Enstrom purported to reanalyze the data used by the American Cancer Society's (ACS) landmark 1995 study demonstrating a positive association between $PM_{2.5}$ exposure and mortality.[130] The ACS has refuted Enstrom's claim that he obtained data from the original ACS study in his reanalysis. The organization has said it cannot verify the data used by Enstrom is even from the original study.[131]

The broader scientific community has also summarily rejected Enstrom's findings of a null association between $PM_{2.5}$ exposure and mortality, due to his reliance on two-decades old modeling techniques, unverified data, and failure to cite or contend with the vast array of studies

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the EPA's *Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)*" ("CASAC Letter"); Enstrom, James E. 2017. "Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis." *Dose-Response* 15 (1): 1559325817693345. https://doi.org/10.1177/1559325817693345. ("Enstrom Study").

[126] ISA at 11-67; U.S. EPA. Integrated Science Assessment (ISA) for Particulate Matter (Final Report, 2019). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-19/188, 2019; U.S. EPA. Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018). U.S. Environmental Protection Agency, Washington, DC, 2018; EPA/600/R-18/179, at 11-65.

[127] ISA at 11-67.

[128] *Id.*

[129] *Id.*

[130] Enstrom Study at 2 (claiming that he obtained "[c]omputer files containing the original 1982 ACS CPS II de-identified questionnaire data and 6-year follow-up data . . . from a source with appropriate access to the data" but admitting that the data used "is not as complete and current as the data and documentation possessed by ACS.") *See also* Pope C. Arden, Thun MJ, Namboodiri MM, et al. "Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults." *American Journal of Respiratory and Critical Care Medicine* 1995; 151: 669–74. https://doi.org/10.1164/ajrccm/151.3_Pt_1.669.

[131] Pope, C. Arden, Daniel Krewski, Susan M. Gapstur, Michelle C. Turner, Michael Jerrett, and Richard T. Burnett. 2017. "Fine Particulate Air Pollution and Mortality: Response to Enstrom's Reanalysis of the American Cancer Society Cancer Prevention Study II Cohort." *Dose-Response* 15 (4): 1559325817746303. https://doi.org/10.1177/1559325817746303, ("ACS Rebuttal") at 3 (citing 23 additional peer-reviewed reanalyses of the original ACS Cohort-II findings confirming the link between PM2.5 exposure to cardiovascular disease, respiratory disease, and lung cancer).

confirming a positive association between $PM_{2.5}$ exposure and mortality.[132] Enstrom's study was based upon non-peer-reviewed and unpublished findings that directly contradict two decades of studies confirming the existence of a positive association between $PM_{2.5}$ exposure and morbidity.[133]

The authors of the original ACS study published a point-by-point rebuke of Enstrom's findings in 2017.[134] Enstrom asserted that ACS manipulated the data via "selective use of CPS-II and PM2.5 data."[135] However, the ACS study authors revisited the data in 2016 with an extended follow-up period and updated exposure methodology.[136] They found that the 2016 reanalysis was not only consistent with the original 1995 findings, but demonstrated *additional* positive associations between long-term particulate matter exposure and death caused by cardiovascular and respiratory illness.[137] Similarly, multiple independent reanalyses and extended analyses of the original data using improved metrics "consistently demonstrated $PM_{2.5}$-mortality associations with cardiovascular . . . and lung cancer mortality."[138] By contrast, Enstrom "use[d] data with a shorter follow-up period, fewer participants, and fewer deaths than any previous $PM_{2.5}$ analysis," and fewer than any other study that reanalyzed the original ACS cohort.[139]

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132 *See generally* Enstrom Rejection Letters.
133 ACS Rebuttal at 4.
134 *See* ACS Rebuttal.
135 *Id.* at 1
136 Jerrett M, Turner MC, Beckerman BS, et al. "Comparing the Health Effects of Ambient Particulate Matter Estimated Using Ground-Based versus Remote Sensing Exposure Estimates," Environmental Health Perspective 2017; 125:552–59.
137 *Id.* at 1 (detailing how the study was expanded and refined in the two decades since its original publication, including by increased follow-up on participants from 7 to 22-26 years, the number of participants from ~295,000 to ~670,000, and number of deaths from 21,000 to 237,000); *see also* Jerrett M, Turner MC, Beckerman BS, et al. "Comparing the Health Effects of Ambient Particulate Matter Estimated Using Ground-Based versus Remote Sensing Exposure Estimates," *Environmental Health Perspective* 2017; 125:552–59 at 553–54.
138 *Id.* at 4 (citing footnotes); *see also id.* at 3, Figure 1 (demonstrating various highlighting the consistency of the original ACS data).
139 *Id.* at 3.

In light of the multitude of failings and flaws in the Enstrom study (flaws well-known to EPA), *any* reliance by EPA on the discredited Enstrom analysis would be unlawful, arbitrary, and capricious, and otherwise an abuse of discretion. The Agency must explain any reliance on the Enstrom study, and any reliance on the CASAC majority recommendations crediting the Enstrom study in any final decision. This includes addressing the systematic critiques of the Enstrom study in the materials discussed in these comments, which we attach. EPA has a duty to "explain the evidence which is available, and must offer a 'rational connection between the facts found and the choice made.'"[140]

In her comments accompanying the CASAC Letter to the Administrator, just one CASAC member, Dr. Lange, attempted to defend the Enstrom study. She wrote that "one would *guess* that [Enstrom's study] had less exposure error and therefore possibly a greater effect estimate" as compared to the Harvard 6 Cities and ACS Cohort studies, two of the most influential and well-regarded studies examining the connection between air pollution and public health.[141] By EPA's own admission, both the Harvard 6 Cities and ACS studies "have undergone extensive independent replication and extended reanalysis."[142] One CASAC member's "guess" that Enstrom's study, which largely discredits the EPA's own views and has been rebuked by the original authors of the ACS study, is the evidence that the Administrator's reliance on some CASAC members' advice in the decision "jump[s] the rails of reasonableness in examining the science."[143] In contrast to one CASAC member's assertion that "one would *guess* that [Enstrom's study] had less exposure error and therefore possibly a greater effect estimate,"[144] ACS highlights that "Enstrom's $PM_{2.5}$ exposure assessment is likely subject to greater exposure misclassification because of inadequate assignment of geographic units of exposure" and ignores "advanced modeling approaches for exposure assessment that have been developed over the last 2 decades."[145] Enstrom confounded the data by mismatching geographical data from volunteers

[140] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 52 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). While EPA is entitled to "great deference when [the Court] evaluates claims about competing bodies of scientific research," basing a national rule on scientific research that has not been verified would undoubtedly be arbitrary, capricious, unlawful, and otherwise an abuse of discretion. *Id.* (citing *Waukesha v. EPA*, 320 F.3d 228, 247 (D.C. Cir. 2003)).
[141] CASAC Letter at A-140 (emphasis added).
[142] ISA, at 11-66.
[143] *National Ass'n of Mfrs. v. EPA*, 750 F.3d 921, 924 (D.C. Cir. 2014) (J. Kavanaugh); *see also* U.S. EPA, Policy Assessment for the Review of the PM NAAQS(2020), EPA-452/R-20-002 at 3-106 ("There is a longstanding body of health evidence supporting relationships between $PM_{2.5}$ exposures (short- and long-term) and mortality or serious morbidity effects" and "[t]he current primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated deaths in the U.S.").
[144] CASAC Letter at A-140 (emphasis added).
[145] ACS Rebuttal at 3.

recruiting study participants with exposure metrics, despite volunteers often not living in the same state as participants, and used decades-old modeling to produce his findings.[146]

ACS also highlighted the Enstrom article's "inexplicable" failure to adequately document "the relevant and extensive peer-reviewed literature."[147] Enstrom's article "include[s] an unconventional mix of unpublished and non-peer-reviewed correspondence," while "[k]ey published extended analyses of the ACS CPS-II cohort, studies of other cohorts, or even major reviews and evaluations of the literature are not cited or discussed."[148]

Any reliance by EPA on the discredited Enstrom study, in disregard of the far broader body of peer-reviewed science showing the relationship between $PM_{2.5}$ exposures (short- and long-term) and mortality, would be unlawful, arbitrary, and capricious, and otherwise an abuse of discretion.

3. Dr. Lipfert (Consultant Pool)

In communication with CASAC during its review of the draft Policy Assessment, Dr. Frederick Lipfert offered his 2018 commentary[149] that calls into question a large study of air pollution and mortality in the Medicare population by Di et al. (2017)[150] based on concerns about residual confounding.[151] This criticism and vague suggestion of confounding issues is suggested frequently, without adequate rationale or detail, by some CASAC members to attack strong air pollution epidemiology studies. For example, Dr. Cox contends that:

> My experience analyzing C-R data sets for $PM_{2.5}$ has been that estimating exposure-response associations without fully controlling for daily temperature extremes, month of year, and other variables does indeed reveal significant positive statistical associations between $PM_{2.5}$ and mortality, consistent with other findings in the literature; but that these associations disappear once measured

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146 *Id.*
147 *Id.*
148 *Id.* at 3–4; *see also id.* at 1, n.2–7 (citing studies that consistently confirm original findings of the ACS cohort).
149 Lipfert, Frederick W. 2018. "Air Pollution and Mortality in the Medicare Population." *JAMA* 319 (20): 2133–34. https://doi.org/10.1001/jama.2018.3939.
150 Di, Qian, Yan Wang, Antonella Zanobetti, Yun Wang, Petros Koutrakis, Christine Choirat, Francesca Dominici, and Joel D. Schwartz. 2017. "Air Pollution and Mortality in the Medicare Population." *New England Journal of Medicine* 376 (26): 2513–22. https://doi.org/10.1056/NEJMoa1702747.
151 CASAC PA Review at D-32.

> confounders such as month and daily high and low temperatures are fully adjusted for.[152]

These assertions are without merit, especially in light of the fact that CASAC itself acknowledges a lack of epidemiology expertise and several CASAC members through their written comments reveal their inability to distinguish between correlation and causation. Indeed, Di et al. (2017) found "significant evidence of adverse effects related to exposure to $PM_{2.5}$ and ozone at concentrations below current national standards" in the original study,[153] and co-author Dr. Schwartz noted in a reply to Dr. Lipfert that confounding issues had been adequately addressed and that there was no reason to assume that indoor air pollution exposures would be correlated (in a causal or non-causal way) to *both* the exposure of interest and independently and causally associated with the health effect under study.[154] As noted by Dr. Schwartz, **"**[t]o confound, daily variation in particles from cooking, smoking, etc, must be correlated with daily variation in outdoor $PM_{2.5}$ of the same person. The Medicare Beneficiary Survey showed that 86% of beneficiaries were nonsmokers. It seems implausible that smokers consistently smoked more or that people fried more food on higher pollution days." Similarly, the IPMRP found that "Di et al. showed that individual smoking and income levels were not associated with PM2.5 exposure, a necessary condition for confounding." IPMRP Advice at B-28. Dr. Cox's suggestion of confounding issues in Di et al. (2017) is without merit because indoor air pollution is not a confounding variable in that study.

4. CASAC concerns about confounding and exposure misclassification ignore scientific evidence presented in the ISA and PA

While CASAC members including Dr. Cox have raised concerns about residual confounding, CASC does not mention Table B-12 (Study characteristics from key studies) in the Policy Assessment Appendix B at pages B 33-71, which contains a study by study description of how each one of these key studies controls for confounding. This table explains EPA's analysis of key studies, including those in Table C-1 of the Policy Assessment that constitute the epidemiology studies presented included in the risk assessment as sources of effect estimates. Table B-12 of the Policy Assessment Appendix demonstrates how key studies control for temperature, humidity, income, and other confounding variables.

On page 9 of its December 2019 letter, some CASAC members find that "the estimated regression C-R functions in Appendix C and Chapter 3 of the Draft PM PA have not been

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152 CASAC PA Review at B-22.

153 Di, Qian, Yan Wang, Antonella Zanobetti, Yun Wang, Petros Koutrakis, Christine Choirat, Francesca Dominici, and Joel D. Schwartz. 2017. "Air Pollution and Mortality in the Medicare Population." New England Journal of Medicine 376 (26): 2513–22. https://doi.org/10.1056/NEJMoa1702747.

154 Schwartz, Joel D. 2018. "Air Pollution and Mortality in the Medicare Population—Reply." *JAMA* 319 (20): 2135–36. https://doi.org/10.1001/jama.2018.3943.

adequately adjusted to correct for confounding, errors in exposure estimates and other covariates, model uncertainty, and heterogeneity in individual biological (causal) CR functions." In this statement, CASAC implies that the regression C-R functions are overestimates. In fact, EPA notes in the PA that a failure to correct for exposure error would bias the C-R functions downward. For example at page 3-20 in the PA, EPA notes that at a failure to correct for exposure error "could result in attenuation or underestimation of risk estimates." Later, on page 3-103 of the PA, EPA notes that "… a recent study reports that correction for PM2.5 exposure error using personal exposure information results in a moderately larger effect estimate for long-term $PM_{2.5}$ exposure and mortality (Hart et al., 2015). While most $PM_{2.5}$ epidemiologic studies have not employed similar corrections for exposure error, several studies report that restricting analyses to populations in close proximity to a monitor (i.e., in order to reduce exposure error) result in larger $PM_{2.5}$ effect estimates (e.g., Willis et al., 2003; Kloog et al., 2013). 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." This passage demonstrates that the effect estimates that EPA employs within the PA could be expected to overestimate, rather than underestimate, effects if errors in exposure estimates are not correctly accounted for.

In their December 2019 letter, some CASAC members expressed concern that because of alleged issues with measured confounders, unmeasured (latent) confounders, and residual confounding and other "methodological details" relating to "how the risk assessment was done" are allegedly missing within the PA and that because of this, the risk estimates are "highly uncertain." However, on page 3-20 of the PA, EPA notes that "The ISA additionally concludes that positive associations between long-term PM2.5 exposures and mortality are robust across statistical models that use different approaches to control for confounders or different sets of confounders."

With regards to the statistical model applied, it is reasonable for EPA to apply Cox proportional hazard models given the strong absence of lack of a threshold. *See, e.g.*, IPMRP Advice at B-21. Furthermore, Shi et al. (2016), which applied a Cox proportional hazard model (see PA Appendix B. B at B-63), found significant acute and chronic effects for analyses restricted to annual concentrations below 10 μg/m^3 and daily concentrations below 30 μg/m^3. (Section VII below further discusses the issue of the shape of a concentration-response function and lack of presence of thresholds.)

In its December 2019 letter, CASAC requested that EPA account for "contributions (if any) to the total associations made by confounding, measurement errors, model uncertainty, and heterogeneity and variability in individual biological (causal) C-R functions, as well as sampling variability." It does not refer to the explanation at page 3-25 of the PA where EPA explains factors that may explain some of the observed heterogeneity. The IPMRP noted at page B-15 of its report that "virtually all PM components have been shown to have some adverse health impacts," notwithstanding varying toxicities of those components.

Importantly, at 3-102 of the PA EPA concludes that "while no individual study adjusts for all potential confounders, a broad range of approaches have been adopted across studies to examine confounding, supporting the robustness of reported associations." Given the coherence of evidence presented in the ISA, it is clear that no confounders could explain why associations are consistently found in different areas, for different populations, exposed to different air quality distributions, and analyzed through different steady methodologies.

The inadequacy of the Administrator's justification for retaining the current standards and the lack of relevant expertise on CASAC, whose recommendations the Administrator relies upon, are laid bare in CASAC members' individual discussions of uncertainty, confounding, and measurement error. In the proposal, the Administrator fails to provide a discussion of these issues and instead only makes vague references to confounding, and similarly vague references to the conclusion of some members of CASAC to retain the current $PM_{2.5}$ primary standards.

The Administrator concludes that, "the overall body of evidence, including controlled human exposure and animal toxicological studies, in addition to epidemiologic studies, indicates continuing uncertainty in the degree to which adverse effects could result from PM2.5 exposures in areas meeting the current annual and 24-hour standards. 85 Fed. Reg. 24,120 (Apr. 30, 2020). Citing some members of CASAC, the Administrator notes that "associations reported 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' (Cox, 2019a, p. 8)." *Id.* at 24,119. Further, he asserts that epidemiologic evidence "without supporting experimental evidence at similar $PM_{2.5}$ concentrations, leave important questions unanswered regarding the degree to which the typical $PM_{2.5}$ exposures likely to occur in areas meeting the current standards can cause the mortality or morbidity outcomes reported in epidemiologic studies." *Id.* at 24,120.

In its letter on the PA, members of CASAC cited by Administrator Wheeler, claim that epidemiologic associations between short- and long-term $PM_{2.5}$ and serious health outcomes, including mortality "can reasonably be explained in light of uncontrolled confounding and other potential sources of error and bias (discussed below); that associations are not effects (Petitti 1991); and that in intervention studies, reductions of $PM_{2.5}$ concentrations have not clearly reduced mortality risks, especially when confounding was tightly controlled (Henneman et al. 2017; Burns et al. 2019)."[155] Other members of CASAC thought that the body of evidence for PM health effects justified the causality determinations used by EPA in its Science Assessment that underpin the health-based standards.

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[155]CASAC Letter, at 2.

Further, some members of CASAC thought the recent US and Canadian studies that found statistically significant effects from particulate matter levels below the current standards need to "more fully account for effects of confounding, measurement and estimation errors, model uncertainty, and heterogeneity" and that additional studies which were not included in the ISA need to be taken into account.[156] In contrast, the IPMRP and other members of CASAC found that this new evidence was "strong, with biological plausibility provided by human controlled exposure and animal toxicological studies." We respond to these mistaken assertions in sections which follow.

5. CASAC's fixation on temperature as an important positive confounder in cohort studies has little basis in logic and contradicts the results of cohort and causal inference studies that have examined the issue.

The group of members referred to as "some" in CASAC noted three major types of confounding that EPA address in evaluating cohort studies used in risk assessment: Measured confounders omitted, Unmeasured (latent) confounders, and Residual confounding and provided examples for each class (Cox, 2019a, p 6). Daily high and low temperatures were listed as examples in all three categories. The emphasis also appears in an Appendix A credited to the group (Cox, 2019a, pp A1-2) and especially in Dr. Cox's individual comments (Cox, 2019a, p B-8-11,B-13-24). He notes this interest is based on some of his early work that focused on the issue:

> "My experience analyzing C-R data sets for $PM_{2.5}$ has been that estimating exposure-response associations without fully controlling for daily temperature extremes, month of year, and other variables does indeed reveal significant positive statistical associations between $PM_{2.5}$ and mortality, consistent with other findings in the literature; but that these associations disappear once measured confounders such as month and daily high and low temperatures are fully adjusted for (sic)." Cox 2019b, p B-22).

He provides three examples of his experience analyzing $PM_{2.5}$ effects on health relevant to temperature, the first of which (Cox et al 2012a),[157] purports to be an assessment of the effects of $PM_{2.5}$ reductions between 1987 to 2000 using data from the 108 sites represented NMMAPs data set. Yet as indicated in HEI's NMMAP report, the bulk of these sites measured PM_{10} during this period and more routine inclusion of $PM_{2.5}$ did not begin until 1999. They apparently used

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[156] Clean Air Scientific Advisory Committee. 2019. "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) (EPA-CASAC-20-001)," at 8, December 16, 2019. https://yosemite.epa.gov/sab/sabproduct.nsf/E2F6C71737201612852584D20069DFB1/$File/EPA-CASAC-20-001.pdf.

[157] Cox, T., Popken, D., Ricci, P. F. (2012). Temperature, not Fine Particulate Matter (PM2.5), is Causally Associated with Short-Term Acute Daily Mortality Rates: Results from One Hundred United States Cities. Dose-Response, 11(3), dose-response.1. https://doi.org/10.2203/dose-response.12-034.cox

adjusted PM_{10} data to estimate $PM_{2.5}$ in the majority of years with little $PM_{2.5}$ data. Several initial approaches examined $PM_{2.5}$ and daily mortality, is not equivalent to a long-term cohort study. The results of these approaches suggested conditioning on daily temperature and month of year eliminates PM effects, suggesting they contribute strong non-linear confounding. One of several causal approaches found "strong evidence of a Granger-causal relationship" between daily minimum temperature and mortality rates, but not $PM_{2.5}$ as is the only case that did not use daily mean. Of course, temperature is widely recognized as a confounder for short-term studies that must be considered, and the paper provides no reason for suggesting why daily minimum or maximum temperature, which tend to be correlated with mean temperature, should be favored.[158]

Given the focus on daily mean temperature in the studies cited as evidence that examine daily mortality and a supplementary analysis even addressing only minimum temperature in these papers, it is surprising so much attention is given to maximum and minimum temperatures in comments by some CASAC members in their letter (Cox, 2019b), Appendix A and in their individual comments. Nothing in any of these cited studies nor in CASAC comments provide any real evidence or even a plausible hypothesis, that any cohort study that does not address daily maximum or minimum temperature is confounded. Yet, in an October 2019 CASAC meeting, Cox insists that the studies under review do not control for confounding and this meeting is when he first offered his 2012 paper(s) that used NMMAPs as the experience that convinced him of the need to consider confounding daily maximum and minimum temperatures in long-term cohort studies. During that meeting, Cox, in referring to eight cohort studies used in the PA risk assessment, stated "... a lot of them just don't adjust for temperature at all." (Cox oral comments, CASAC Meeting, October 24, 2019).

Dr. Joel Schwartz recently submitted supplemental comments that address some conceptual issues with Dr. Cox's and some followers on CASAC's position on temperature as a major confounder of cohort studies.

[158] The other NMMAPs related study cited on B-22 of Cox's individual comments limits the NMMAP data to just two years, and appears to focus on daily average temperatures and not daily max/min temperature. They find increasing temperatures reduce mortalty while Warmer is healthier: effects on mortality rates of changes in average fine particulate matter reductions have no effect. (Cox LA Jr, Popken DA, Ricci PF. Warmer is healthier: effects on mortality rates of changes in average fine particulate matter ($PM_{2.5}$) concentrations and temperatures in 100 U.S. cities. *Regl Toxicol Pharmacol*. 2013 Aug;66(3):336-46). Because this focused more on comparing a one-year change in average daily temperature, daily Warmer is healthier: effects on mortality rates of changes in average fine particulate matter and daily mortality using causal methods, it appears to provide no basis for suggesting daily max/min temperatures have any relevance for confounding long-term cohort studies of long-term exposures to air pollution. While adopting interesting methods, these papers are of particular interest in terms of their main results as they either use transformed daily PM_{10} data to estimate effects on daily mortality rates and changes in average fine particulate matter or compare only two years of data.

> First I want to elucidate why it is so implausible. For a variable to confound an association, it needs to be associated with both exposure and outcome. Daily temperature is associated with daily deaths. However, the cohorts did not analyze daily deaths, they analyzed annual deaths. A typical study of daily deaths that examined heat waves reported that daily deaths during heat waves increased by 3-5%. A typical U.S. city has fewer than one heat wave per year. Suppose deaths increased by 4% per day during that heatwave, and its duration was 3 days. Then the annual mortality would have increased by < 0.04% as a result. And that is an overstatement since the percent increase in heat waves is an increase in daily deaths in the summer, which are substantially fewer than daily deaths in winter and spring, when respiratory epidemics are prevalent. In contrast, using the meta-analysis of Vodonos[1], the percent increase in annual deaths due to $PM_{2.5}$ exposure in the vicinity of 10 $\mu g/m^3$ was 1.3% per $\mu g/m^3$. So the difference between 10 and 8 $\mu g/m^3$ due to $PM_{2.5}$ is a hundred times larger. Hence it is impossible for so small a temperature effect, even if all attributed to $PM_{2.5}$, to be responsible for the observed $PM_{2.5}$ effect.
>
> Of course, for any of the daily temperature effect to be attributed to annual $PM_{2.5}$, daily temperature must be correlated with annual $PM_{2.5}$. The differing time-scales also make this implausible. Daily temperature is high for deaths that occur in the summer, and low for deaths that occur in the winter, while in an analysis of annual $PM_{2.5}$ and annual deaths, the annual $PM_{2.5}$ is the same for all of those days. How can it be correlated? (Schwartz 2020b).

In fact, the HEI reanalysis of the first modern $PM_{2.5}$ cohort studies did examine maximum annual temperature in the ACS study among other variables and found it had little or no effect on the results (Krewski et al, 2000, HEI report).[159] Some other studies have considered inclusion of seasonal averages. Wang et al.(2016)[160] used a variant of a difference in difference approach in a study of long-term PM2.5 exposures for each year from 2004 to 2009 and included an assessment of mean summer and winter temperatures as a potential confounder. They found that seasonal temperature modified, as opposed to confounded the effects of PM2.5 on mortality.

They found an increase in mean winter temperatures was associated with an increase with the effects of PM2.5 on mortality and a reduced risk of mortality in association with PM2.5 where summer temperatures were lower than average. They note that under changing climate conditions, a rise in temperature not only would increase mortality through the direct effects of temperature but also would increase the effects of long-term $PM_{2.5}$ exposure on mortality, which

[159] https://www.healtheffects.org/system/files/HEI-Reanalysis-2000.pdf

[160] Discussed in section (accountability section #. Subsection b, - it's in causal inference methods in the ISA section) below.

would appear to contradict the strange suggestion in Cox et al 2012b who, based on their daily temperature results, concluded that warmer summers would reduce mortality.

Wang et al (2016) noted their results were consistent with a survival analysis among > 35 million Medicare beneficiaries residing in 207 U.S. cities during 2000–2010 found that an increase in annual, summer, or winter temperature was associated with an increase in the hazard ratio of death associated with $PM_{2.5}$.[161]

Both of these cohort studies were available and included in the ISA. In his aforementioned comments, Dr. Schwartz responded directly to a request made by Dr. Cox in a colloquy with Dr. Lianne Sheppard, an academic biostatistician who is a member of the IPMRP who argued that for cohort studies that confounding a by daily maximum and minimum temperatures was implausible. He notes Dr. Cox suggested that needed to be tested.

"I am attaching to this comment a paper[162] where we did just that, and find no confounding, as expected." This paper uses causal modeling techniques and evaluated both daily and annual exposures simultaneously. He writes that "specifically we controlled for both long- (lag 0–364) and short-term (both lag 0–1 and lag 2–6) exposures to temperature. The accepted, peer reviewed manuscript is attached. It clearly shows a significant association with long-term $PM_{2.5}$ after controlling for both long and short-term temperature." (Schwartz et al, 2020b).

The most recent and comprehensive accountability study using both conventional and causal inference models summarized below (Wu et al., 2020) included adjustments for multiple potential confounders, include four meteorological variables, summer and winter averages of humidity and maximum daily temperature. The study used five distinct statistical approaches, including three using causal inference methods, to examine $PM_{2.5}$ reductions between 2000 and 2016. Based on their extensive analysis and sensitivity analysis the authors stated: "We conclude that long-term PM2.5 exposure is causally related to mortality." Wu et al. (2020). A sensitivity analysis showed that the adjustments for meteorological variables were successful.

In short, the need to include daily maximum and minimum temperatures in long-term cohort studies as opposed to seasonal adjustments was not supported by the references the chair provided, or simple logic. Moreover, actual cohort studies that did examine annual, seasonal and in one case, even daily temperature found some evidence of effects modification, which may be important for risk estimates, but after adjusting for seasonal or daily temperatures these studies still found a significant relationship between $PM_{2.5}$ and health effects. This includes a powerful new accountability study that included only subjects living in areas that met the annual standard

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[161] Kioumourtzoglou MA, Schwartz J, James P, Dominici F, Zanobetti A. 2016. PM2.5 and mortality in 207 US cities: modification by temperature and city characteristics. Epidemiology 27:221–227.

[162] Wei Y, Wang Y, Wu X, Di Q, Shi L, Koutrakis P, Zanobetti A, Dominici F, Schwartz JD. Causal effect

in 2000 and found that further reductions through 2016 were significantly associated with reduced mortality.(Wu et al. 2020).

The IPMRP also refuted unfounded suggestions that the associations seen consistently in the key epidemiological studies could be explained by unmeasured confounding. First, in the key cohort studies, the associations with $PM_{2.5}$ are adjusted for individual life-style characteristics such as smoking.[163] In national cohort studies where individual life-style characteristics are unavailable, indirect adjustments were made drawing on other life-style characteristics, as in the Canadian CanCHEK study.[164] The IPMRP expressly found that "mortality associations with long-term PM2.5 exposures were consistent after direct and indirect adjustment for individual life-style factors in all of these key U.S. and Canadian studies. Although not every study is able to control as well as possible for socioeconomic status at both the individual and neighborhood level, in those for which the data are available, the findings are robust to that adjustment."[165]

6. The suggestion by some CASAC members that the recent epidemiology studies finding significant associations between $PM_{2.5}$ and serious health effects at concentrations well below the current standards add nothing new are wholly in error, which is evidence of the members' lack of experience and understanding of the primary bases for EPA staff and CASAC recommendations on the standards in past reviews of the PM criteria and standards.

    i. Even taking the narrow focus on extrapolated linear concentration-response functions as a basis for saying nothing is new, some CASAC members provide a distorted picture of the comparative evidence.

The basis for some members' claims in this matter reflect a narrow view of the newer evidence that focuses solely on linear extrapolations from studies available in 2009 studies as compared to some of the newer studies. Linear plots that assume no thresholds already suggest effects at levels below the earlier standards, meaning that newer studies since then that actually observe such effects do not go beyond what was expected or assumed in the previous review. The draft of CASAC's letter contained the figure below to illustrate such a comparison, which in the final letter appears only in the individual comments by Dr. Lange.

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163 IPMRP Advice at B-28 (citing Pinault et al. 2016, Pope et al. 2015; Jerrett et al. 2016; Thurston et al.2016; Turner et al. 2016).
164 IPMRP Advice at B-28 (citing Weichenthal et al. 2016); see generally Policy Assessment App. B at B-22 to B-66 (documenting the methodology for controlling confounding in each of the key epidemiological studies).
165 *Id.*

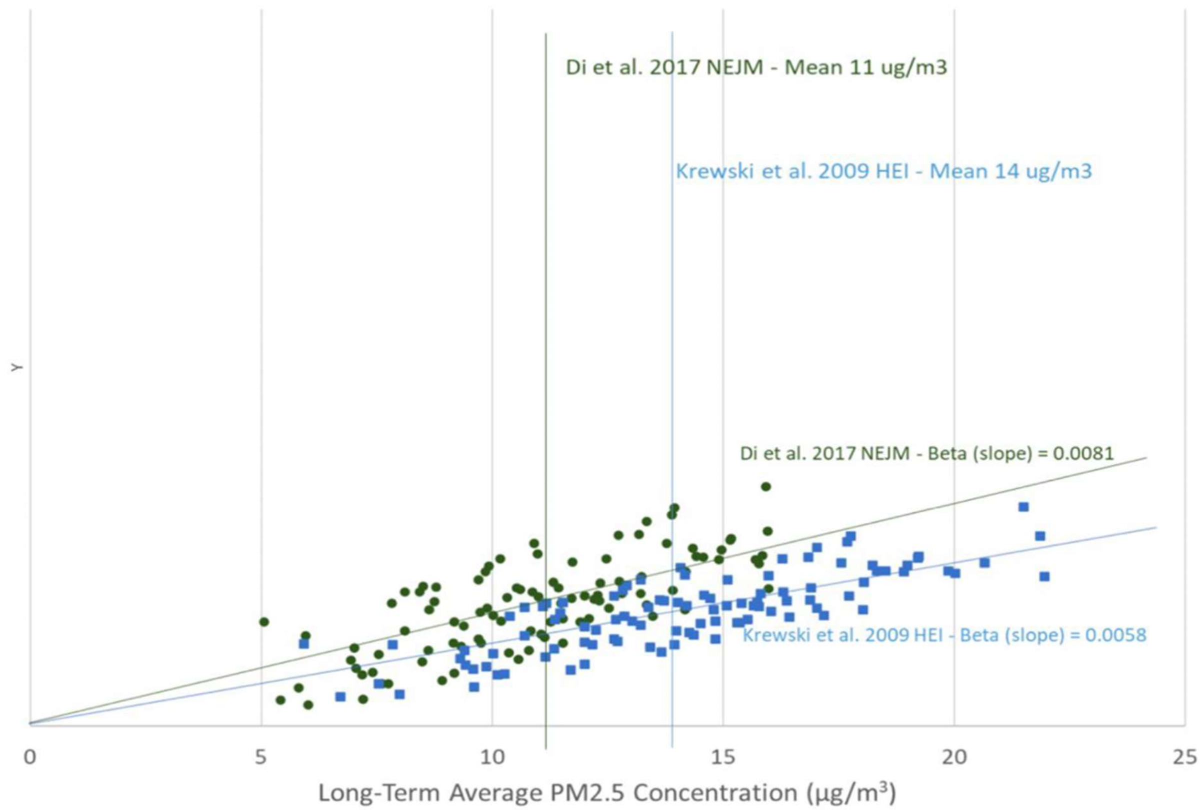

Figure 1. Illustrative simulation of linear relationship between health effect (Y) variable and long-term average $PM_{2.5}$ concentration based on concentration distributions presented in Krewski et al. (2009) and Di et al. (2017). (Cox, 2019a, p B-42).

The figure is notable by the lack of a scale for the health variable, which in the case of the Di at al. (2017) study's own figure was a hazard ratio. The figure is also notable for the use of "simulated" data points suggesting uncertainties that were not taken from the original studies. Because the Di cohort included over 60 million subjects, more than two orders of magnitude larger than that in Krewski et al., the confidence bands for Di are much narrower than suggested here, and the visual impression of the relative number of data points between the two is both meaningless and highly misleading. Lange suggests that this picture illustrates the difficulty of comparing effects of two studies with different mean concentration, yet this difficulty is actually hard-wired in plots that do not present the actual confidence bounds for each study. The figure also does not provide a simulation of the analysis in Di et al. 2017 that examines a C-R function that includes results only for Medicare beneficiaries living in areas with levels below the current annual standard. Such an analysis was not done in Krewski et al. 2009, yet another relevant difference.

These CASAC members' constrained view of linear extrapolations in many studies also ignores emerging evidence that the concentration response function in some recent studies is supralinear at lower levels (*i.e.*, an upwards curving slope) suggestive of increased risk at the lower levels of the distribution. ISA Table 11-7; see also IPMRP Advice at B-22 ("[i]ndeed, it is possible that the annual concentration response relationship is steeper at lower exposures"). This is illustrated in the figure below, which is taken from a meta-analysis of 53 cohort studies by Vodonos et al. 2018. Although this study was published after the ISA cutoff date of January 2018, one of the authors, Joel Schwartz, submitted it to CASAC and EPA in his written comments on the draft CASAC letter. These comments were reviewed in a CASAC teleconference on March 28, 2019.[166]

[166] CASAC never included this study in any list of additional studies EPA should consider, in either the main body of their letter, individual comments on the ISA (Cox, 2019a) or the PA (Cox, 2019b).

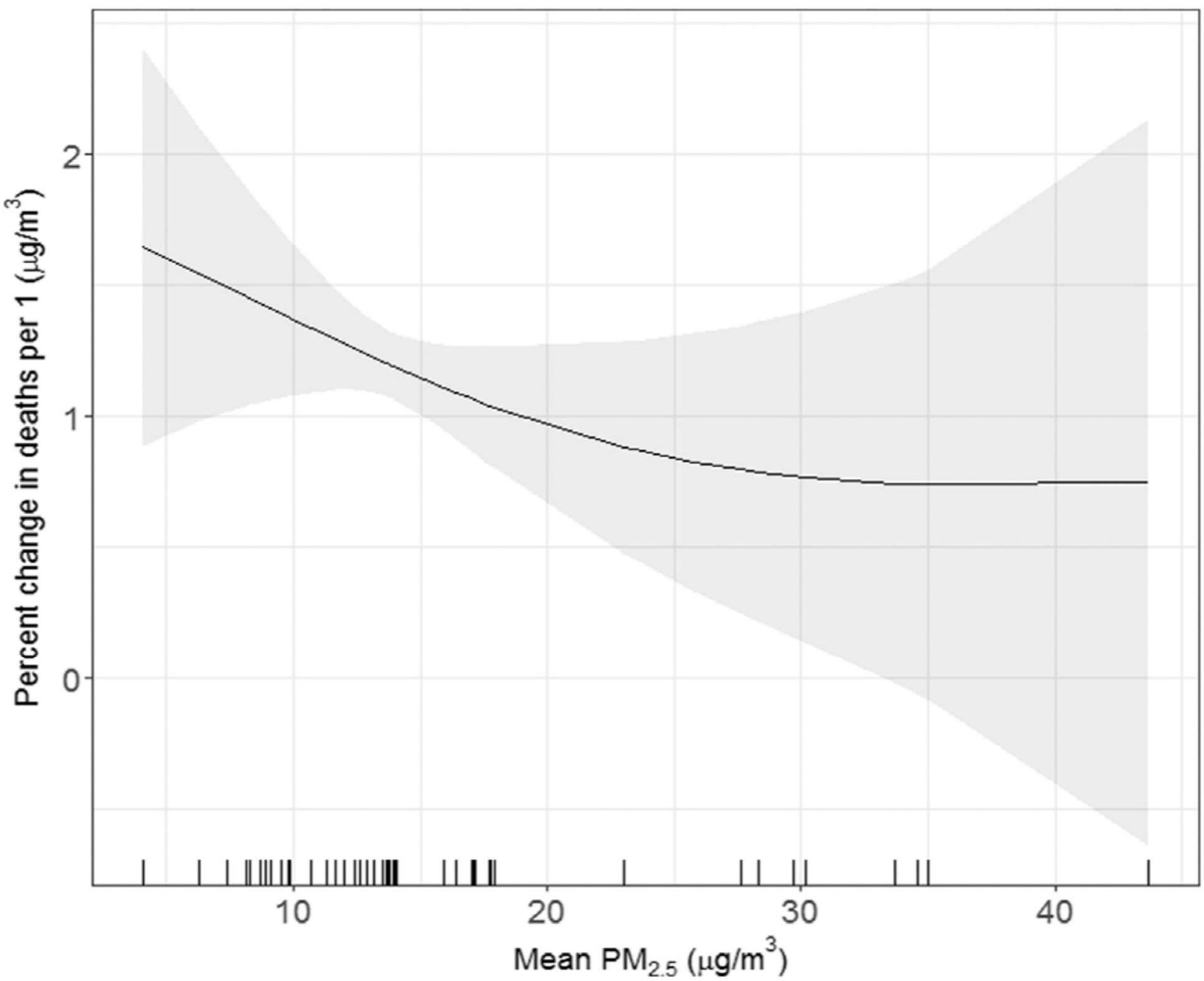

Figure 2. Percent change in death rates for a 1 μg/m3 change in exposure vs. mean $PM_{2.5}$ concentration, which combines the results across 52 cohorts using a penalized spline model. The gray bands reflect the 95% confidence interval. Vodonos et al. 2018.

Thirty-nine of the cohort studies were from North America, with the rest from Europe and Asia. This analysis indicates the greatest statistical certainty occurs at levels below 12 ug/m,[3] which likely is driven more by US and Canadian cohorts, as Asian and, to a lesser extent, some European countries tend to have higher average $PM_{2.5}$ concentrations than he U.S. By contrast, the PA notes that Di et al. 2017 is among those studies with a generally declining hazard ratio at lower concentration that also show some departures from linearity. PA at 3-21. In any event, some CASAC members' reliance on simplistic linear extrapolations loses important information relevant to standard setting, such as the shape and confidence intervals revealed in the analyses. They cannot seriously support a statement that nothing is new by putting blinders on the results.

ii. Some CASAC members' findings on the import of recent epidemiology studies also ignore that these studies show effects at levels less than those allowed by the current standards, and further ignore that more qualified past CASACs and past Administrators have found that such evidence compelled revision of the standards.

The more egregious error in these members' suggestion that recent studies add nothing new is that they completely ignore the core elements of recommendations made by EPA science/policy experts and all CASAC panels in past $PM_{2.5}$ NAAQS reviews for determining whether the then current standards remained sufficiently protective, and if not what range of alternative standards is best supported by the available scientific information. In previous reviews, EPA Administrators have generally placed significant weight on these recommendations, and in such cases the courts have upheld the final decisions reached by the Administrator.[167] Because most of the current six members who reviewed the Policy Assessment had no prior experience in PM NAAQS reviews and the group included no epidemiologists, they apparently lack a clear understanding of this record.

One of the clearest summaries of a core element of the use of epidemiology studies in all past $PM_{2.5}$ NAAQS reviews is summarized in the 2012 proposal: "The general approach used to translate scientific information into standards used in the previous reviews focused on consideration of alternative standard levels that were somewhat below the long-term mean $PM_{2.5}$ concentrations reported in epidemiological studies" (U.S. EPA, 2011a, section 2.1.1). This evidence-based approach was also used by EPA staff in the current final Policy assessment, which used a number of credible studies that suggested effects well below the current standards as a basis for specifying alternative annual standards.

To be clear about the import of this statement, it means that in general, the annual standard should be controlling, and should be set a level somewhat below the mean $PM_{2.5}$ concentrations in both short-term and long-term studies that find effects at levels below the standard. In this approach, the daily standard is set to supplement the annual standard and limit the risk of peak exposures in areas that meet the annual standards. This approach was the basis for the PA and CASAC - recommended standards adopted in the prior review ending in 2013.

In fact, the original $PM_{2.5}$ standards promulgated in 1997 adopted this approach. The final preamble summarized the following key conclusion from CASAC chairman George Wolff: "While the results of the epidemiological studies should be interpreted cautiously, they

[167] Cases where courts upheld EPA's determination, consistent with CASAC's advice, to revise a primary NAAQS because epidemiological studies showed associations at concentrations lower than allowed by the current standard include *ATA III*, 283 F. 3d 355, 370 (D.C. Cir. 2002); and *National Ass'n of Mfr's v. EPA*, 750 F. 3d 921, 924 (D.C. Cir. 2014).

nonetheless provide ample reason to be concerned that there are detectable health effects attributable to PM at levels below the current NAAQS. [U.S. EPA, 1996a, p. 13-92] 62 FR at 38656-7). In deciding that the annual standard should be controlling, the proposal notes insights from the risk assessment and the nature of protection afforded by an annual vs. a daily standard. "…the Administrator recognizes that an annual standard would have the effect of improving air quality broadly across the entire annual distribution of 24-hour $PM_{2.5}$ concentrations, although such a standard would not as effectively limit peak 24-hour concentrations as would a 24-hour standard. The risk assessment summarized above found that because such 24-hour peaks contribute much less to the total health risk over a year than the more numerous low- to midrange $PM_{2.5}$ levels, an annual standard could also provide effective protection from health effects associated with short-term exposures to $PM_{2.5}$ as well as those associated with long-term exposures (see figure 2; 61 Fed. Reg. 65,652-65,653, Dec. 13, 1996). 62 Fed. Reg., at 38669.

In the end, the final decision on the level of the first annual $PM_{2.5}$ standard of 15 ug/m^3 was based on ensuring the level of the standard was somewhat below the annual average in the short-term epidemiology studies, noting that "the strength of the evidence of effects increases for concentrations that are at or above the long-term (e.g. annual) mean levels reported for these studies. Given the serious nature of the potential effects, the Administrator believes it is both prudent and appropriate to select a level for an annual standard at or below such concentrations" (62 Fed. Reg., at 38,376).[168]

As noted above, a similar approach was adopted in the most recent review for the annual standard, with the Policy Assessment recommendations based on the annual means and distributions found in both long-and short-term studies, (EPA 2011, Figure 2-8).[169] The CASAC understood and agreed with this approach: "CASAC agrees that it is appropriate to return to the strategy used in 1997 that considers the annual and the short-term standards together, with the annual standard as the controlling standard, and the short-term standard supplementing the protection afforded by the annual standard." (Samet, 2010 p 1).[170]

The current EPA Policy Assessment (EPA, 2020) reaches the same conclusions:
"we focus on alternative levels of the annual $PM_{2.5}$ standard as the principle means of providing increased public health protection against the bulk of the distribution of short- and long-term

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[168] By contrast, the mean levels derived from the then new Harvard Six City (18 ug/m^3, Dockery et al, 1993) and American Cancer Society (22-21 ug/m^3, Pope et al. 1995) cohort studies were considerably higher than the daily studies, and were used more as additional support.
[169] EPA, 2011. Policy Assessment for the Review of the PM NAAQS
https://www3.epa.gov/ttn/naaqs/standards/pm/data/20110419pmpafinal.pdf
[170]Samet 2010 . CASAC Review of Policy Assessment for the Review of the PM NAAQS – Second External Review Draft (June 2010)
https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/CCF9F4C0500C500F8525779D0073C593/$File/EPA-CASAC-10-015-unsigned.pdf.

$PM_{2.5}$ exposures, and thus protecting against the exposures that provide strong support for associations with mortality and morbidity in key epidemiologic studies." (PA, p 3-113). These conclusions are based on the same reasoning approved and adopted in past reviews: the annual standard, with its form based on the arithmetic mean concentration, is more likely to effectively limit the $PM_{2.5}$ concentrations that comprise the middle portion of the air quality distribution, affording protection against the daily and annual $PM_{2.5}$ exposures that strongly support associations with the most serious $PM_{2.5}$ -related effects in epidemiologic studies (e.g., mortality, hospitalizations) (PA, p 3-112).

Although the CASAC letter indicates that discussions at the meeting clarified this reasoning, later on the same page, some members showed persistent confusion in asking : "what information can be gained from determining if an area from a short-term $PM_{2.5}$ study was in attainment of the 3-year annual average $PM_{2.5}$ standard (because the association between $PM_{2.5}$ and the short-term health effect is based on daily changes in $PM_{2.5}$ that may have little to do with the annual average). (Cox, 2019b, p 5). Whether they understood and were calling for clarity in the revised PA, or not, the question suggests that they did not appreciate the effectiveness of how an annual controlling standard reduces both daily as well as annual levels of $PM_{2.5}$.

The effectiveness of a controlling annual standard is evident in the marked reductions in both annual and 98th percentile 24-hour levels of $PM_{2.5}$ between 2000 and 2017 (PA, p 2-30). These are most consistent in the Eastern U.S. and coastal California, and less so in many western sites, and the correlations between annual and 98th percentiles are generally high, with low values in some western areas (PA, Figure 2-17). This is consistent with expectations that in the majority of sites where the annual standard is controlling or nearly so, it more efficiently reduces the entire distribution of $PM_{2.5}$ over the year, including the peak and upper quartile concentrations, as well as the middle of the distribution. The daily standard is intended to ensure adequate protection to public health from periodic high daily values in areas that meet the annual standard, e.g. areas affected by seasonal sources like home heating.

As in the previous NAAQS review, this Policy Assessment considered the annual averages from both short-term and long-term cohort studies that showed effects in areas that meet the current standards. As in all past reviews, the assessment did not base recommendations on the level of the standards on linear extrapolations well below the mean levels of these studies, but on examining levels somewhat below the means in such studies. This is because EPA has to be guided by the requirement that the standard must be requisite to protect public health. The Administrator is not free to extrapolate to an arbitrarily low level that cannot be reasonably documented in the available epidemiologic and other evidence. As noted in the PA, this has been interpreted as somewhat below the mean in associational epidemiology studies, below which the uncertainties tend to increase. (PA 3-53).

In the last review, those assessments informed the Policy Assessment and a far more qualified CASAC/panel recommendations on a range of levels for a controlling annual standard, which concluded that the lower bound of the range should be 11 ug/m^3. (78 Fed. Reg., at 3,136). In the current ISA, the Policy Assessment review examined levels below the mean in a number of studies concluding that the standards should be revised and that the lowest level reached as low as 8 ug/m^3. The IPMRP, for the same reasons, agreed. IPMRP Advice at B-27 to 28 (explaining that their recommendations as to the lower end of a range for a revised annual primary standard reflects "that it is appropriate to consider the means of key epidemiologic studies, which is consistent with past practice in previous reviews", and further, that "the uncertainties at such lower levels become larger", referring to study results at the 25th and 10th percentiles of these studies' data.).

Despite the unsupported suggestions by some on CASAC, based on the major principles that have guided base EPA staff assessments, CASAC recommendations, and final decision in past reviews, many additions to the scientific information since the 2012 review have found highly relevant new insights of effects resulting from exposure to air quality distributions allowed by the current standards. The Administrator is mistaken, as a matter of law, in placing any weight on some CASAC members' suggestions that these new studies do not provide information relevant to—and necessitating—revision of the current standards.

D. EPA must follow the advice of the Independent Particulate Matter Review Panel because it reflects the latest scientific knowledge

The IPMRP has advised that the body of science in the ISA strongly mandates a revision of those standards to provide the requisite protection for air quality and the public health and welfare. As explained more fully below, the Panel points to a robust and profoundly coherent body of epidemiological, clinical, and animal toxicity evidence, "buttresse[d]" by the results of the risk assessment, which provides "qualitative" support.[171] The Panel reads the accountability/ intervention study literature as supporting revision of the primary standard.[172] The advice further provides a detailed account of prior CASAC reviews and endorsements of the causality framework reflected in the ISA and PA.[173]

The Panel asserts that there are no legitimate arguments for keeping the current primary standard: "[t]he Panel finds that the draft PA's alternative argument in favor of retaining the current standard"—which the Administrator essentially adopted in the proposal—"is a scientifically unjustifiable interpretation of the evidence that over-emphasizes and

[171] IPMRP Advice at B-14 and B-21 (coherence), B-15 and B-31 (clinical evidence, including characterizing some studies as occurring at policy-relevant levels); B-22 (animal toxicity); B-11 and B-23 (risk assessment).
[172] IPMRP Advice at B-24.
[173] IPMRP Advice at C-56-61.

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."[174]

In particular, the Panel pointed to the coherent body of epidemiological studies showing associations over a range of levels and averaging times, examining different endpoints and populations, using different study designs; past CASAC interpretations of that body of epidemiological evidence; multiple studies in this review of very strong statistical power showing associations in areas with air quality distributions well below the level allowed by the current annual and 24-hour NAAQS; supporting evidence from clinical, animal toxicity, and accountability studies, and qualitative support from the risk assessment.[175] The Panel found no basis to discard this body of evidence: "in order to accept the current standards as adequate, multiple implausible and scientifically unjustifiable assumptions and conclusions are necessary. Applying Occam's razor – i.e., the more assumptions that are required, the more implausible the explanation – the IPMRP concludes that the arguments in favor of retaining the current standard are specious."[176]

EPA's proposal fails to even acknowledge this expert advice, much less respond to it. This is arbitrary. Given the Panel's selection by CASAC through traditional and legitimate process, given its longstanding role approved by CASAC and EPA via the Integrated Review Plan, given its participation in the review, and given the reconstituted CASAC's plea for expert assistance from this Panel or a Panel of equal expertise,[177] EPA must not only consider the IPMRP comments and advice, but should accord them special weight. EPA must either accept the Panel's advice, or, if it does not do so, must "fully explain its reasons for any departure" from that advice. *Mississippi v. EPA*, 744 F. 3d 1334, 1354. It must do so both as a matter of administrative law, and by close analogy with CAA section 307(d)(3), which requires such an explanation for any deviation from CASAC recommendations.

It is fortunate that the improperly excluded panel of experts conducted a meticulous and detailed review of the Independent Science Assessment and Policy Assessment and provided that advice to the Administrator, as described more fully in section IV.B.3. The Panel was selected by CASAC and their function agreed to by EPA in the Integrated Review Plan for this review. The review and recommendations of this panel provide a far more meaningful scientific review than the advice provided by the reconstituted CASAC alone.

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[174] IPMRP Advice at B-23.
[175] IPMRP Advice at B-23 to 25.
[176] IPMRP Advice at B-25.
[177] As explained above, the pool of subject matter experts picked to aid CASAC, and the process for CASAC interaction with this pool of experts, falls well short of the accuracy and thoroughness that the CAA demands.

E. EPA's proposal is a violation of the CAA on its face because it fails to consider sensitive populations and contains no margin of safety for them

Section 109 of the Clean Air Act requires that when setting or revising the NAAQS, EPA achieve one thing at minimum: protect public health with an *adequate margin of safety*. 42 U.S.C. 7409. This mandate "carries the promise that ambient air in all parts of the country shall have no adverse effects upon *any* American's health." 116 Cong. Rec. 42,329, 42,381 (Dec. 18, 1970) (remarks of Senator Muskie, floor manager of the conference agreement) (emphasis added).[178] As a result:

> Standards must be based on a judgment of a safe air quality level and not on an estimate of how many persons will intersect given concentration levels. EPA interprets the Clean Air Act as providing citizens the opportunity to pursue their normal activities in a healthy environment.

44 Fed. Reg. 8,210 (Feb. 8, 1979). Thus, EPA cannot deny protection from air pollution's effects by claiming that the people experiencing those effects are insufficiently numerous, or that levels that are likely to cause adverse health effects occur only in areas that are infrequently visited.

Similarly, EPA cannot deny protection against adverse health and welfare effects merely because those effects are confined to subgroups of the population or to persons especially sensitive to air pollution. Indeed, those persons are the very members of our society whose health is a special concern of the Act. It is inherent in NAAQS-setting that adverse effects are experienced by less than the entire population, and that we do not know in advance precisely which individuals will experience a given effect. As a result, opponents of protective NAAQS sometimes argue that NAAQS-setting involves evaluating "risk" and setting a level of risk that is "acceptable." But where—as here—peer-reviewed science shows that adverse effects stem from a given pollutant concentration, EPA must set NAAQS that protect against those effects with an adequate margin of safety. It cannot, under the guise of risk management, set NAAQS that allow such effects to

[178] *See also* 116 Cong. Rec. 31,967, 32,901 (Sept. 21, 1970) (remarks of Senator Muskie) ("This bill states that all Americans in all parts of the Nation should have clean air to breathe, air that will have no adverse effects on their health."); *id.* at33,114 (September 22, 1970) (remarks of Senator Nelson) ("This bill before us is a firm congressional statement that all Americans in all parts of the Nation should have clean air to breathe, air which does not attack their health."); *id.* at 33,116 (remarks of Senator Cooper) ("The committee modified the President's proposal somewhat so that the national ambient air quality standard for any pollution agent represents the level of air quality necessary to protect the health of persons."); *id.* at 42,392 (December 18, 1970) (remarks of Senator Randolph) ("we have to insure the protection of the health of the citizens of this Nation, and we have to protect against environmental insults -- for when the health of the Nation is endangered, so is our welfare, and so is our economic prosperity"); *id.* at 42,523 (remarks of Congressman Vanik) ("Human health and comfort has been placed in the priority in which it belongs -- first place.").

persist. Indeed, given the scientific evidence documenting the occurrence of adverse effects year after year in numerous individuals at levels allowed by the current NAAQS, risks are by definition “significant” enough to require protection under the Act's protective and precautionary approach. *See* H. Rep. No. 294, 95th Cong., 1st Sess., at 43-51 (1977); *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976). That is all the more true where the effects involved include highly serious ones like death and hospitalization. *See id.* at 18 ("the public health may properly be found endangered by a lesser risk of a greater harm").

EPA must set a standard that protects against potential health effects—not just those impacts that have been well established by science. *See ATA III*, 283 F.3d at 369 (citing Ozone NAAQS, 62 Fed. Reg. 38,857)) (“explaining that section 109(b)(1)’s ‘margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information ... as well as to provide a reasonable degree of protection against hazards that research has not yet identified’”); *see also Am. Petroleum Inst. v. EPA*, 684 F.3d 1342, 1352 (D.C. Cir. 2012).

With regards to the NAAQS, the D.C. Circuit found that Congress “specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement.” *Lead Indus. Ass’n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980). Limited data is not an excuse for failing to establish the level at which there is an absence of adverse effect. To the contrary, “Congress’ directive to the Administrator to allow an ‘adequate margin of safety’ alone 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 1154-55.

EPA has failed to consider the implications of this proposal on vulnerable groups and cannot and does not explain how retaining the NAAQS protects vulnerable groups with an adequate margin of safety. Indeed, in laying out the proposed rationale for leaving the annual standard in place, it never once mentions any sensitive population. Similarly, in that same section, it makes a few bare mentions of the margin of safety, but entirely fails to consider how the existing standard provides an adequate margin of safety for anyone, much less sensitive populations, in view of the strengthened evidence that $PM_{2.5}$ exposure results in adverse effects. Notably, too, EPA fails to consider how the uncontroverted finding that $PM_{2.5}$ is a non-threshold pollutant combines with the strengthened evidence of $PM_{2.5}$’s harms at levels at and below the current NAAQS: strongly supporting a strengthened NAAQS. In all these failures, EPA has violated section 109 of the Act, and its actions are arbitrary, capricious, and an abuse of discretion.

Numerous studies have identified major respiratory health risks to older Americans from $PM_{2.5}$ pollution at levels below the current NAAQS.[179] These risks are especially urgent as the previous decline in exposures to $PM_{2.5}$ appears to have levelled off, in part due to the increasing burden of wildfire smoke. There is substantial evidence in the record of mortality and cardiovascular effects in older adults.[180] There is strong evidence of PM-related cardiovascular effects in people with pre-existing cardiovascular disease.[181] Likewise, there is strong evidence of PM-related respiratory effects in people with pre-existing respiratory disease, particularly asthma.[182] In a study by Liu et al. (2017),[183] short-term exposure to wildfire-specific $PM_{2.5}$ was associated with heightened risk of respiratory diseases in the elderly population in the Western United States.

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179 DeFlorio-Barker, Stephanie, James Crooks, Jeanette Reyes, and Ana G. Rappold. 2019. "Cardiopulmonary Effects of Fine Particulate Matter Exposure among Older Adults, during Wildfire and Non-Wildfire Periods, in the United States 2008–2010." *Environmental Health Perspectives* 127 (3): 037006. https://doi.org/10.1289/EHP3860.
Pope, C. Arden, Jacob S. Lefler, Majid Ezzati, Joshua D. Higbee, Julian D. Marshall, Sun-Young Kim, Matthew Bechle, et al. 2019. "Mortality Risk and Fine Particulate Air Pollution in a Large, Representative Cohort of U.S. Adults." *Environmental Health Perspectives* 127 (7): 077007. https://doi.org/10.1289/EHP4438.
Rhee, Jongeun, Francesca Dominici, Antonella Zanobetti, Joel Schwartz, Yun Wang, Qian Di, John Balmes, and David C. Christiani. 2019. "Impact of Long-Term Exposures to Ambient PM2.5 and Ozone on ARDS Risk for Older Adults in the United States." *Chest* 156 (1): 71–79. https://doi.org/10.1016/j.chest.2019.03.017.
Woo, Bongki, Nicole Kravitz-Wirtz, Victoria Sass, Kyle Crowder, Samantha Teixeira, and David T. Takeuchi. 2019. "Residential Segregation and Racial/Ethnic Disparities in Ambient Air Pollution." Race and Social Problems 11 (1): 60–67. https://doi.org/10.1007/s12552-018-9254-0.
180 ISA sections 11.1, 11.2, 6.1 and 6.2.
181 *ISA* section 6.1.
182 ISA section 5.1.
183 Liu, Jia Coco, Ander Wilson, Loretta J. Mickley, Francesca Dominici, Keita Ebisu, Yun Wang, Melissa P. Sulprizio, et al. 2017. "Wildfire-Specific Fine Particulate Matter and Risk of Hospital Admissions in Urban and Rural Counties:" *Epidemiology* 28 (1): 77–85. https://doi.org/10.1097/EDE.0000000000000556.

Similarly, the implications of this proposal to potentially exacerbate racial disparities in air pollution exposures[184,185,186,187] are not addressed by the Administrator, despite evidence that racial minorities experience disproportionate air pollution burdens. Most dramatically, the seminal Medicare chronic mortality study (Di et al. 2017a) showed three times higher relative risk (hazard ratio) for black populations compared to the general population (a hazard ratio of 1.21 per 10 µg/m3 increase in PM2.5).[188] A study by Thind et al. (2019)[189] identified high air pollution exposures among African Americans from electricity generation. In that study, disparities by race/ethnicity were observed for each income category, indicating that the racial/ethnic differences hold even after accounting for differences in income.[190] The ISA notes specifically that analyses that directly compare PM-related health effects across groups—i.e. stratified analyses—indicate that minority populations have higher PM2.5 exposures than white populations, contributing to adverse health risk in non-white populations.[191] Coupled with the fact that multiple epidemiologic studies show adverse effects—including premature mortality—in many areas of the country with air quality allowed by the current NAAQS, it is evident, as the Policy Assessment finds, that the groups at increased risk "represent a substantial portion of the total U.S. population". Policy Assessment at 3-44. The proposal ignores all of these issues—the Administrator literally does not discuss them. This is arbitrary and antithetical to both evidence of record, and to the protective and precautionary requirements of section 109 (d) of the Act.

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184 Mikati, Ihab, Adam F. Benson, Thomas J. Luben, Jason D. Sacks, and Jennifer Richmond-Bryant. 2018. "Disparities in Distribution of Particulate Matter Emission Sources by Race and Poverty Status." American Journal of Public Health 108 (4): 480–85. https://doi.org/10.2105/AJPH.2017.304297.

185 Tessum, Christopher W., Joshua S. Apte, Andrew L. Goodkind, Nicholas Z. Muller, Kimberley A. Mullins, David A. Paolella, Stephen Polasky, et al. 2019. "Inequity in Consumption of Goods and Services Adds to Racial–Ethnic Disparities in Air Pollution Exposure." Proceedings of the National Academy of Sciences 116 (13): 6001–6. https://doi.org/10.1073/pnas.1818859116.

186 Kravitz-Wirtz, Nicole, Kyle Crowder, Anjum Hajat, and Victoria Sass. 2016. "The Long-Term Dynamics of Racial/Ethnic Inequality in Neighborhood Air Pollution Exposure, 1990-2009." Du Bois Review: Social Science Research on Race 13 (2): 237–59.

187 Parker, Jennifer D., Nataliya Kravets, and Ambarish Vaidyanathan. 2018. "Particulate Matter Air Pollution Exposure and Heart Disease Mortality Risks by Race and Ethnicity in the United States: 1997 to 2009 National Health Interview Survey With Mortality Follow-Up Through 2011." Circulation 137 (16): 1688–97. https://doi.org/10.1161/CIRCULATIONAHA.117.029376.

188 IPMRP Advice, at B-12.

189 Thind, Maninder P. S., Christopher W. Tessum, Inês L. Azevedo, and Julian D. Marshall. 2019. "Fine Particulate Air Pollution from Electricity Generation in the US: Health Impacts by Race, Income, and Geography." Environmental Science & Technology 53 (23): 14010–19. https://doi.org/10.1021/acs.est.9b02527.

190 *Id. See also* ISA section 11.

191 ISA section 12.5.4.

VI. Administrator Wheeler's Proposed Decision to Retain the Primary Standards for $PM_{2.5}$ is Arbitrary and Unlawful

Defying the advice of EPA's own expert staff scientists, not to mention the Independent Particulate Matter Review Panel, Administrator Wheeler has refused to recognize the "clear and compelling scientific evidence that the current $PM_{2.5}$ standards are not adequate to protect human health."[192] In his proposed decision, the Administrator instead argues that the key epidemiological studies new to this review—which consistently report adverse health effects in areas meeting the existing standards—are somehow inadequate to justify the establishment of additional protections.[193] Because the Administrator's proposed decision is contrary to the Clean Air Act, unsupported by the record, and internally inconsistent, it must be abandoned.

A. The Administrator's effort to disregard recent epidemiological studies is arbitrary and unlawful

As the D.C. Circuit emphasized in its latest decision on the particulate NAAQS, the EPA has long relied on epidemiological studies when determining the requisite limits for $PM_{2.5}$.[194] In adopting its current standards, for instance, the agency "explained that several key epidemiological studies had reported statistically significant associations between adverse health effects and particulate matter exposure at concentrations between 12.8 and 14.8 $\mu g/m^3$."[195] The EPA's 2013 rule accordingly "revis[ed] the level of the annual standard for particulate matter emissions from 15.0 $\mu g/m^3$ to 12.0 $\mu g/m^3$, a level slightly lower than the lowest concentrations reported as causing adverse health effects in the epidemiological studies" the agency had reviewed.[196] The EPA "followed a similar approach in earlier particulate matter NAAQS revisions, and … [the D.C. Circuit] upheld those EPA decisions."[197]

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192 IPMRP Advice at 4, B-14; *see also* Policy Assessment for the Review of the National Ambient Air Quality Standarsds for Particulate Matter (Jan. 2020), at 3-80 (concluding "that a number of key epidemiologic studies report positive and statistically significant $PM_{2.5}$ health effect associations based largely, or entirely, on air quality that is likely to be allowed by the current primary PM2.5 standards").

193 Proposed Decision, 85 Fed. Reg. at 24,119-21.

194 *Nat'l Ass'n of Mfrs. v. EPA*, 750 F.3d 921, 923-24 (D.C. Cir. 2014) (Kavanaugh, J.) (affirming the EPA's decision to "tighten[]" the primary standard for particulate matter on the basis of new epidemiologic research).

195 *Id.* at 923.

196 *Id.*

197 *Id.* at 924 (citing *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 526-27 (D.C. Cir. 2009) (holding that the EPA had "reasonably decided to address long-term exposure with an annual standard somewhat below the long-term mean concentrations in the ACS and Six Cities studies"), and *Am. Trucking Ass'ns, Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002) (upholding the EPA's particulate standards where the agency "ultimately set the standard just below the range of mean annual [particulate matter] concentrations observed in studies showing a statistically significant association between fine particulate matter and health effects")). Other cases with the same holding are *American Petroleum Inst. v. EPA*, 655 F. 2d 1176, 1185 (D.C. Cir. 1981); and *National Ass'n of Mfr's v. EPA*, 750 F. 3d 921, 924 (D.C. Cir. 2014).

During the present review, the EPA's experts turned again to the latest epidemiological research—research demonstrating that the existing standards for $PM_{2.5}$ are inadequate to protect public health. As the agency noted in its January 2020 Policy Assessment, "key studies" from the United States and Canada have now found statistically significant associations between adverse health effects and particulate concentrations that are "lower than those in key studies from the last review."[198] The "large majority" of these studies, the agency explained, "report health effect associations for air quality distributions characterized by overall mean $PM_{2.5}$ concentrations ranging from 8.1 $\mu g/m^3$ to 16.5 $\mu g/m^3$, with mean concentrations in most of these studies (and all but one key U.S. study) at or above 9.6 $\mu g/m^3$."[199] The Policy Assessment accordingly concluded that "a number of key epidemiologic studies [now] report positive and statistically significant $PM_{2.5}$ health effect associations based largely, or entirely, on air quality that is likely to be allowed by the current primary $PM_{2.5}$ standards."[200]

Of particular note are two of the largest cohort studies yet undertaken, involving U.S. Medicare cohorts including over 61 million enrollees. Di et al. (2017b); Shi et al. (2016). These studies have statistical power orders of magnitude greater than any previous such study The long-term mean in Shi et al. was near 8 µg/m3; in Di et al. the long term mean was 11 µg/m3 (Policy Assessment at 3-55) . These associations remained statistically significant even when data were truncated to remove all data below the level of the current annual NAAQS. Indeed, in the truncated analysis in Shi et al., associations remained statistically significant when all data less than 10 µg/m3 were removed.[201]

These analyses indicate that the bulk of adverse effects are not disproportionately associated with the higher end of the air quality distributions, and therefore offer strong support not only to the association being causal, but to using the mean of the long-term data as the basis for establishing the level of the annual standard.[202] Di et al. adjusted for temperature, but did not control for individual co-variates (e.g. age, sex, ethnicity, SES, smoking) since these co-variates do not vary day-by-day, and this study compared daily air pollution exposure on the case day with the daily control day. See Policy Assessment App. B at B-43. Shi et al. controlled for time, for temporal co-variates (temperature, day of week) and for spatial co-variates (including zip-code level socio-economic variables). Id. at B-63. As noted above, the IPMRP noted that Di et al. showed, using a subset of the Medicare cohort "that individual smoking and income levels were not associated with PM2.5 exposure, a necessary condition for confounding." IPMRP Advice at B-28.

198 Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (Jan. 2020), at 3-78–3-79.
199 *Id.* at 3-79.
200 *Id.* at 3-80.
201 Di et al. 2017b; Shi et al. 2016; see Policy Assessment at 3-106.
202 See Policy Assessment at 3-52.

These two studies also have important ramifications for assessing the adequacy of the 24-hour standard, and for a level of a revised 24-hour level. Not only did each of those powerful studies show associations with the mean of 24-hour concentrations below the level of the 24-hour standard, but continued to show statistically significant associations in restricted analyses when 24-hour PM2.5 concentrations were truncated at less than 25 µg/m3 (Di et al. 2017a), or 30 µg/m3 (Shi et al. 2016). See Policy Assessment at 3-70.

Consistent with the approach taken in previous reviews, the research summarized in the EPA's Policy Assessment should have prompted—indeed, compelled—Administrator Wheeler to propose a new annual standard that is "lower than the lowest concentrations" associated with adverse health effects in these recent probative epidemiological studies.[203] Rather than identifying such a limit, however, Administrator Wheeler has decided to argue that epidemiological research should no longer serve as the basis for establishing particulate standards.[204]

The Administrator's attack on epidemiological research rests on an avowed preference for experimental studies and selective consideration of scientific evidence, rather than a reliance on the latest scientific understanding across disciplines. According to the proposed decision,

> epidemiologic studies examine associations between distributions of $PM_{2.5}$ air quality and health outcomes, and they do not identify particular $PM_{2.5}$ exposures that cause effects[.] … In contrast, … experimental studies (*i.e.*, controlled human exposure, animal toxicology) do provide evidence for health effects following particular $PM_{2.5}$ exposures under carefully controlled laboratory conditions … [and can] demonstrate biologically plausible mechanisms through which such … [effects] could occur[.][205]

Based on the asserted advantages of experimental studies, the proposed decision reports that Administrator Wheeler feels "most confident" about particulate limits that are "supported by multiple types of studies, including experimental studies as well as epidemiologic studies."[206]

Given that the Administrator's own expert staff and the IPMRP read the clinical evidence as strongly corroborating the epidemiologic evidence, and settled law that this type of corroborative clinical information is not needed to justify revising a NAAQS to provide requisite

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[203] *Nat'l Ass'n of Mfrs.*, 750 F.3d at 923.
[204] Proposed Decision, 85 Fed. Reg. at 24,119-21.
[205] *Id.* at 24,119.
[206] *Id.*

protection,[207] this is a clear example of a manufactured justification for a desired outcome—which is contrary to the statutory requirements for decision making and a clear abuse of the Administrator's discretion in NAAQS standard setting. By challenging the sufficiency of the epidemiological research the EPA has long used in establishing particulate standards, Administrator Wheeler has attempted to manufacture a justification for leaving the agency's inadequate standards in place. According to the Administrator's proposed decision, while "controlled human exposure and animal toxicology studies report a wide range of effects, many of which are plausibly linked to the serious cardiovascular and respiratory outcomes reported in epidemiologic studies (including mortality), … the $PM_{2.5}$ exposures examined in these studies are above the concentrations typically measured in areas meeting the current annual and 24-hour standards[.]"[208] As a result, the proposal declares,

> the Administrator does not think recent epidemiologic studies reporting health effect associations at $PM_{2.5}$ air quality concentrations likely to have met the current primary standards support revising those standards. Rather, he judges that the overall body of evidence, including controlled human exposure and animal toxicological studies, in addition to epidemiologic studies, indicates continuing uncertainty in the degree to which adverse effects could result from $PM_{2.5}$ exposures in areas meeting the current annual and 24-hour standards.[209]

This argument is arbitrary and unlawful.

1. The Administrator's rejection of the EPA's established practice of relying on epidemiological studies is arbitrary

In declaring that the latest epidemiological studies cannot justify a decision to strengthen the particulate NAAQS, the Administrator has rejected—without acknowledgment or explanation—the EPA's long history of relying on such research as the basis for its primary standards. As the D.C. Circuit emphasized in affirming the agency's current limits, the EPA has consistently adopted standards for $PM_{2.5}$ that are "lower than the lowest concentrations" associated with

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[207] Policy Assessment at 3-46; IPMRP Advice at B-31; ATA I, 175 F. 3d at 1055-56. See also the fuller discussion below, and in section VII.C.

[208] *Id.*

[209] *Id.* at 24,120.

adverse health effects in epidemiological studies.[210] Given this history, the Administrator's "unexplained change of position" is arbitrary.[211]

Administrator Wheeler's attempt to reject epidemiological research is all the more arbitrary in light of his ultimate decision to reaffirm the EPA's existing standards for $PM_{2.5}$—standards that were established using epidemiological studies. In her 2013 decision, Administrator Lisa Jackson noted that the "annual standard level of 12 μg/m^3 [wa]s below the long-term mean $PM_{2.5}$ concentrations reported in *each* of the key multi-city, long- and short-term exposures studies providing evidence of an array of serious health effects (e.g., premature mortality, increased hospitalization for cardiovascular and respiratory effects)."[212] According to the former Administrator, "the importance of considering a level somewhat below the lowest long-term mean concentration in the full set of studies considered is to set a standard that would provide appropriate protection against the observed effects in all such studies."[213] In attempting to adopt Administrator Jackson's standard while rejecting its rationale, Administrator Wheeler has fallen well short of the requirements of reasonableness.

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210 *Nat'l Ass'n of Mfrs.*, 750 F.3d at 923. *See also* National Ambient Air Quality Standards for Particulate Matter: Final Rule, 78 Fed. Reg. 3,086, 3,161 (Jan. 15, 2013) (noting that the selected "annual standard level of 12 μg/m^3 [wa]s below the long-term mean $PM_{2.5}$ concentrations reported in *each* of the key multi-city, long- and short-term exposures studies providing evidence of an array of serious health effects (e.g., premature mortality, increased hospitalization for cardiovascular and respiratory effects)" (emphasis in original)); National Ambient Air Quality Standards for Particulate Matter: Final Rule, 71 Fed. Reg. 61,144, 61,173 (Oct. 17, 2006) (noting that the selected annual standard of 15 μg/m^3 was "somewhat below the long-term mean concentrations in the key mortality studies and consistent with the interpretation of the evidence from … morbidity studies"); National Ambient Air Quality Standards for Particulate Matter: Final Rule, 62 Fed. Reg. 38,652, 38,676 (July 18, 1997) ("[t]aking the epidemiological studies of both short- and long-term exposures together" and concluding that "the concordance of evidence for PM effects and associated levels provide[d] clear support for an annual $PM_{2.5}$ standard level of 15 μg/m^3[,]" which was "below the range of annual data most strongly associated with both short- and long-term exposure effects").

211 *See, e.g.*, *Am. Farm Bureau Fed'n*, 559 F.3d at 521-22 (holding that the EPA had failed to adequately explain why it "no longer believe[d] it useful to look … to short-term studies in order to design the suite of standards that will most effectively reduce the risks associated with short-term exposure"). *See also Am. Trucking Ass'ns*, 283 F.3d at 373 (noting that the EPA's judgment regarding the sufficiency of a standard would only be "worthy of deference … until formerly polluted areas come into compliance with the … standard and new health effects data from those areas become available").

212 78 Fed. Reg. at 3,161 (emphasis in original). While the Administrator's proposed decision suggests—in a single sentence—that the EPA's existing standard might be justified based on a different set of studies, "including experimental and accountability studies conducted at levels just above the current standard," 85 Fed. Reg. at 24,120-21, this conclusory assertion falls well short of the reasoned explanation required under the Clean Air Act. *See, e.g.*, *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 392 (D.C. Cir. 1998) (noting that "[w]here, as here, Congress has delegated to an administrative agency the critical task of assessing the public health and the power to make decisions of national import in which individuals' lives and welfare hang in the balance, that agency has the heaviest of obligations to explain and expose every step of its reasoning").

213 78 Fed. Reg. at 3,161.

2. The Administrator's attempt to disregard the "highly compelling" results of the latest epidemiological studies is arbitrary

In addition to being at odds with the EPA's longstanding approach to particulate-matter reviews, the Administrator's effort to disregard the latest epidemiological studies is scientifically indefensible and, because he does rely on the latest scientific knowledge, is unlawful. As the Independent Particulate Matter Review Panel has explained, the research the Administrator would like to ignore is "groundbreaking" and "provide[s] new results since the last review that are highly compelling."[214] In the words of the panel's October 2019 report, the studies at issue:

> consider huge populations and report effects below the current standard, either by restriction of the cohort to individuals living in areas with lower exposures … , or because the average cohort exposures are well below the annual standard[.] … The populations quantified in such recent studies are more than an order-of-magnitude larger than studies available in previous reviews, which has been made possible by scientific developments in the quantification of spatial variability in exposure concentrations using new modeling tools. The ambient air quality hybrid modeling tools are found to perform well and provide a solid foundation for including populations that are not well-served by the existing ambient monitoring network. Furthermore, these studies do not show any evidence of a threshold, including under a variety of statistical approaches and for analyses restricted to concentrations below the levels of the current primary $PM_{2.5}$ standards. Indeed, it is possible that the annual concentration-response relationship is steeper at lower exposures.[215]

Given the scale and quality of the epidemiological studies that have appeared since the last review, and the consistent evidence of associations with mortality and other effects in areas with

[214] Advice from the Independent Particulate Matter Review Panel on EPA's Policy Assessment, at B-15.
[215] *Id.* at B-22. *See also, e.g.*, *id.* at B-13 (noting that the studies rejected by Administrator Wheeler were "conducted throughout North America, in locations with varying exposure scenarios, using a range of exposure estimation and concentration-response modeling methods, which collectively provide strong evidence-based support for assessment of the adequacy of the current PM standards"); *id.* at B-24 (noting that "[t]he current review is bolstered by ground-breaking new epidemiologic studies, based on far larger study populations, as a result of the emergence of new generation of models that quantify spatial variability in exposure concentrations and include populations that are not served by the existing monitoring network[,]" and that "[t]hese new studies reaffirm and substantially augment and strengthen the scientific evidence compared to the prior review").

air quality allowed by the current NAAQS, the independent panel had no difficulty in concluding that the existing particulate standards are inadequate to protect human health.[216] The EPA's own experts were similarly persuaded, noting in their Policy Assessment that "epidemiologic studies do support the need to consider increasing protection against the typical 24-hour and annual $PM_{2.5}$ exposures that provide strong support for reported health effect associations[.]"[217]

In attempting to offer a defensible rationale for disregarding the latest epidemiological studies, the Administrator points, as previously noted, to the supposed need for more experimental research.[218] In his proposed decision, the Administrator declares that he "is cautious about placing too much weight on reported $PM_{2.5}$ health effect associations for air quality" that satisfies the current standards "[i]n the absence of evidence from experimental studies that $PM_{2.5}$ exposures typical of areas meeting the … standards can activate biological pathways that plausibly contribute to serious health outcomes[.]"[219] According to the Administrator, "associations alone, without supporting experimental evidence at similar $PM_{2.5}$ concentrations, leave important questions unanswered regarding the degree to which the typical $PM_{2.5}$ exposures likely to occur in areas meeting the current standards can cause the mortality or morbidity outcomes reported in epidemiologic studies."[220]

The Administrator's argument defies the scientific record. As the Independent Particulate Matter Review Panel explained in its report, the experimental evidence already supports the associations found in recent epidemiological studies. In the words of the panel, "[t]he 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."[221] While the panel noted its "expert scientific judgment … that the evidence is credible even based on the epidemiologic studies alone[,]" it emphasized that "other studies, including animal toxicology and human controlled exposure studies support and strengthen this evidence."[222] "In particular," the panel explained, "*the animal study evidence supports biologic plausibility for PM effects on the cardiovascular, respiratory, and nervous systems, as well as for cancer effects*."[223] The

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[216] *Id.* at B-22.
[217] Policy Assessment at 3-120. The Administrator's failure to address these expert staff recommendations is, in and of itself, legal error. *Am. Farm Bureau*, 559 F. 3d at 522-23 (remanding in part due to failure to consider and discuss expert staff recommendations in Policy Assessment).
[218] 85 Fed. Reg. at 24,119-21.
[219] *Id.* at 24,119-20.
[220] *Id.* at 24,120.
[221] IPMRP Advice at B-21.
[222] *Id.* at B-21–B-22.
[223] *Id.* at B-22 (emphasis added).

Administrator's declarations of uncertainty, in other words, disregard the entire body of available scientific research. They must be abandoned.[224]

The Administrator also ignores the profound coherence of the epidemiological evidence even considered apart from the corroborating evidence from controlled human and animal toxicity studies. The epidemiological studies show consistently positive associations between long-term $PM_{2.5}$ exposures and adverse effects - including mortality - which remain robust across different methodologies for estimating $PM_{2.5}$ exposure (monitors, satellite, newly emerging hybrid methods); across different statistical approaches to control for confounders or multiple sets of confounders; across different geographic regions and populations; and across ranges of temporal periods including periods of declining $PM_{2.5}$ concentrations. See ISA section 11.2.5.1 (different monitoring); 11,2,3 and 11.2.5 (different approaches to accounting for potential confounding); 11.2.2.5 and 11.2.5.3 (different areas, and declining $PM_{2.5}$ concentrations). Pretending that this body of diverse but consistent evidence can be explained away by unspecified "uncontrolled confounding," 85 Fed. Reg. at 24119, is irrational, irresponsible, and certainly not legal. See *State of Mississippi*, 744 F. 3d at 1244 (endorsing EPA's weight of evidence approach).

B. The Administrator's proposed decision fails to provide a margin of safety, as required under the Clean Air Act

As discussed above, Section 109 of the Clean Air Act requires that when setting or revising the NAAQS, EPA achieve one thing at minimum: protect public health with an *adequate margin of safety*. 42 U.S.C. 7409. In addition to being at odds with the scientific record, the Administrator's effort to rely on "uncertainty" as a rationale for inaction is contrary to this mandate in the Act.[225] Under the statute, the EPA is obligated to "err on the side of caution by setting primary NAAQS that 'allow[] an adequate margin of safety[.]'"[226] As the D.C. Circuit has explained, "[b]y requiring an 'adequate margin of safety,' Congress was directing EPA to build a buffer to protect against uncertain and unknown dangers to human health."[227] The Administrator's proposed decision does the opposite, using an unfounded assertion of "uncertainty" as justification for withholding Clean Air Act protections from the public. It is accordingly unlawful.

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[224] *See, e.g.*, *Murray Energy Corp. v. EPA*, 936 F.3d 597, 619 (D.C. Cir. 2019) ("We defer to EPA's judgment that the available evidence is too uncertain only when the agency reasonably explains its decision[.]"); *Mississippi v. EPA*, 744 F.3d 1334, 1357 (D.C. Cir. 2013) (noting that the question of whether "the scientific evidence is actually uncertain … itself requires a scientific determination[,]" as "agencies may not 'merely recite the terms "substantial uncertainty" as a justification for [their] actions'").
[225] *See* Proposed Decision, 85 Fed. Reg. at 24,119-21.
[226] *Am. Trucking Associations, Inc. v. E.P.A.*, 283 F.3d 355, 369 (D.C. Cir. 2002) (quoting 42 U.S.C. § 7409(b)(1)).
[227] *Mississippi*, 744 F.3d at 1353.

The NGO commenters support the recommendation of the Policy Assessment to use the evidence-based approach, as opposed to the risk-based approach, as the basis for ascertaining whether and how to revise the primary standards. Nonetheless, it bears mentioning that the risk-based approach provides, at the very least, qualitative support for the expert staff and IPMRP recommendations to revise the standards. See IPMRP Advice at B-23. Whether or not one accepts the quantitative risk estimates—and the IPMRP found the assessment to be "thoughtfully and reasonably conducted given the compressed timeframe," *id*. at 16—the number of persons exposed to unhealthy $PM_{2.5}$ concentrations under the current NAAQS are very large, and the vulnerable sub-populations comprise a substantial total of the U.S. population. Policy Assessment at 3-44. The risk assessment finds the number of avoided deaths, and cardiovascular and respiratory events, resulting from retention of the standards to number in the many thousands with substantial reductions in these events as the annual standard level decreases. Given the Act's precautionary thrust, the risk analysis offers further support to the need, and legal obligation to revise the primary standards, and to do so in a way that provides an adequate margin of safety.

VII. The Administrator's Reliance on Fringe Scientific Arguments by an Understaffed CASAC is Undercut by EPA's Own Final Assessments of the Science, the Assessment by the Disbanded PM Panel and the Substantial Body of the Most Recent Accountability and Related Studies Of $PM_{2.5}$ Reductions, as well as Other Causal Inference Studies Published After January 2018

A. The Administrator's rationale relies on mistaken assertions from CASAC about the scientific evidence that are inconsistent with the scientific conclusions reached in EPA's Own Expert Staff's Findings in the Integrated Science Assessment.

It is notable that EPA asserts in the proposal that "recent cohort studies, which have become available since the 2009 ISA, continue to provide consistent evidence of positive associations between long-term PM2.5 exposures and mortality and that the evidence "further demonstrates that associations with mortality remain robust in co-pollutant analyses, and that associations persist in analyses restricted to long-term exposures below 12 $\mu g/m^3$ (Di et al., 2017b) or 10 $\mu g/m^3$ (Shi et al., 2016)." While the divided CASAC lacks confidence in these findings and does not agree with EPA's assessment, no explanation is given for that distrust in the latest scientific knowledge.

Specifically, CASAC's December 2019 letter to EPA notes that "some CASAC members conclude that the Draft PM PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the current 2012 PM2.5 annual standard." As explained in the sections that follow, CASAC has not identified valid reasons for its distrust of the latest scientific evidence, and the CASAC statement does not comport with the best available scientific evidence.

Indeed, even the proposal notes that collectively, recent studies analyzed in the latest ISA reaffirm and further strengthen the body of evidence from the 2009 ISA for the relationship between long-term PM2.5 exposure and mortality. In the latest ISA, EPA "concludes that there is consistent evidence from multiple epidemiologic studies illustrating that long-term exposure to PM2.5 is associated with mortality from cardiovascular causes."

Despite the EPA expert staff's sound assessment in the ISA, the current CASAC could not reach consensus on basic issues related to the assessment of the PM2.5 health effects evidence and instead raises unfounded questions about residual confounding and exposure misclassification in the available evidence. Specifically, CASAC members "had varying opinions on whether there is robust and convincing evidence to support the EPA's conclusion that there is a causal relationship between PM2.5 exposure and mortality" (Cox, 2019b, p. 3 of letter). While EPA revisited its causal determination for UFP and nervous system effects in the final ISA, it did not weaken its causality determination for fine particle-related mortality as suggested. The causal determination in the final ISA is representative of the best available science and, as some CASAC noted, it is "highly unlikely" that "the extensive body of evidence indicating positive associations at low estimated exposures could be fully explained by confounding or by other non-causal explanations (Cox, 2019a, p. 8 of consensus responses)."

Instead of following the scientific evidence, EPA relies on misguided, unfounded, and erroneous assertions from an unqualified CASAC as an excuse to retain the NAAQS despite EPA's own assessment in the PA that the adequacy of the current standards can reasonably called into question.

B. The Administrator's reliance on CASAC statements suggesting $PM_{2.5}$ cannot be causally related to mortality and other effects based on recent epidemiology studies is misplaced and inconsistent with the scientific conclusions on causality reached in EPA's Policy Assessments.

In the proposal, EPA also fails to address information in the final Policy Assessment calling the efficacy of the current standards into question, and that are in conflict with the Science Assessment. On page 3-102 of the Policy Assessment, EPA notes that it has considered a wide range of studies with varying exposure estimation techniques, including data from multiple sources (e.g., satellites, land use information, modeling), in addition to monitors. It goes on to state that, "While none of these approaches eliminates the potential for exposure error in epidemiologic studies, such error does not call into question the fundamental findings of the broad body of $PM_{2.5}$ epidemiologic evidence." Furthermore, EPA states that "In fact, the ISA notes that while bias in either direction can occur, exposure error tends to lead to underestimation of health effects in epidemiologic studies of PM exposure (2019 Integrated Science Assessment, section 3.5)."[228] The Administrator does not address these conclusions in the proposed rule, and misrepresents the bias that may affect epidemiology studies of $PM_{2.5}$-related health effects at levels below the current NAAQS.

C. The Administrator's conclusion that it is not appropriate to strengthen the standards unless experimental evidence is available from controlled human and animal studies is both unreasoned and inconsistent with the main role of current PM experimental studies in this review.

As noted above, the Administrator relied on the comments of some CASAC members regarding confounding, bias, and other uncertainties to conclude that epidemiological evidence finding associations at levels below the current standards "without supporting experimental evidence at similar $PM_{2.5}$ concentrations" did not support revising the standards. 85 Fed. Reg. at 24,120. Although recognizing EPA's position with respect to the use of such information with respect to providing "biological plausibility" and citing the Preamble to the ISA (EPA, 2015), 85 Fed. Reg. at 24,119, "the Administrator does not think that recent epidemiologic studies reporting health effect associations at $PM_{2.5}$ air quality concentrations likely to have met the current primary standards support revising those standards." 85 Fed. Reg. at 24,120.

The Administrator's demand for absolute proof of effects from experimental studies to support the use of epidemiology studies is inconsistent with Section 109(d)(1) of the Act, ignores the agency's scientific conclusions on the use of such studies, especially for particulate matter, and indicates a profound lack of understanding of the practical and ethical obstacles in delivering such results.

The Administrator admits that "controlled human exposure and animal toxicology studies report a wide range of effects, many of which are plausibly linked to the serious cardiovascular and respiratory outcomes reported in epidemiological studies (including mortality)." 85 Fed. Reg. at 24,119. He nonetheless states that this body of evidence could only support a conclusion that the associations in the epidemiologic studies are causal if the experimental studies showed effects at $PM_{2.5}$ levels allowed by the current $PM_{2.5}$ standards. *Id.* Of course, epidemiological evidence standing alone, without any experimental evidence of biological plausibility, is amply sufficient

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[228] Pages 3-102 to 3-103 of U.S. Environmental Protection Agency. 2020. "Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter." https://www.epa.gov/sites/production/files/2020-01/documents/final_policy_assessment_for_the_review_of_the_pm_naaqs_01-2020.pdf.

to justify revision of a primary NAAQS.[229] But here, the clinical and toxicological evidence of biological plausibility is part of the profoundly coherent body of evidence supporting the causal link between $PM_{2.5}$ exposure and the most serious adverse effects at levels below the level of the current primary annual $PM_{2.5}$ NAAQS.

In twice recognizing EPA's scientific conclusions regarding the importance of experimental studies in providing mechanisms that support biological plausibility, 85 Fed. Reg. 24,119, the Administrator ignores that Preamble's statements about the relative concentrations of pollutants that would be of relevance for this purpose:

> "Controlled human exposure or animal toxicological studies that approximate expected human exposures in terms of concentration, duration, and route of exposure are of particular interest. *Relevant pollutant exposures are considered to be those generally within two orders of magnitude of recent ambient concentrations.* This range in relevant exposures is to account for differences in dosimetry, toxicokinetics, and biological sensitivity of various species, strains, or potentially at-risk populations. Studies using higher concentration exposures or doses will be considered to the extent that they provide information relevant to understanding mode of action or mechanisms, inter-species variation, or at-risk human populations. In vitro studies may provide mechanistic insight for effects examined in vivo or in epidemiologic studies."[230]

This standalone preamble for the ISA's for all NAAQS reviews previously was integrated in the first section of all draft ISAs over the last decade or more, which were reviewed by multiple CASAC and pollutant specific expert panels. In fact, all of the controlled human studies highlighted in the Policy Assessment (PA) summary (Table 3-2, EPA 2020) had concentrations within a single order of magnitude of current short-term $PM_{2.5}$ ambient levels, and one found impaired vascular function and altered heart rate variability (HRV) at 5 hour levels of 24 µg/m3, which is well below the level of the 24 hour $PM_{2.5}$ standard (Hemmingsen et al., 2015a,b). While the PA was doing due diligence in examining whether these studies might support a more

[229] *ATA I*, 175 F. 3d at 1055 (Clean Air Act sections 109 (b) and (d) require no explanation of "the biological mechanism by which particle pollution causes adverse health effects" to justify standards). See also the detailed discussion in section VII.A above.
[230] Page 12 of U.S. Environmental Protection Agency. 2015. "Preamble to the Integrated Science Assessments." (emphasis added). *See American Farm Bureau*, 559 F. 3d at 533 ("occupational studies showing health effects from nonurban coarse at occupational exposure levels 'lend further support to a cautious approach in considering revision to the standards affording protection form thoracic coarse particles.'") (quoting U.S. EPA, National Ambient Air Quality Standards for Particulate Matter, 71 Fed. Reg. 61,114, 61,191 (Oct. 17, 2006)).

stringent or alternative short-term standard, it recognized that these "studies support the plausibility of the serious cardiovascular effects that have been linked with ambient $PM_{2.5}$ exposures." (2020 Policy Assessment, p. 3-49).

The IPMRP interpreted the controlled human study results in Table 3-2 as not only providing biological plausibility but also being conducted at policy-relevant concentrations once the sub-daily measuring times were extrapolated over 24-hours. The IPMRP thus viewed these studies as supporting a revision of the 24-hour standard. *See* IPMRP Advice at B-15-16 and B-31.

The ISA highlights evidence of a number of animal and human exposure studies published since the 2009 PM ISA that provide biological plausibility for supporting a causal or likely causal relationship between $PM_{2.5}$ exposure and a variety of effects including respiratory, cardiovascular nervous system, cancer, and through those effects, mortality (2019 Integrated Science Assessment, Table 1-2). The ISA chapters on each of these topics illustrate a sequence of responses that comprise potential biological pathways for effects following short or long-term exposures based on experimental and epidemiology studies.

The cardiovascular effects from these studies are of particular importance as they provide plausibility for both morbidity and mortality pathways (Chapter 6. EPA 2019). The empirical studies in human and animal exposure studies have focused on cardiovascular outcomes. Though most addressed short-term exposures,[231] some of these pathways are relevant to long-term effects and some longer-term studies exposed animals to repeated peaks of concentrated ambient particles for longer periods.[232] These studies provide coherent evidence of conduction abnormalities and arrhythmia, changes in HRV, changes in blood pressure, and evidence for systemic inflammation and oxidative stress.[233] The coherence of the science across disciplines and between human subjects and animal models is documented in each effects chapter in the ISA. (EPA 2019).

Some long-term animal studies using repeated peak exposures produced long term (multiple weeks to months) concentrations near or less than a factor of two higher than the current annual standard. Kampfrath et al (2011) (exposures over 20 weeks averaged 24.7 ug/m3). As documented in public comments by Dr. Joel Schwartz and in the 2009 EPA ISA, "animals

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[231] For reasons discussed below, EPA found no long-term controlled human studies for $PM_{2.5}$ in the literature.
[232] *E.g.*, Kampfrath, T; Maiseyeu, A; Ying, Z; Shah, Z; Deiuliis, JA; Xu, X; Kherada, N; Brook, RD; Reddy, KM; Padture, NP; Parthasarathy, S; Chen, LC; Moffatt-Bruce, S; Sun, Q; Morawietz, H; Rajagopalan, S. (2011). Chronic fine particulate matter exposure induces systemic vascular dysfunction via NADPH oxidase and TLR4 pathways. Circ Res 108: 716-726. http://dx.doi.org/10.1161/CIRCRESAHA.110.237560.
[233] *Cf. Lead Industries*, 647 F. 2d at 1158 (upholding standard directed at preventing a subclinical effect since those effects can be an indication of more substantial harm).

exposed to an average of 15.2 µg/m3 PM2.5 had substantially increased area covered by atherosclerotic plaque compared to filtered-air mice (p=0.04)(Sun et al. 2008). It is the rupture of such plaque that produces heart attacks. Given this, it is not surprising that any incremental increase in these processes produces incremental damage."[234] While care should be taken in interpreting annual averages in studies of intermittent peaks, even the daily peak exposures in these two studies were well below a factor of ten greater than are typical in ambient air.

In addressing the extent to which more recent evidence strengthens or otherwise alters the conclusions on the health effects of fine particles in the previous review, the PA noted the following newer regarding experimental studies:

> "Recent evidence from animal toxicology and/or controlled human exposure studies provides stronger support, compared to previous reviews, for potential biologic pathways by which long-term $PM_{2.5}$ exposures could lead to effects on the cardiovascular and respiratory systems, effects on the nervous system, and to lung cancer. In addition to providing insight into potential mechanisms, experimental studies also demonstrate direct effects of $PM_{2.5}$ exposures, providing further support for independent effects of particle exposures on health (i.e., not confounded by co-occurring pollutants)."

(2020 Policy Assessment, p. 3-42-43). It is clear that, in each successive review of the $PM_{2.5}$ criteria and standards, experimental studies of the fine particle pollutants and components have provided increasing and unconfounded support for mechanisms and plausibility, which the ISA has used in making causal inferences regarding various effects observed in epidemiology studies. But to argue that experimental studies must now somehow demonstrate such effects at levels permitted by the current standard is not only unprecedented in all past PM NAAQS reviews, unreasonable and illegal, but highly impractical as well.

The most extreme requirement is a demand for human studies that would show even intermediate effects at levels below the current annual standard—the generally controlling standard. It is simply unreasonable and unrealistic to imagine controlled human studies exposures that would last a year or more. Even repeated peaks simulating levels allowed by an annual standard that lasted multiple days or weeks would have the obvious problems of confining subjects for the entire period to avoid contamination from uncontrolled exposures. In addition to the difficulty in securing willing subjects, ethical issues and review boards would limit participation by

[234] Comment submitted by J. Schwartz (June 9, 2020), available at https://www.regulations.gov/document?D=EPA-HQ-OAR-2015-0072-0569 (citing Sun Q, Yue P, Kirk RI, Wang A, Moatti D, Jin X, et al. 2008. Ambient air particulate matter exposure and tissue factor expression in atherosclerosis. Inhal Toxicol 20:127-137.)

individuals with the kinds of sensitivity that are most likely in play in producing the effects observed in epidemiology studies.[235] These are the main reasons why the ISA's literature search could find no long-term controlled human studies of fine particles.

If a single sub-daily exposure producing an intermediate effect of concern in a single study were sufficient in the view of the Administrator, then as noted above, such a study already exists. Clearly it is not. While the PA notes that, based on current data, longer exposure times and/or repeated exposures might help, (2020 Policy Assessment, p. 3-49), these would still be assessing short-term exposures. It is not clear whether any potentially practical durations of single or repeated exposures could satisfy the Administrator's demand.

While it is certainly possible to conduct longer animal toxicology studies, it is also the case that such studies have been more focused on mechanisms than proving effects at low levels. A practical issue here is to find a variety of animal models that might match the wide variation in genetic and acquired sensitivities (e.g. disease, access to medical care, age) that exist in today's epidemiology studies where populations range from hundreds of thousands to over 60 million people, counting only those 65 or over. The reason for higher concentrations in many animal studies is to avoid the need for large numbers of animals needed to detect relatively smaller risks at lower levels. Such low-level studies involving long-durations would be subject to higher costs as well the increasing concerns regarding ethical issues. In part for these reasons, there is a trend toward increased use of in vitro studies.[236] The Administrator himself has announced his intent to eventually eliminate the use of whole animals in EPA studies.[237] It is unclear how future in vitro work, which has been useful in examining mechanisms and pathways in air pollution research might provide quantitative evidence with respect to levels below the annual standards.

In sum, it is not clear that realistic human or animal studies could ever meet the Administrator's unreasonable and illegal requirement of a direct demonstration of $PM_{2.5}$ health effects at levels below the current standards. And it is arbitrary for EPA to establish an unattainable burden of proof.

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[235] *See Nat'l Envtl. Dev. Assn's v. EPA*, 686 F. 3d 803, 811 (D.C. Cir. 2012) ("It could not then exceed EPA's authority to choose a level below that which produced adverse effects in the clinical studies in order to set a standard that allows an adequate margin of safety. Further, the clinical studies did not test severe asthmatics or very long children. EPA concluded that it was reasonable to assume that these vulnerable populations would suffer more serious health effects than mild and moderate asthmatics.")

[236] Zavala et al. 2020. New Approach Methods to Evaluate Health Risks of Air Pollutants: Critical Design Considerations for In Vitro Exposure Testing. Int. J. Environ. Res. Public Health 2020, 17, 2124; doi:10.3390/ijerph17062124.

[237] EPA, *Administrator Wheeler Signs Memo to Reduce Animal Testing, Awards $4.25 Million to Advance Research on Alternative Methods to Animal Testing* (Sept. 10, 2019), available at: https://www.epa.gov/newsreleases/administrator-wheeler-signs-memo-reduce-animal-testing-awards-425-million-advance.

D. The Administrator's summary of epidemiology studies that examine $PM_{2.5}$ reductions, including interventions and accountability studies, as well as other studies that use causal inference, and his reliance on certain CASAC members' advice regarding such literature is deeply mistaken; further, EPA does not consider the latest scientific information now available in this emerging category of epidemiology studies.

The Administrator refers to the lack of intervention and related studies as one reason for not revising the primary standards. He points to advice from certain CASAC members in doing so. In fact, this advice is mistaken and reflects outright misstatements of fact. It further reflects misinterpretations of studies, which misinterpretations were called out by the study authors themselves. These errors are compounded by failure to consider the full extent of the (still relatively nascent) literature on this type of study. The Administrator's reliance on this advice is consequently as arbitrarily mistaken as the advice itself.

Moreover, the Administrator acts contrary to the evidence of record. The record shows, and the ISA, PA, and IPMRP found, that intervention and related accountability and causal inference study literature supports the causal nature of the association of exposure to $PM_{2.5}$ and mortality, and supports the need to revise the primary standards to provide requisite public health protection. In addition, EPA's review did not consider the latest scientific literature in this area published since January 2018. The Administrator's further insistence that evidence from intervention studies has to come from studies conducted in locations with air quality that would be allowed by the current NAAQS is both illegal, and at odds with the factual record.

1. The Administrator Improperly Relies on CASAC members' errors and misinterpretations of specific studies and past EPA reviews

The Administrator's rationale places great weight on a statement by some CASAC members that "in intervention studies, reductions of $PM_{2.5}$ concentrations have not clearly reduced mortality risks, especially when confounding was tightly controlled." 85 Fed. Reg. 24,120. The CASAC letter cites Henneman et al. 2017 and Burns et al. 2019 as support for this statement (Cox Dec. 16, 2019, Letter, p. 8). Reflecting the views of the same CASAC members, the letter goes on to cite these two secondary references again, along with others as "relevant time-series studies, intervention studies, and accountability studies that are not included in the literature reviewed in the Draft PM ISA and relied on in the Draft PM PA (*e.g.*, Burns et al., 2019 and studies reviewed therein; Eum et al., 2018; Greven et al., 2011; Henneman et al., 2017; Pun et al., 2017)." *Id.*.

In response to CASAC's recommendations, the final EPA Policy Assessment (PA) examined the two recent secondary references CASAC cited on interventions and accountability and found they consisted of many studies that did not examine $PM_{2.5}$, or did not provide information regarding whether the interventions reduced $PM_{2.5}$, while some others "were not able to disentangle health impact of the intervention from background trends in health." 2020 Policy Assessment, p. 3-103 n.74. The PA highlighted one Japanese intervention study in these reviews (Yorifuji et al., 2016) that "was able to link a particular policy intervention to a decline in ambient $PM_{2.5}$concentrations, and that did include a control population to correct for background trends in mortality." 2020 Policy Assessment, p. 3-103 n.74. Another issue with Burns et al. 2019 is that it intentionally excludes a number of cohort studies that examined mortality during periods of decreases in $PM_{2.5}$.[238] Yet, such studies are of obvious relevance to the issues the Administrator and CASAC raise. The EPA 2020 Policy Assessment highlights *some* of these studies in Table 3-3 in support of its conclusions that the current standards are inadequate to protect public health and should be strengthened.[239]

In any event, EPA's assessment of the latest scientific information should not rely on such secondary references; EPA should instead identify and assess the original relevant studies. The two reviews recommended by CASAC contained only studies published as of August 2016, well before the cutoff date for the ISA. The Yorifuji et al. intervention study noted in the Policy Assessment was, in fact, reviewed in the 2018 draft of the ISA in section 11.1.2.1, which examined studies using causal modeling methods, including quasi-experimental designs. This study supports the PA staff conclusion. 2020 Policy Assessment, p. 3-103; *see also* 85 Fed. Reg. at 24,120 (Administrator recognizes that this study shows reductions in mortality due to reduction of diesel particulate). Other studies examining the health benefits of long-term

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[238] Burns, Jacob, Hanna Boogaard, Stephanie Polus, Lisa M. Pfadenhauer, Anke C. Rohwer, Annemoon M. van Erp, Ruth Turley, and Eva Rehfuess. 2019. "Interventions to Reduce Ambient Particulate Matter Air Pollution and Their Effect on Health." Burns et al. state, "We did not include studies that have taken an indirect approach, such as cohort studies, to assessing the effects of interventions. Such studies have been conducted in Switzerland (Schindler et al., 2009), California (Gauderman et al., 2015; Gilliland et al., 2017), the entire US (Correia et al., 2013; Dominici et al., 2007; Pope et al., 2009), and the Netherlands (Boogaard et al., 2013), among others. Put simply, these studies show that decreases in pollutant concentrations, observed over time periods when interventions were implemented, were associated with improvements in health outcomes." *Id.*

[239] As is evident in our examination of the literature in section D-2-1 below, the Administrator errs in suggesting that the number of studies EPA has examined in the current and past reviews reporting health improvements after $PM_{2.5}$ reductions are limited to the four studies in Table 3-3 of the PA and a Japanese study. 85 Fed. Reg. at 24,121. As discussed in section D-2-2, CASAC failed to consider newer accountability studies published in early 2018 brought to CASAC and EPA's attention (Bachmann, J. Public Comments November 16, 2019) *before* the CASAC finalized its December 16th letter, while recommending consideration of studies that were published *later* in 2018 and 2019. This is further evidence that the Administrator should not place great weight on CASAC's advice in the matter of accountability and related studies. As noted in section D-2-1, such selective consideration of studies is itself illegal.

reductions in $PM_{2.5}$ cited in the draft Policy Assessment (Table 3-3) were also reviewed in the draft and final ISA.

CASAC's errors do not end there. These members' recommendation for including discussion of the Greven, Pun, and Eum studies in the review (Cox Dec. 16, 2019, Letter, p. 8) reflects their misinterpretation of the main findings and inferences in these studies. EPA addressed Greven et al. (2011) in the previous PM NAAQS review, although it was published after closure of the ISA in 2009, because it was raised in public comments on the proposal. EPA assessed Greven et al. (2011) in its 2012 Provisional Science Assessment of significant studies published after 2009 and responded to commenters' arguments in the preamble to the final rule (78 Fed. Reg. at 3,116-17) and in the Response to Comment (RTC) document.[240] Like some on CASAC in 2019, these commenters maintained, based on their own interpretations, that Greven et al. (2011) and an earlier study (Janes et al. 2007) suggested unmeasured confounding that raised fundamental questions regarding EPA's determination of a causal relationship between long-term $PM_{2.5}$ exposure and mortality (78 Fed. Reg. at 3,116).

The authors of Greven et al. (2011) and Janes et al. (2007) submitted comments to the docket to clarify these issues (Dominici et al., 2012). At the outset, the authors stated, "[t]he fact that this particular study does not find an association at this specific time scale of variation of exposure to air pollution and for the study population considered cannot lead to a conclusion that all the other epidemiological studies are confounded and that air pollution is not causally linked to mortality." (Dominici et al., 2012). The statistical approaches used in these studies are aimed at eliminating spatial information and focusing in local temporal trends of $PM_{2.5}$ and mortality. While the majority of cohort studies focused on spatial information over multiple years, this study examined lagged month-to-month changes in the annual average, which by design excludes the larger variance that exists when including spatial data. Because both $PM_{2.5}$ and other determinants of mortality vary across seasons, and control programs often do not result in large

[240] EPA, Responses to Significant Comments on the 2012 Proposed Rule on the National Ambient Air Quality Standards for Particulate Matter (Dec. 2012) ("RTC"), available at https://www3.epa.gov/ttn/naaqs/ standards/pm/data/20121214rtc.pdf.

changes on a month to month basis, this should not be compared to an intervention or accountability study, as implied in CASAC's statement.[241,242]

In the prior final rule, EPA found "[i]n conclusion, the EPA interprets the results of the analyses conducted by Janes et al. (2007) and Greven et al. (2011) as being consistent with prior knowledge of examining associations with long-term exposure to $PM_{2.5}$ at the national scale using long-term average $PM_{2.5}$ concentrations. For the reasons presented above and discussed in more detail in the Response to Comments document, the Agency disagrees with the commenters' assumption that the results of Janes et al. (2007) and Greven et al. (2011) indicate unmeasured confounding in the results of other cohort studies of long-term exposure to $PM_{2.5}$ and mortality. Therefore, the EPA concludes that these studies do not invalidate the large body of epidemiological evidence that supports the EPA's determination that a causal relationship exists between long-term $PM_{2.5}$ exposure and mortality." 78 Fed. Reg. at 3,117.

Similarly, CASAC members' suggestions concerning the Pun et al. (2017) and Eum et al. (2018)[243] studies are misplaced. Section 11.2.2.4 of the ISA (EPA, 2019) discusses the Pun et al. (2017) study and compares the sensitivity analysis conducted as part of that study with the main analysis in Greven et al. 2011. *See 2019 Integrated Science Assessment,* at 11-79. The ISA reported the potential presence of unmeasured confounders, but added that "[i]t is important to note that the "temporal" and "spatiotemporal" coefficients are uninterpretable when examined individually, and can only be used in comparison with one another to evaluate the potential for unmeasured confounding bias." 2019 Integrated Science Assessment, at 11-79.

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[241] The 2012 RTC goes on to explain that the design of Janes and Greven are "fundamentally different from those used in other long-term exposure studies," such that "any evidence of potential confounding of the $PM_{2.5}$ -mortality risk relationship derived from these two studies cannot be extrapolated to draw conclusions related to potential spatial confounding in studies based on the spatial variation in $PM_{2.5}$ concentrations"; RTC, at II-16 to 17. It states that the cohort studies underlying the causality determinations for long-term $PM_{2.5}$ exposure and mortality "'have developed approaches to adjust for measured and unmeasured confounders'" (quoting Drs. Janes and Greven themselves); *id.*, at II-17; and therefore that "EPA disagrees that the results of these studies are comparable to the results of other cohort studies of long-term exposure to $PM_{2.5}$ and mortality, or that the results presented in these two studies invalidate either the results themselves, or the consistency of the results observed across other cohort studies of long-term exposure to $PM_{2.5}$ and mortality." *Id.*, at II-19.

[242] These CASAC members' ignorance of extensive preamble and RTC discussions and analyses from the immediately preceding PM review is one more instance of their lack of experience in NAAQS reviews and their unfitness to properly evaluate "knowledge useful in indicating the kind and effect" of fine particles the National on public health -- *i.e.*, their ability to accurately evaluate what the air quality criteria are. CAA section 108(a)(1)(C).

[243] Eum *et al.* (2018) was published after the cutoff date for the ISA.

The authors of the Pun and Eum studies submitted written comments to CASAC and EPA to address issues they found with a public commenter, Stewart E. Holm,[244] on their work, and with written comments by the CASAC chair, Tony Cox.[245] They note that "both Mr. Holm and Dr. Cox draw inaccurate conclusions regarding our study findings and their policy relevance." [246] Both of these commenters focused on the sensitivity analysis. These authors stress the major findings in Pun et al. 2017: "We found clear and consistent associations of 12-month moving average $PM_{2.5}$ exposures and increased mortality from cardiovascular (CVD) disease, cancer, and for the first time, respiratory disease in a US population of Medicare beneficiaries." (Suh et al. 2019).

With respect to the sensitivity analysis that separated temporal and spatiotemporal components, as in Greven et al. (2011), these authors state that "the presence of unmeasured confounding after adjustment for behavioral risk factors was expected given that we did not control for several potential confounders that may impact $PM_{2.5}$ -mortality associations, such as smoking, socio-economic status (SES), gaseous pollutants, $PM_{2.5}$ components, and long-term time trends in $PM_{2.5}$." (Suh et al. 2019). These special sensitivity results should not be used to impugn cohort studies that do examine some or all of these potential confounders.

With respect to the approach used to focus on temporal $PM_{2.5}$as done in Greven, the authors noted that "*[t]his method, however, cannot be used to examine the association of overall $PM_{2.5}$ on mortality controlling for long-term time trends in $PM_{2.5}$."* (Suh et al. 2019) (emphasis added). For that reason they followed up with the Eum et al. 2018 study, which appeared too late to be included in the ISA. They summarized the findings in Eum as follows: "Even after controlling for long-term temporal $PM_{2.5}$ trends, we found a statistically significant 11.7% increase in all-cause mortality among Medicare beneficiaries for a 10 µg/ m3 increase in $PM_{2.5}$. Our findings were consistent across regions, length of study period, and variations in methods to control for long-term time trends in $PM_{2.5}$. As such, our findings provide direct evidence of a significant association between long-term $PM_{2.5}$ exposures and increased mortality that cannot be explained by declining $PM_{2.5}$ levels over time." (Suh et al. 2019).

The authors' summary states: "Together, findings from Pun et al. (2017) and Eum et al. (2018) provide compelling evidence of a clear and consistent association between long-term $PM_{2.5}$ exposures and increased mortality that is independent of long-term time trends in $PM_{2.5}$. Our findings are in direct contradiction to conclusions reached by Mr. Holm and Dr. Cox in their

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[244] Representing the National Council for Air and Stream Improvement (NCASI).
[245] The final PA briefly summarizes both Pun and Eum, and summarize the comments from the original authors (2020 Policy Assessment, p. 3-21 n.17).
[246] Comments of Helen Suh, Justin Manjourides, Ki-Do Eum, Vivian Pun. Regarding the proper interpretation of major findings from our work in Pun et al. (2017) and Eum et al. (2018). November 5, 2019. Available at https://www.regulations.gov/document?D=EPA-HQ-OAR-2015-0072-0065.

comments, reflecting their misreading of Pun et al. (2017) and a lack of consideration of findings from Eum et al. (2018)." (Suh et al. 2019).

Thus, the original authors of three studies that CASAC members recommend as supporting their arguments regarding uncertainties in the epidemiological evidence provide reasoned rebuttals to CASAC's misinterpretation of their findings, including rebuttals to the mistaken notion that the studies provide any evidence that reductions in $PM_{2.5}$ do not produce health benefits. CASAC and the Administrator compound this misinterpretation by failing to respond to the comments of the study authors[247], who explained how their work was misinterpreted. These failings are further evidence that the recommendations and the proposal are arbitrary and capricious, and an abuse of discretion.

In summary, none of the five studies referenced by some CASAC members as supporting their conclusions regarding uncertainties in epidemiology studies prove convincing when examined. The EPA PA pointed out why the Henneman et al. (2017) and Burns et al. (2019) secondary references were not sufficiently informative. We note above that Burns et al. intentionally excluded a number of cohort studies that found reducing $PM_{2.5}$ resulted in health benefits. Contrary to CASAC's suggestion to add these studies, EPA had examined two of the remaining three studies in the previous review and/or in the draft and final ISA, and, as the authors note, there is no evidence that CASAC considered the results of the third (Eum et al. 2018)—despite referencing it. Those assessments, along with comments by the original authors of the three studies, undermine the interpretation of CASAC, as well as the relevance to issues addressed in accountability studies. It is clear that none of the three were designed to address the relationship between reductions in $PM_{2.5}$ and mortality over multiple years.

The evidence instead supports the contrasting conclusions reached by others on CASAC and the twenty members of the IPMRP, which collectively have far more depth and breadth of experience and expertise in critical disciplines like epidemiology than exists in the six CASAC members.[248] As noted in the CASAC letter: "Other members of the CASAC, as well as the Independent PM Review Panel (members of the disbanded CASAC PM Review Panel), think that the epidemiologic evidence demonstrating the health effects of $PM_{2.5}$ is strong, with biological plausibility provided by human controlled exposure and animal toxicological studies." (Cox Dec. 16, 2019, Letter). The CASAC letter goes on to say, "These CASAC members do not think that this evidence is diminished because of the lack of consistent support from newer intervention and accountability studies." *Id.* at 9. Indeed, the evidence presented above and in the next subsection of these comments undermines the notion that there is an overall lack of

[247] Cox took note of the Suh et al. comments in his individual comments but did not withdraw the recommendation from the main letter (Cox, 2019b).
[248] *See* Advice from the Independent Particulate Matter Review Panel to Administrator Wheeler, at 1 (Oct. 22, 2019) (describing expertise of IPMRP relative to CASAC).

"consistent support" from intervention and accountability studies. EPA's own Policy Assessment, the IPMRP, the comments submitted by Dr. Joel Schwartz, and our assessment in this section all find that the accountability and related studies reviewed in the ISA and PA support the need to strengthen the primary $PM_{2.5}$ standards.

The Administrator's proposed reading of the evidence is contrary to the evidence of record. The proposal's reliance on these errors by CASAC, and the proposal's failure to explain its inconsistency with EPA's prior review, discussed above, make clear the proposal is unlawful, arbitrary and capricious and an abuse of discretion.

3. The rationales by CASAC and the Administrator also have failed to properly consider the latest scientific information on causal analyses, intervention, accountability and related studies assessed in EPA's ISA and PA, and important new studies published after January 2018, the cut-off date for the ISA.

i. a. Summary of relevant causal inference, intervention, accountability, and related studies published available after the ISA cut-off date of January 2018.

As in previous reviews, EPA established a cutoff date for studies to be included in the first draft of the ISA. The final ISA notes the cutoff was about January 2018, or about nine months before release of the first draft. In past reviews, if particularly significant new or otherwise missed studies appeared during the review of the ISA, they could be identified by CASAC and added during the preparation of the second draft, which would be reviewed by CASAC. As noted above, the so-called "streamlined" new NAAQS review process precluded second reviews of the ISA and PA by CASAC and the public, missing the normal opportunity for inclusion of potentially significant new studies.[249] Moreover, given the continuing explosion of research on fine particles since the 1997 standards, recent PM proposals have announced and conducted "provisional assessment" of studies published after the cutoff date for the science (criteria) assessment, reflecting the Clean Air Act 108(a)(2) requirement that such assessments accurately reflect "the latest scientific knowledge." Though many relevant studies have been published since the January 2018 cutoff date, EPA has apparently ignored this step and its obligations under Clean Air Act section 108(a)(2). EPA's failure to even acknowledge this deviation from its past practice, much less provide a reasoned explanation for it, is yet another elementary legal

[249] CASAC did make recommendations for inclusion of studies published after the cutoff date during the review, including one that was not available online until late 2019. By contrast, some highly relevant studies published in 2018 recommended for inclusion in public comments to CASAC and EPA were not included. These failings are further evidence that the proposal is arbitrary and capricious, and an abuse of discretion.

violation.[250] Further, by accepting CASAC's recommendation to consider a secondary reference on accountability studies that was published online only in late 2019 and published in February 2020, EPA cannot now legally close the door to adding a number of important new studies that are far more relevant to the current decision.[251] Such a step would be arbitrary and capricious, and an abuse of discretion.

The next two subsections provide a non-exhaustive summary of relevant new studies EPA should consider before reaching final conclusions on the adequacy of the current standards.

1. Accountability and intervention studies published after January 2018.

This subsection highlights several significant new accountability and life extension studies using causal inference methods that assess specific and collective regulatory actions that resulted in $PM_{2.5}$ reductions and health benefits. Individually and collectively these studies challenge the Administrator's stated rationale for not changing the standard, and invalidate CASAC's erroneous characterization regarding the lack of new evidence relating to recent interventions and accountability.

Corrigan et al., Fine Particulate Matters: the Impact of Air Quality Standards on Cardiovascular Mortality. Environ Res 2018;161:364–369.

This accountability study[252] was the first to examine the impact of EPA's designation of areas for the 1997 annual $PM_{2.5}$ standard. Corrigan and coworkers[253] used difference in difference and linear regression models, adjusted for sociodemographic confounders to examine whether the change in cardiovascular (CV) mortality rate before (2000-2004) and after (2005-2010) the first implementation of the 1997 annual $PM_{2.5}$ NAAQS standard was associated with the change in $PM_{2.5}$. The results showed a significant improvement to health per unit decrease in $PM_{2.5}$, 1.10 (95% CI: 0.37, 1.82) fewer CV-deaths per year per 100,000 people per 1 μg/m^3 decline in $PM_{2.5}$. They found that "Nonattainment counties had a twofold larger reduction in mean annual $PM_{2.5}$, 2.1 μg/m^3, compared to attainment counties, 0.97 μg/m^3. CV-mortality rate decreased by 0.59

[250] *See Physicians for Social Responsibility v. Wheeler*, 956 F. 3d 634, 644 (D.C. Cir. 2020) (noting that APA requirement for a reasoned explanation is especially important when "an agency changes course").
[251] *See ATA I*, 175 F. 3d at 1052-53 (shifting criteria for inclusion of studies for consideration is arbitrary and constitutes reversible error).
[252] Corrigan AE, Becker MM, Neas LM, Cascio WE, Rappold AG. 2018. Fine Particulate Matters: the Impact of Air Quality Standards on Cardiovascular Mortality. *Environ Res* 2018;161:364–369.
[253] This study was conducted by EPA researchers and published only one month after the cutoff date. Inclusion of this study in the review was recommended in written comments to CASAC and EPA on the draft Policy Assessment (Bachmann, J., 12 Nov. 2019).

(95% CI: −0.54, 1.71) in nonattainment and 1.96 (95% CI: 0.77, 3.15) deaths per 100,000 people for each 1μg/m^3 decrease in $PM_{2.5}$ in attainment counties." (Corrigan et al. 2018, p. 2).

Perhaps of most direct relevance to the current review, the authors also stratified counties based on two factors related to NAAQS compliance to further examine this association, including a look at counties that started with levels below the current annual standard and experienced further reductions. They found that "the results of our analysis suggest that the health benefit per unit decrease in $PM_{2.5}$ persists in counties with concentrations below our current national standard for annual $PM_{2.5}$ (12 μg/m^3)." (Corrigan et al. 2018, p. 7).

Zigler et al., 2018. Impact of National Ambient Air Quality Standards Nonattainment Designations on Particulate Pollution and Health. Epidemiology 29: 165–174

Zigler et al., another accountability study[254] used causal inference methods and spatial hierarchical regression modelling to "characterize the extent to which a designation of 'nonattainment' with the 1997 National Ambient Air Quality Standard for ambient fine particulate matter (PM) in 2005 causally affected ambient PM and health outcomes among over 10 million Medicare beneficiaries in the Eastern US in 2009–2012."[255] The stratification analysis was necessary to separate the effects of nonattainment designations from those attainment areas of the east due to EPA regulations that produced regional reductions in fine particles across the entire Eastern U.S. The authors report that the more targeted analysis "indicates substantial health impacts of the nonattainment designations among the subset of areas where the designations are estimated to have actually reduced ambient PM beyond levels achieved by regional measures, with noteworthy reductions in all-cause mortality, chronic obstructive pulmonary disorder, heart failure, ischemic heart disease, and respiratory tract infections.

An important aspect of this work is that it noted the difference between areas in which designations did not include local measures as opposed to those that did. The analysis found that "the designations did not causally impact health outcomes among locations where designations did not meaningfully affect ambient $PM_{2.5}$ in 2010-2012." (Zigler et al. 2018). By contrast, the "associative effects" in non-attainment areas that did adopt local measures were estimated to suggest causal reductions in rates of all-cause Medicare mortality and hospitalization for COPD, heart failure, IHD, and respiratory tract infections among locations where the designations decreased ambient PM by at least 1.0 μg/m^3.

[254] Zigler CM, Choirat C, Dominici F. 2018. Impact of National Ambient Air Quality Standards Nonattainment Designations on Particulate Pollution and Health. *Epidemiology* 29: 165–74
[255] This study was published in March 2018. It was recognized as "Epidemiology Paper of the Year" for 2018. Inclusion of this study in the review was recommended in written comments to CASAC and EPA on the draft Policy Assessment (Bachmann, J., 12 Nov. 2019).

The authors also caution "While the analysis strategy adopted here is specifically designed to mitigate bias due to measured confounders, the prospect of unmeasured confounding remains a threat to the validity of results." (Zigler et al. 2018). They conclude that "Despite the limitations of the present analysis, it provides evidence of the effectiveness of one integral feature of air quality management in the US, and represents a distinct perspective that should be interpreted in conjunction with - not instead of - the large body of epidemiological research motivating the setting and implementation of NAAQS." (Zigler et al. 2018).

Henneman et al., 2019. Accountability assessment of health improvements in the United States associated with reduced coal emissions between 2005 and 2012. Epidemiology 30:477-485.

Henneman et al., another accountability study[256] used difference in difference methods, combined with a unique approach of using a trajectory model to sort receptor populations in the Eastern U.S. into groups more affected by plumes from coal fired power plants that did not adopt SO_2 scrubbers and those more affected by plumes from plants that did adopt these controls. They also developed a simulated estimate of total $PM_{2.5}$ concentrations in the Eastern United States using a regional air pollution model, satellite retrieved optical depth, and an earlier data base of observed $PM_{2.5}$ data. They used these results to associate health outcome rates in 30 million Medicare beneficiaries with exposure changes in $PM_{2.5}$ between 2005 and 2012 in two difference-in-difference regression approaches designed to mitigate observed and unobserved confounding.

They found significant reduction in six cardiac and respiratory health outcomes – all cardiovascular disease, chronic obstructive pulmonary disorder, cardiovascular stroke, heart failure, ischemic heart disease, and respiratory tract infections, with mixed results for other effects. A secondary analysis found "that nonlinearities in relationships between changing health outcome rates and coal exposure may explain differences in their associations." (Henneman et al. 2019). The authors concluded that "The direct analyses of emissions reductions estimate substantial health benefits via coal power plant emission and $PM_{2.5}$ concentration reductions. Differing responses associated with changes in the two exposure metrics underscore the importance of isolating source-specific impacts from those due to total $PM_{2.5}$ exposure." (Henneman et al. 2019).

[256] Henneman LRF, Choirat C, Zigler CM. 2019. Accountability assessment of health improvements in the United States associated with reduced coal emissions between 2005 and 2012. Epidemiology 30:477-485.

Bennett et al., 2019. Particulate Matter Air Pollution and National and County Life Expectancy Loss in the USA: A Spatiotemporal Analysis. PLoS Med 16(7)

The Bennett et al. study[257] used four Bayesian spatiotemporal models with different adjustments for other determinants of mortality, to directly estimate mortality and life expectancy loss due to current $PM_{2.5}$ pollution and the benefits of reductions from 1999 to 2015, nationally and by county. The methodology complements and extends the life expectancy studies discussed above that the EPA PA relied on in their conclusions using a different cohort (NCHS). They included the following covariates:

> "per capita income, percentage of population whose family income is below the poverty threshold, who are of Black or African American race, who have graduated from high school, who live in urban areas, and who are unemployed; cumulative smoking; and mean temperature and relative humidity. In the main model, which adjusted for these covariates and for unobserved county characteristics through the use of county-specific random intercepts, $PM_{2.5}$ pollution in excess of the lowest observed concentration (2.8 μg/m^3) was responsible for an estimated 15,612 deaths (95% credible interval 13,248–17,945) in females and 14,757 deaths (12,617–16,919) in males. These deaths would lower national life expectancy by an estimated 0.15 years (0.13–0.17) for women and 0.13 years (0.11–0.15) for men." (Bennet et al. 2019).

While they cannot rule out county level data on some other important determinants of mortality, these factors were adjusted for with use of county-specific random intercepts.

In 1999, 59% of the 1,339 merged county units exceeded the current annual standard of 12 μg/m^3. By 2015, only four of this merged group were above, meaning a substantial amount of the life extension took place when levels were below that standard. While not fully meeting the Administrators unreasonable and illegal demand that such studies show benefits when levels are reduced from below to further below before he would consider revising the standard, it certainly adds materially to the evidence that reducing $PM_{2.5}$ levels from a population weighted average of 13.9 μg/m^3 to 8.0 μg/m^3 in 2015 produces substantial public health benefits.[258]

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[257] Bennett JE, Tamura-Wicks H, Parks RM, Burnett RT, Pope CA, III, Bechle MJ, et al. (2019) Particulate Matter Air Pollution and National and County Life Expectancy Loss in the USA: A Spatiotemporal Analysis. *PLoS Med* 16(7): e1002856. https://doi.org/10.1371/ journal.pmed.1002856.

[258] It also calls into question one of the individual CASAC members, who suggested that the Correia et al (2016) study results for the limited number of counties below 12 μg/m^3 suggest a threshold. (Comments of Dr. Mark Frampton, Dec. 16, 2019, Letter, p. B-44).)

Sanders et al., 2020. Estimating Causal Effects of Particulate Matter Regulation on Mortality. *Epidemiology* March 2020 31(2) 169-167.

This accountability study[259] used a quasi-experimental design to examine the causal relationship between PM2.5 and mortality for years before (2000-2005) and years after (2006-2013) EPA and states designated areas as non-attainment with the 1997 standard of 15 μg/m3. The investigators used a differences-in-differences approach to compare changes in mortality within designated nonattainment (treatment) counties with those in compliance with the standard (control counties). They found that $PM_{2.5}$ reductions were in general greater in non-attainment than attainment counties and were accompanied by a greater reduction in mortality rates for those aged 65 years and older. The analysis further included weather data (maximum and mean temperature and precipitation), economic data (per capita income and percent employed), and migration. All data were aggregated on a yearly and county basis.

The authors concluded that "This analysis suggests large health returns to the 2005 $PM_{2.5}$ designations, and provides evidence of a causal association between pollution and mortality among the Medicare population." (Sanders et al. 2020). They added that the focus on policy variation rather than per-unit pollution levels, provides more robust evidence on the causal link between pollution policy and human health. The results are generally consistent with those of Zigler et al. (2018), who. As summarized above, addressed the same intervention using alternative causal inference methods.

Wu et al., 2020. Evaluating the Impact of Long-term Exposure to Fine Particulate Matter on 4 Mortality Among the Elderly. *Science Advances*.

Wu et al., a nationwide study, is easily the most sophisticated and comprehensive example of the application of causal inference methods in air pollution epidemiology to date. Wu et al leveraged 16 years of US $PM_{2.5}$ data with the largest ever air pollution cohort —68.5 million Medicare enrollees and 570 million observations. Building on the group's past development of methods for causal inference and accountability methods,[260] they applied traditional regression and causal inference approaches to the same data, and assessed sensitivity to modeling

[259] Sanders, Nicholas J; Barreca, Alan I; Neidell, Matthew J. 2020. Estimating Causal Effects of Particulate Matter Regulation on Mortality. *Epidemiology* March 2020 31(2) 169-167.
p doi: 10.1097/EDE.0000000000001153.

[260] *See*, *e.g.*, F. Dominici, C. Zigler, Best Practices For Gauging Evidence Of Causality In Air Pollution 496 epidemiology. Am J Epidemiol 186, 1303-1309 (2017), D. Braun, M. Gorfine, G. Parmigiani, N. D. Arvold, F. Dominici, C. Zigler, Propensity 506 scores with misclassified treatment assignment: a likelihood-based adjustment. 507 Biostatistics 18, 695-710 (2017), Zigler et al. 2018 (see summary above), X. Wu, D. Braun, M. A. Kioumourtzoglou, C. Choirat, Q. Di, F. Dominici, Causal 511 inference in the context of an error prone exposure: air pollution and mortality. Ann Appl 512 Stat 13, 520-547 (2019) (see summary in causal inference section).

assumptions and study period. The analysis addressed 10 socioeconomic confounders at a zip code level as well as summer and winter temperature and humidity, and calendar year. Using five distinct statistical approaches, the investigators found that a decrease of 10 $\mu g/m^3$ $PM_{2.5}$ leads to a statistically significant 6%–7% decrease in mortality risk.

The investigators address the strength of their conclusions regarding causality in the following:

> "This study provides the most robust and reproducible evidence to date on the causal link between exposure to $PM_{2.5}$, *even at levels below 12 μg/m³*, and mortality among Medicare enrollees. Considering 1) the massive study population; 2) the numerous sensitivity analyses; and 3) the transparent assessment of covariate balance that indicates the quality of causal inference for recovering randomized experiments, *we conclude that long-term $PM_{2.5}$ exposure is causally related to mortality.* This conclusion assumes that the causal inference assumptions hold and, more specifically, that we were able to adequately account for confounding bias. We explored various modeling approaches and conducted extensive sensitivity analyses, and found the results were robust across approaches and models. This work relies on publicly available data and we provide code that allows for reproducibility of our analyses." (emphasis added).

For the period 2000–2016, they found that all statistical approaches provide consistent results: a 10 μg/m3 decrease in $PM_{2.5}$ led to a statistically significant decrease in mortality rate ranging between 6% and 7%. Significantly, the estimated HRs were larger when studying the cohort of Medicare enrollees that were always exposed to $PM_{2.5}$ levels lower than 12 $\mu g/m.^3$ Based on these models, the investigators estimated the total number of deaths avoided among elderly in a decade if, hypothetically, US standards followed the WHO guideline and met a level of 10 $\mu g/m.^3$ Using their most conservative model they estimated lowering the annual standard even to that level[261] would save 143,257 lives (95% 30 confidence interval 115,581–170,645) in one decade.

In comparing their results to traditional approaches used in cohort studies, they found that a more flexible regression model specification may help adequately adjust for confounding in such studies; when implementing these flexible models, they observed similar results compared to the

[261] This is at the upper end of the range of annual standards recommended by the IPMRP.(Frey et al, 2019). Given that the current annual US PM2.5 levels are 8 µµg/3, (EPA 2020, Chapter 2) many more areas would be affected by a standard at that level and the additional benefits of a standard of 8 $\mu\mu g/m^3$ would be disproportionately larger.

causal inference approaches. The authors also restate their view (see Dominici and Zigler 2017) that establishing causality in air pollution studies should not be limited to studies using causal methods. They stress that "the collective evidence across studies conducted in different populations, using different study designs and methods, is also imperative to inform regulatory action."

Clearly this study is an important addition to the epidemiological literature, one that strengthens the already strong case for causality of made in the ISA for $PM_{2.5}$ and mortality, based on assessing the weight of evidence from multiple epidemiology studies as well as supporting experimental work that provides coherent evidence of biological plausibility and mode of action.

These new accountability and life extension studies used causal inference methods to examine the health benefits of specific or general interventions that reduce $PM_{2.5}$. The most recent work by Wu et al 2020 is of particular importance as it addresses many of the issues raised by CASAC and the Administrator, including an accountability study using advanced causal inference methods to show that a reduction of $PM_{2.5}$ that begins at levels below the current standard is causally related to a significant reduction in serious health effects. They add significantly in terms of their complementary approaches to addressing potential confounders and, together with studies already assessed in EPA's ISA and PA, show that reductions in fine particles result in health benefits. They paint a wholly different picture than that provided in the December 16, 2019 CASAC letter that suggests there is a "lack of consistent support from newer intervention and accountability studies."

2. Additional causal inference studies published after January 2018.

Above, we address a number of studies addressed in the ISA and noted in the PA using causal inference methods that did not attempt to assess effects of long-term changes in $PM_{2.5}$. Examples include Pun et al. (2017), Greven et al. (2011), and Wang et al. (2016). We also summarized several studies using causal inference techniques that were published before January 2018 but not included in the ISA that EPA should consider. These were identified in the extensive public comments by Dr. Joel Schwartz (2020). Dr. Schwartz summarized and provided references for a number of additional such causal inference studies that were published after January 2018 that the Administrator must now consider in making his final conclusions. These include the following long-term studies:

Wu et al., 2019. Causal Inference In The Context Of An Error Prone Exposure: Air Pollution And Mortality. Ann Appl Stat 13(1):520-547

As part of a larger project,[262] Wu et al (2019)[263] proposed a new approach for estimating causal effects that uses a measurement error correction technique (regression calibration) combined with matching on propensity score to estimate exposure error corrected causal effects. Although it is largely a methodology paper, they applied the approach to a rich data platform to estimate the causal effect of long-term exposure to fine particles (PM2.5) on mortality in New England Medicare beneficiaries for the period from 2000 to 2012. They reported "Under assumptions of noninterference and weak un-confoundedness, using matching we found that exposure to moderate levels of $PM_{2.5}$ ($8 < PM_{2.5} \leq 10$ μg/m3) causes a 2.8% (95% CI: 0.6%, 3.6%) increase in all-cause mortality compared to low exposure ($PM_{2.5} \leq 8$ μg/m3)." (Wu et al. 2019).

Although not evaluating reductions, this study using advanced causal methods, found a substantial increase in mortality risk when comparing PM2.5 concentrations below 8 μg/m^3 and "higher" concentrations in a range between 8 and 10 μg/m^3. It clearly adds to the already ample evidence that long-term exposures well below the current standards may be causally associated with serious effects.

Yitshak-Sade et al., 2019. Estimating The Causal Effect Of Annual Pm2.5 Exposure On Mortality Rates In The Northeastern And Mid-atlantic States. *Environmental Epidemiology Online*

Another study,[264] Yitshak-Sade et al., used a differences-in-differences method for Medicare deaths and $PM_{2.5}$ in the Northeast and Mid-Atlantic states, finding a significant association for $PM_{2.5}$ and mortality.

Abu Awad et al. 2019. Change In Pm2.5 Exposure And Mortality Among Medicare Recipients. *Environmental Epidemiology* 3:e054.

Separately, Abu Awad et al., investigators examined[265] $PM_{2.5}$ changes for over 12 million U.S. Medicare beneficiaries, who moved to a new zip code. This enabled a quasi-experimental approach with a propensity score approach to find the change in exposure due to the move was

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262 Dominici F, Schwartz J, Di Q, Braun D, Choirat C., Zanobetti A. 2019. Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1. Research Report 200. Boston, MA: Health Effects Institute. Available at: https://www.healtheffects.org/system/files /dominici-rr-200-report.pdf

263 Wu X, Braun D, Kioumourtzoglou MA, Choirat C, Di Q, Dominici F. 2019. Causal inference in the context of an error prone exposure: Air pollution and mortality. Ann Appl Stat 13(1):520-547. March 2019

264 Yitshak-Sade M, Kloog I, Zanobetti A, Schwartz JD. 2019. Estimating the causal effect of annual PM2.5 exposure on mortality rates in the Northeastern and Mid-Atlantic states. *Environmental Epidemiology Online* June 2019. DOI: 10.1097/EE9.0000000000000052

265 Abu Awad Y, Di Q, Wang Y, Choirat C, Coull B, Zanobetti A, et al. 2019. Change in pm2.5 exposure and mortality among medicare recipients. *Environmental Epidemiology* 3:e054.

associated with a change in mortality rates consistent with a significant association with PM2.5 at higher exposures. As Schwartz (2020) notes, "since prior exposure was identical between participants moving from the same Zip code, this analysis directly assessed the effect of change in exposure on mortality rate, precisely the analysis the Administrator argues is needed." The investigators conclude that "This study provides evidence of likely causal effects at concentrations below current limits of $PM_{2.5}$." (Awad et al. 2019).

Schwartz et al., 2018. Estimating The Effects Of Pm2.5 On Life Expectancy Using Causal Modeling Methods. *Environ Health Perspect* 126:127002.

This Schwartz et al., 2018 study[266] used propensity score causal modeling that analyzed directly the effect of PM2.5 on life expectancy for nearly 17 million Medicare beneficiaries in the Northeast and Mid-Atlantic states. They found that "The estimated mean age at death for a population with an annual average $PM_{2.5}$ exposure of 12 μg/m^3 (the 2012 National Ambient Air Quality Standard) was 0.89 y less (95% CI: 0.88, 0.91) than estimated for a counterfactual $PM_{2.5}$ exposure of 7.5 μg/m^3. (Schwartz et al. 2018).

Higbee et al., 2020. Estimating Long-term Pollution Exposure Effects Through Inverse Probability Weighting Methods With Cox Proportional Hazards Models. Environmental Epidemiology. 4(2): e085.

This Higbee et al., study[267] used inverse probability weighting based on propensity scores, to examine the relationship between $PM_{2.5}$ and total and CV mortality in a cohort of 635,000 US individuals in the NHIS database. Long-term air quality reflected a 17-year average (1999-2015).The analysis included multiple covariates as confounders. "Covariate-adjusted estimated relative risks per 10 μg/m3 increase in PM exposure were estimated to be 1.117 (1.083, 1.152) for all-cause mortality and 1.232 (1.174, 1.292) for cardiopulmonary mortality." (Higbee et al. 2020). The investigators concluded that "These results provide evidence that long-term exposure to PM contributes to increased mortality risk in US adults and that the estimated effects are generally robust to modeling choices… Estimated confounding due to measured covariates

[266] Schwartz JD, Wang Y, Kloog I, Yitshak-Sade M, Dominici F, Zanobetti A. 2018. Estimating the effects of PM2.5 on life expectancy using causal modeling methods. *Environ Health Perspect* 126:127002.

[267] Higbee, Joshua D.; Lefler, Jacob S; Burnett, Richard T; Ezzati, Majidd; Marshall, Julian D Kim, Sun-Young; Bechle, Matthew; Robinson, Allen L. Pope, C. Arden III. 2020. Estimating long-term pollution exposure effects through inverse probability weighting methods with Cox proportional hazards models. *Environmental Epidemiology*. 4(2): e085. April 2020. doi: 10.1097/EE9.0000000000000085

appears minimal in the NHIS cohort, and various distributional assumptions have little bearing on the magnitude or standard errors of estimated causal associations.” (Higbee et al. 2020).

Wei et al., 2020. Causal effects of air pollution in Massachusetts. *Am J Epidemiology* in press.

Implementing a generalized propensity score adjustment approach with 3.8 billion person-days of follow-up, this Wei et al. study[268] simultaneously assessed causal associations of long- (one-year moving average) and short-term (two-day moving average) $PM_{2.5}$, O3, and NO2 exposures with all-cause mortality on an additive scale among Medicare beneficiaries in Massachusetts, 2000–2012. In summary they found “long- and short-term $PM_{2.5}$, O_3, and NO_2 were all associated with increased mortality risk. Mortality associated with long-term $PM_{2.5}$ and O_3 increased substantially at low levels.” (Wei et al. 2020).The investigators stated that “The findings suggest air pollution was causally associated with mortality, even at levels below national standards.” (Wei et al. in press).

In supplemental comments, Dr. Schwartz noted that the results of this study answered the suggestion by the CASAC Chairman that temperature may confound cohort studies (Comment Submitted by J Schwartz, June 22, 2020). Specifically he noted Wei et al included daily temperature as a covariate in the propensity score and the result “clearly shows a significant association with long-term $PM_{2.5}$ after controlling for both long and short-term temperature.” *Id*.

Schwartz also identified two additional studies[269] using causal methods for assessing short-term (daily) PM2.5 exposures.

ii. Additional studies not considered by CASAC or EPA

[268] Wei Y, Wang Y, Wu X, Di Q, Shi L, Koutrakis P, Zanobetti A., Dominici F, and JD. Schwartz. 2020. Causal effects of air pollution in Massachusetts. *Am J Epidemiogyl* in press.
[269] Schwartz J, Fong K, Zanobetti A. 2018. A national multi-city analysis of the causal effect of local pollution, NO_2, and $PM_{2.5}$ on mortality. *Environmental Health Perpectives*.126(8) August 2018. Yitshak-Sade M, Nethery R, Abu Awad Y, Mealli F, Dominici F, Kloog I, et al. 2020. Lowering air pollution levels in Massachusetts may prevent cardiovascular hospital admissions. J Am Coll Cardiol 75:2642-2644.

In its communication to EPA, the CASAC[270] has selectively included only a handful of newer studies for consideration.[271] These recommendations are biased and do not include other studies that would help to justify stronger NAAQS. Recommended studies by CASAC also include

[270] Clean Air Sci. Advisory Comm. EPA-CASAC-20-001, 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), (Dec. 16, 2019), https://yosemite.epa.gov/sab/sabproduct.nsf/E2F6C71737201612852584D20069DFB1/$File/EPA-CASAC-20-001.pdf.

[271] Eum, Ki-Do, Helen H. Suh, Vivian Chit Pun, and Justin Manjourides (2018). "Impact of Long-Term Temporal Trends in Fine Particulate Matter (PM2.5) on Associations of Annual PM2.5 Exposure and Mortality: An Analysis of over 20 Million Medicare Beneficiaries." *Environmental Epidemiology* 2(2): e009. https://doi.org/10.1097/EE9.0000000000000009; Samset, B. H., M. Sand, C. J. Smith, S. E. Bauer, P. M. Forster, J. S. Fuglestvedt, S. Osprey, and C.-F. Schleussner (2018). "Climate Impacts From a Removal of Anthropogenic Aerosol Emissions." *Geophysical Research Letters* 45(2): 1020–29. https://doi.org/10.1002/2017GL076079; Harvey, Chelsea, *Cleaning Up Air Pollution May Strengthen Global Warming,* Sci. Am., (Jan. 22, 2018), https://www.scientificamerican.com/article/cleaning-up-air-pollution-may-strengthen-global-warming/; Burns, Jacob, Hanna Boogaard, Stephanie Polus, Lisa M. Pfadenhauer, Anke C. Rohwer, Annemoon M. van Erp, Ruth Turley, and Eva Rehfuess (2019). "Interventions to Reduce Ambient Particulate Matter Air Pollution and Their Effect on Health." *The Cochrane Database of Systematic Reviews* 5: CD010919, https://doi.org/10.1002/14651858.CD010919.pub2; Bind, Marie-Abèle (2019). "Causal Modeling in Environmental Health." *Annual Review of Public Health* 40(1): 23–43, https://doi.org/10.1146/annurev-publhealth-040218-044048; American Association for the Advancement of Science (2019). "Erratum for the Research Article 'Aerosol-Driven Droplet Concentrations Dominate Coverage and Water of Oceanic Low-Level Clouds' by D. Rosenfeld, Y. Zhu, M. Wang, Y. Zheng, T. Goren, S. Yu." *Science* 364 (6446), https://doi.org/10.1126/science.aay4194; Jerrett, Michael, Michelle C. Turner, Bernardo S. Beckerman, C. ArdenPope, Aaronvan Donkelaar, Randall V.Martin , Marc Serre, et al. (2017). "Comparing the Health Effects of Ambient Particulate Matter Estimated Using Ground-Based versus Remote Sensing Exposure Estimates." *Environmental Health Perspectives* 125(4): 552–59, https://doi.org/10.1289/EHP575. Pearl, Judea, and Dana Mackenzie, *The Book of Why: The New Science of Cause and Effect* (2018); Cox Jr., Louis Anthony (2018). "Modernizing the Bradford Hill Criteria for Assessing Causal Relationships in Observational Data." *Critical Reviews in Toxicology* 48(8): 682–712, https://doi.org/10.1080/10408444.2018.1518404; Pope, C. Arden, Daniel Krewski, Susan M. Gapstur, Michelle C. Turner, Michael Jerrett, and Richard T. Burnett (2017). "Fine Particulate Air Pollution and Mortality: Response to Enstrom's Reanalysis of the American Cancer Society Cancer Prevention Study II Cohort." *Dose-Response* 15(4): 1559325817746303, https://doi.org/10.1177/1559325817746303.

research published for populations in China[272] and Australia[273] and investigations authored by CASAC members,[274] to the exclusion of relevant studies conducted for populations in the United States by renowned air pollution epidemiologists who are not current CASAC members. CASAC showed bias in not recommending at least three and likely more studies recommended by public commenters that were far more relevant than Enstrom et al. (2017). These include Zigler et al. (March 2018)[275] and Vodonos et al. (2018).[276]One study recommended by CASAC was formally published in January 2020,[277] the same month when the final ISA was published by EPA.

This selective consideration of studies excluded from the Integrated Science Assessment is particularly arbitrary and capricious and an abuse of discretion, given that EPA has cited several of the CASAC-selected studies in the final Policy Assessment. For example, in making concluding statements on the primary $PM_{2.5}$ standards, EPA notes that its "approach to reaching conclusions is based on considering the EPA's assessment of the current scientific evidence for health effects attributable to $PM_{2.5}$ exposures (discussed in detail in the ISA; U.S. EPA, 2019), quantitative assessments of $PM_{2.5}$-associated health risks, and analyses of $PM_{2.5}$ air quality. We also consider the range of advice received from the CASAC (Cox, 2019) and comments from the members of the public."[278] EPA does not consider additional studies that are directly relevant to

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[272] Luo, Hao, Yong Han, Chunsong Lu, Jun Yang, and Yonghua Wu (2019). "Characteristics of Surface Solar Radiation under Different Air Pollution Conditions over Nanjing, China: Observation and Simulation." *Advances in Atmospheric Sciences* 36(10): 1047–59, https://doi.org/10.1007/s00376-019-9010-4; Li, Chengming, Zhaoxin Dai, Lina Yang, and Zhaoting Ma. (2019). "Spatiotemporal Characteristics of Air Quality across Weifang from 2014-2018." *International Journal of Environmental Research and Public Health* 16(17), https://doi.org/10.3390/ijerph16173122.

[273] Patel, Dimpalben, Le Jian, Jianguo Xiao, Janis Jansz, Grace Yun, and Andrew Robertson (2019). "Joint Effect of Heatwaves and Air Quality on Emergency Department Attendances for Vulnerable Population in Perth, Western Australia, 2006 to 2015." *Environmental Research* 174(July): 80–87, https://doi.org/10.1016/j.envres.2019.04.013.

[274] Cox Jr., Louis Anthony (2018). "Effects of Exposure Estimation Errors on Estimated Exposure-Response Relations for PM2.5." *Environmental Research* 164 (July): 636–46, https://doi.org/10.1016/j.envres.2018.03.038.

[275] Zigler, Corwin M., Christine Choirat, and Francesca Dominici. 2018. "Impact of National Ambient Air Quality Standards Nonattainment Designations on Particulate Pollution and Health." *Epidemiology (Cambridge, Mass.)* 29 (2): 165–74. https://doi.org/10.1097/EDE.0000000000000777.

[276] Vodonos, Alina, Yara Abu Awad, and Joel Schwartz. 2018. "The Concentration-Response between Long-Term PM2.5 Exposure and Mortality; A Meta-Regression Approach." *Environmental Research* 166 (October): 677–89. https://doi.org/10.1016/j.envres.2018.06.021.

[277] Carone, Marco, Francesca Dominici, and Lianne Sheppard (2020). "In Pursuit of Evidence in Air Pollution Epidemiology: The Role of Causally Driven Data Science." *Epidemiology* 31(1): 1–6, https://doi.org/10.1097/EDE.0000000000001090.

[278] U.S. Envtl. Prot. Agency, EPA-452/R-20-002, Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, at 3-100 (2020),

the proposed rulemaking. This excludes many other relevant scientific studies not analyzed through the ISA, [279] and reflects decisionmaking that is arbitrary and capricious, and an abuse of discretion.

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https://www.epa.gov/sites/production/files/2020-01/documents/final_policy_assessment_for_the_review_of_the_pm_naaqs_01-2020.pdf.

[279] Vodonos, Alina, Yara Abu Awad, and Joel Schwartz. 2018. "The Concentration-Response between Long-Term PM2.5 Exposure and Mortality; A Meta-Regression Approach." *Environmental Research* 166 (October): 677–89. https://doi.org/10.1016/j.envres.2018.06.021. https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002856Bowe, Benjamin, Yan Xie, Yan Yan, and Ziyad Al-Aly (2019). "Burden of Cause-Specific Mortality Associated With PM2.5 Air Pollution in the United States." *JAMA Network Open* 2(11): e1915834, https://doi.org/10.1001/jamanetworkopen.2019.15834;Brokamp, Cole, Jeffrey R. Strawn, Andrew F. Beck, and Ryan Patrick (2019). "Pediatric Psychiatric Emergency Department Utilization and Fine Particulate Matter: A Case-Crossover Study." *Environmental Health Perspectives* 127(9): 097006, https://doi.org/10.1289/EHP4815;Dedoussi, Irene C., Sebastian D. Eastham, Erwan Monier, and Steven R. H. Barrett (2020). "Premature Mortality Related to United States Cross-State Air Pollution." *Nature* 578(7794): 261–65, https://doi.org/10.1038/s41586-020-1983-8;DeFlorio-Barker, Stephanie, James Crooks, Jeanette Reyes, and Ana G. Rappold (2019). "Cardiopulmonary Effects of Fine Particulate Matter Exposure Among Older Adults, During Wildfire and Non-Wildfire Periods, in the United States 2008–2010." *Environmental Health Perspectives* 127(3): 037006, https://doi.org/10.1289/EHP3860;Dominici, Francesca, Joel A. Schwartz, Qian Di, Danielle Braun, Christine Choirat, and Antonella Zanobetti (2019). "Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution." 200. *Health Effects Institute*, https://www.healtheffects.org/system/files/dominici-rr-200-report.pdf;Fan, Maoyong, and Yi Wang (2020). "The Impact of $PM_{2.5}$ on Mortality in Older Adults: Evidence from Retirement of Coal-Fired Power Plants in the United States." *Environmental Health* 19(1): 28, https://doi.org/10.1186/s12940-020-00573-2;Fann, Neal, Kirk R. Baker, Elizabeth A. W. Chan, Alison Eyth, Alexander Macpherson, Elizabeth Miller, and Jennifer Snyder (2018). "Assessing Human Health $PM_{2.5}$ and Ozone Impacts from U.S. Oil and Natural Gas Sector Emissions in 2025." *Environmental Science & Technology* 52(15): 8095–103, https://doi.org/10.1021/acs.est.8b02050;Fu, Pengfei, Xinbiao Guo, Felix Man Ho Cheung, and Ken Kin Lam Yung (2019). "The Association between $PM_{2.5}$ Exposure and Neurological Disorders: A Systematic Review and Meta-Analysis." *Science of The Total Environment* 655(March): 1240–48, https://doi.org/10.1016/j.scitotenv.2018.11.218;
Goodkind, Andrew L., Christopher W. Tessum, Jay S. Coggins, Jason D. Hill, and Julian D. Marshall (2019). "Fine-Scale Damage Estimates of Particulate Matter Air Pollution Reveal Opportunities for Location-Specific Mitigation of Emissions." *Proceedings of the National Academy of Sciences* 116(18): 8775–80, https://doi.org/10.1073/pnas.1816102116;Huang, Keyong, Jianzhao Bi, Xia Meng, Guannan Geng, Alexei Lyapustin, Kevin J. Lane, Dongfeng Gu, Patrick L. Kinney, and Yang Liu (2019). "Estimating Daily $PM_{2.5}$ Concentrations in New York City at the Neighborhood-Scale: Implications for Integrating Non-Regulatory Measurements." *Science of the Total Environment* 697(December): 134094, https://doi.org/10.1016/j.scitotenv.2019.134094; Independent Particulate Matter Review Panel (2020). "The Need for a Tighter Particulate-Matter Air-Quality Standard." *New England Journal of Medicine*,

https://doi.org/10.1056/NEJMsb2011009; Leiser, Claire L., Ken R. Smith, James A. VanDerslice, Jason P. Glotzbach, Timothy W. Farrell, and Heidi A. Hanson (2019). "Evaluation of the Sex-and-Age-Specific Effects of $PM_{2.5}$ on Hospital Readmission in the Presence of the Competing Risk of Mortality in the Medicare Population of Utah 1999–2009." *Journal of Clinical Medicine* 8(12): 2114, https://doi.org/10.3390/jcm8122114; Liu, Ying, Naizhuo Zhao, Jennifer K. Vanos, and Guofeng Cao (2019). "Revisiting the Estimations of $PM_{2.5}$-Attributable Mortality with Advancements in $PM_{2.5}$ Mapping and Mortality Statistics." *Science of The Total Environment* 666(May): 499–507, https://doi.org/10.1016/j.scitotenv.2019.02.269; Loxham, Matthew, Donna E. Davies, and Stephen T. Holgate (2019). "The Health Effects of Fine Particulate Air Pollution." *BMJ* 367(8224): l6609, https://doi.org/10.1136/bmj.l6609; Pappin, Amanda J., Tanya Christidis, Lauren L. Pinault, Dan L. Crouse, Jeffrey R. Brook, Anders Erickson, Perry Hystad et al. (2019). "Examining the Shape of the Association between Low Levels of Fine Particulate Matter and Mortality across Three Cycles of the Canadian Census Health and Environment Cohort." *Environmental Health Perspectives* 127(10): 107008, https://doi.org/10.1289/EHP5204; Peterson, Geoffrey Colin L., Christian Hogrefe, Anne E. Corrigan, Lucas M. Neas, Rohit Mathur, and Ana G. Rappold (2020). "Impact of Reductions in Emissions from Major Source Sectors on Fine Particulate Matter–Related Cardiovascular Mortality." *Environmental Health Perspectives* 128(1): 017005, https://doi.org/10.1289/EHP5692; Pope, C. Arden, Nathan Coleman, Zachari A. Pond, and Richard T. Burnett (2020). "Fine Particulate Air Pollution and Human Mortality: 25+ Years of Cohort Studies." *Environmental Research* 183(April): 108924, https://doi.org/10.1016/j.envres.2019.108924; Pope, C. Arden, Jacob S. Lefler, Majid Ezzati, Joshua D. Higbee, Julian D. Marshall, Sun-Young Kim, Matthew Bechle et al. (2019). "Mortality Risk and Fine Particulate Air Pollution in a Large, Representative Cohort of U.S. Adults." *Environmental Health Perspectives* 127(7): 077007, https://doi.org/10.1289/EHP4438; Rhee, Jongeun, Francesca Dominici, Antonella Zanobetti, Joel Schwartz, Yun Wang, Qian Di, John Balmes, and David C. Christiani (2019). "Impact of Long-Term Exposures to Ambient $PM_{2.5}$ and Ozone on ARDS Risk for Older Adults in the United States." *Chest* 156(1): 71–79, https://doi.org/10.1016/j.chest.2019.03.017; Schwartz, Joel D., Yan Wang, Itai Kloog, Ma'ayan Yitshak-Sade, Francesca Dominici, and Antonella Zanobetti (2018). "Estimating the Effects of $PM_{2.5}$ on Life Expectancy Using Causal Modeling Methods." *Environmental Health Perspectives* 126(12): 127002, https://doi.org/10.1289/EHP3130; Ścibor, Monika, Andrzej Galbarczyk, and Grazyna Jasienska (2019). "Living Well with Pollution? The Impact of the Concentration of $PM_{2.5}$ on the Quality of Life of Patients with Asthma." *International Journal of Environmental Research and Public Health* 16(14): 2502, https://doi.org/10.3390/ijerph16142502; Thind, Maninder P. S., Christopher W. Tessum, Inês L. Azevedo, and Julian D. Marshall (2019). "Fine Particulate Air Pollution from Electricity Generation in the US: Health Impacts by Race, Income, and Geography." *Environmental Science & Technology* 53(23): 14010–19, https://doi.org/10.1021/acs.est.9b02527; Wei, Yaguang, Yan Wang, Qian Di, Christine Choirat, Yun Wang, Petros Koutrakis, Antonella Zanobetti, Francesca Dominici, and Joel D Schwartz (2019). "Short Term Exposure to Fine Particulate Matter and Hospital Admission Risks and Costs in the Medicare Population: Time Stratified, Case Crossover Study." *BMJ* 367(8224): l6258, https://doi.org/10.1136/bmj.l6258;

3. The Administrator's further insistence that evidence from studies examining the health effects of past reductions in $PM_{2.5}$ has to come from studies conducted in locations with air quality that would be allowed by the current NAAQS is both unlawful and at odds with the factual record

The Administrator errs by looking at accountability and other studies examining the health effects of reductions in $PM_{2.5}$ as necessary to confirm that the associations observed over and over in the epidemiologic studies are causal, and refuses to revise the standard unless these studies come from areas with air quality distributions allowed by the current primary NAAQS. This is a prime example of the Administrator's insistence on absolute proof and absence of uncertainty which is unlawful as explained above.

The Administrator also acts directly counter to the evidence of record. The ISA, PA, IPMRP all found, with detailed support, that this literature both supports that the associations in the epidemiologic literature are causal, and supports the need to revise the primary standard (or at least the annual standard). The additional studies discussed in these comments, and in the comments of Dr. Schwartz, provide considerable further support for both conclusions. All that the Administrator can cite in support are the two secondary references referred by certain CASAC members, which secondary sources turned out to be misread upon examination.[280]

As noted in some detail in our comments above, the Administrator statements regarding the lack of studies that show benefits of reductions of $PM_{2.5}$ in general is also factually inaccurate, whether based on the studies reviewed in the ISA and PA, or adding a number of powerful new accountability and causal inference studies summarized above.. Even under the Administrator's mistaken insistence on reductions in effects in areas with air quality distributions allowed by the primary NAAQS, the record shows that the long-term benefits of $PM_{2.5}$ reductions or causal comparisons of exposures (*e.g.*, Corrigan et al., 2018; Bennet et al., 2019, and Wu et al. 2019) appear to persist to levels well below the current annual standard.

Nor can the Administrator hide behind the advice of certain CASAC members. Their assessment of these epidemiological studies was already hampered by the fact that none of the six members who contributed to the review of the PA and standards are epidemiologists, with no direct interactions with the far more capable PM panel that was eliminated. As detailed in our comments above, those CASAC members' advice with regard to the current literature on studies examining the benefits of $PM_{2.5}$ reduction has been fraught with errors. Even more arbitrary is the fact that CASAC disregarded public comments from authors of studies they misinterpreted and chose not recommend that EPA consider two obviously relevant accountability studies (Corrigan et al 2018; Zigler et al 2018) that were presented to them and to EPA in public

[280] See *Business Roundtable v. SEC*, 647 F. 3d 1144, 1150-51 (D.C. Cir. 2011) (reliance on a few unpersuasive studies is arbitrary when at odds with a large body of contrary evidence)

comments well before they completed their final letter to the Administrator. Instead they chose to recommend a secondary reference published in late 2018 that EPA found to be of little relevance.

In short, this aspect of the rationale for the proposed decision fails on all counts and cannot support a decision to retain the current primary standards.

VIII. EPA Failed to Conduct Required Analyses Including an Adequate Environmental Justice Assessment under Executive Order 12,898.

Compounding the error of disregarding the Act's requirements to provide requisite protection and adequate margin of safety to susceptible sub-populations, EPA's proposal also violates Executive Order 12,898. In the Proposed Rule, the Agency asserts: "The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 Fed. Reg. 7,629, Feb. 16, 1994) . . . the EPA expressly considered the available information regarding health effects among at-risk populations in reaching the proposed decision that the existing standard is requisite."

The disproportionate effect of $PM_{2.5}$ exposure on vulnerable and disadvantaged communities is well-documented, as already described above. Executive Order 12,898 requires federal agencies, including EPA, to make environmental justice part of its mission "to the greatest extent practicable." Specifically, the E.O. requires EPA to "identify[] and address[]" "disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States." EPA must assess whether its proposal to "retain, without revision" the outdated PM NAAQS harms human health or the environment, and whether those impacts will be disproportionately borne by minority populations and low-income populations. EPA's own record makes clear that the human health harms of maintaining the outdated standard are disproportionately distributed and, as already described, EPA is already flouting the Clean Air Act's separate statutory mandate under the NAAQS Program to consider effects on these same populations.

While nearly half of all Americans breathe unhealthy air on a daily basis, disadvantaged communities and communities of color suffer disproportionately. EPA's most recent literature review of the science related to the health and welfare effects of particle pollution concluded that nonwhites, particularly blacks, are at a greater risk for health impacts from fine particles, as are low socioeconomic populations.[281] African Americans and Hispanics tend to live in places where

[281] ISA at 12-31 to 12-38.

they are exposed to greater levels of air pollution.[282] And numerous studies have found that Hispanics, Asians and especially blacks have a higher risk of premature death from particle pollution than whites do.[283] The largest examination of particle pollution-related mortality nationwide found that low socioeconomic status consistently increased the risk of premature death from fine particulate pollution.[284] And the risk of dying and likelihood for asthma increase in populations with higher unemployment, higher use of public transportation and among people eligible for Medicaid.[285]

EPA also squarely acknowledges that the 2011 PM NAAQS review, which the agency now draws on heavily, made certain adjustments to the standard based on disproportionate effects on certain disadvantaged populations, including on the issue of spatial averaging. 85 Fed. Reg. at 24,104 ("An analysis of air quality and population demographic information indicated that the highest $PM_{2.5}$ concentrations in a given area tended to be measured at monitors in locations where the surrounding populations were more likely to live below the poverty line and to include larger percentages of racial and ethnic minorities (U.S. EPA, 2011, p. 2–60).") As the D.C. Circuit explained, in upholding the elimination of spatial averaging, " spatial averaging would enable some portions of a compliance area – particularly those areas where sensitive individuals are likely to live – to exceed the NAAQS for periods of time . . . EPA reasonably concluded that allowing those excess emissions under all the circumstances here was inconsistent with EPA's

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[282] Nardone A, Casey JA, Morello-Frosch R, Mujahid M, Balmes JR, Thakur N. "Associations between historical residential redlining and current age-adjusted rates of emergency department visits due to asthma across eight cities in California: an ecological study." Lancet Planet Health. 2020:4(1):e24-e31; Miranda ML, Edwards SE, Keating MH, Paul CJ. "Making the environmental justice grade: The relative burden of air pollution exposure in the United States." Int J Environ Res Public Health. 2011; 8: 1755-1771; Ihab Mikati, Adam F. Benson, Thomas J. Luben, Jason D. Sacks, Jennifer Richmond-Bryant, "Disparities in Distribution of Particulate Matter Emission Sources by Race and Poverty Status", American Journal of Public Health 108, no. 4 (April 1, 2018): pp. 480-485, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5844406/.

[283] Kioumourtzoglou MA, Schwartz J, James P, Dominici F, Zanobetti A. PM2.5 and mortality in 207 US cities: Modification by temperature and city characteristics. Epidemiology, 2016; 27: 221-227. Di Q, et al, Air Pollution and Mortality in the Medicare Population. N Engl J Med, 2017; 376:2513-2522.

[284] Zeger, Scott L., Francesca Dominici, Aidan McDermott, and Jonathan M. Samet. "Mortality in the Medicare population and chronic exposure to fine particulate air pollution in urban centers (2000–2005)." Environmental Health Perspectives 116, no. 12 (2008): 1614-1619. See above noting that Di et al. (2017a) showed chronic mortality risk three times higher for African Americans. The study, as noted above, involved air quality distributions allowed by the current NAAQS.

[285] Bell ML, Dominici F. Effect modification by community characteristics on the short-term effects of ozone exposure and mortality in 98 US communities. Am J Epidemiol. 2008; 167: 986-997. Wang Y, Kloog I, Coul BA, Kosheleva A, Zanobetti A, Schwartz JD. Estimating causal effects of long-term PM2.5 exposure on mortality in New Jersey. Environ Health Perspect. 2016; 124: 1182-1188. O'Lenick, CR et al. Assessment of neighbourhood-level socioeconomic status as a modifier of air pollution-asthma associations among children in Atlanta. J Epi Comm Health. 2017:71(2):129-136; Strickland MJ, et al. Modification of the effect of ambient air pollution on pediatric asthma emergency visits: susceptible subpopulations, Epidemiology. 2014; 25: 843-850

goal of ensuring that the NAAQS provides requisite protection for all individuals."[286] But the Agency has undertaken no similar effort during the 2020 review to update aspects of the standard based on similar continuing dipartites.

Similarly, EPA required that near-roadway monitors be installed for purposes of ascertaining attainment with the PM NAAQS, and again was upheld by the D.C. Circuit especially due to the need to protect susceptible minority populations: "[EPA] stated, 'Ignoring monitoring results from [near-road] areas (or not monitoring at all) would abdicate this responsibility. Put another way, monitoring in such areas does not make the standard more stringent, but rather affords requisite protection to the populations, among them at-risk populations, exposed to fine particulate in these areas.'"[287]

Notwithstanding the Agency's attempt to characterize its proposal as merely maintaining the status quo, the studies contained in EPA's own record are sufficient to trigger EPA's responsibility under E.O. 12,898 to assess whether health harms from maintaining the current PM standard are disproportionately borne by vulnerable communities and, if so, how EPA should address this disparity. As clearly prescribed by the Clean Air Act: the standards must be revised to provide requisite protection to this susceptible subpopulation. EPA's failure to do so is a violation of its legal requirement under E.O. 12,898 review.

Contrary to EPA's assertion, sections II through IV of its April 30, 2020 Federal Register notice do not document that this proposed action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, or indigenous peoples, as specified in the Executive Order. *See* 85 Fed. Reg. at 24,140. Aside from the discussion mentioned above on spatial averaging, the only mention of such effects is a reference to an ISA finding that PM2.5 *does* disproportionately impact black and Hispanic populations:

> The ISA additionally notes that stratified analyses (i.e., analyses that directly compare PM-related health effects across groups) provide support for racial and ethnic differences in PM2.5 exposures and in PM2.5-related health risk (U.S. EPA, 2019, section 12.5.4). Drawing from such studies, the ISA concludes that ''[t]here is strong evidence demonstrating that black and Hispanic populations, in particular, have higher PM2.5 exposures than non-Hispanic white populations'' and that ''there is consistent evidence across multiple studies demonstrating an increase in risk for nonwhite populations'' (U.S. EPA, 2019, p. 12–38).

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[286] Nat'l Ass'n of Mfrs.v. EPA, 750 F. 3d 921, 925 (D.C. Cir. 2014) (Kavanaugh, J.).
[287] *Id.* at 926.

Id. at 24,114. Despite this finding, EPA arbitrarily fails to propose any action to address the disparate impact on the above-identified populations from retaining the current standards.

IX. EPA's Proposal Process Further Demonstrates that It's Proposed Decision to Leave the $PM_{2.5}$ Standard Unchanged is Unsupported and Unlawful.

A. EPA's current PM NAAQS review process has been flawed, riddled with arbitrary and capricious decisions, and is unlawful.

EPA's proposal to retain the current PM NAAQS should not be finalized because it is arbitrary and capricious and fails to satisfy the requirements of the Clean Air Act. EPA should reopen the review process to ensure that the Agency satisfies its statutory obligations, as the current NAAQS review process has been marred by critical process flaws that have rendered it unlawful, and because the proposal is not based on the latest scientific knowledge, as the Act requires. EPA implemented significant changes that truncated the review process and deviated from past practice and the CASAC-approved IRP in ways that impaired the CASAC's ability to conduct its statutorily required external review. 42 U.S.C. § 7409(d). These changes included having CASAC review the draft PM PA before the PM ISA had been finalized, a procedure the full CASAC referred to as "unusual."[288] In addition to being unusual, this change subverted the logically sequential process intended to separate the science and policy considerations. EPA also refused to provide revised drafts of these documents for review, as contemplated by the IRP, despite prior experience showing that these documents often require substantial revisions. EPA's deviation from the IRP without a reasoned explanation was arbitrary and capricious, as was the Agency's implementation of a new schedule and process that failed to provide the CASAC an opportunity for meaningful scientific review.

Furthermore, even if EPA had provided CASAC an adequate review opportunity, the committee was unlawfully selected and lacked the necessary expertise to conduct a meaningful scientific review. EPA unlawfully and arbitrarily excluded recipients of EPA grants from consideration for CASAC membership and disbanded the PM Panel previously assembled to assist CASAC in its review by providing additional expertise. Despite a request from CASAC, EPA declined to reinstate the expert PM Panel, and instead created a smaller panel of consultants who were incapable of providing the necessary assistance to CASAC. The unbalanced composition of CASAC, which for this review included only one academic research scientist, and the lack of NAAQS review experience among most of the members, further contributed to CASAC's

[288] Clean Air Sci. Advisory Comm. EPA-CASAC-20-001, 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), (Dec. 16, 2019), https://yosemite.epa.gov/sab/sabproduct.nsf/E2F6C71737201612852584D20069DFB1/$File/EPA-CASAC-20-001.pdf.

inability to conduct a meaningful external review of the NAAQS documents. For these reasons, the Administrator's reliance on some CASAC members' recommendations in the Proposal is unlawful, arbitrary and capricious, and an abuse of discretion.

EPA's truncated review process also resulted in a failure to reflect the latest scientific knowledge, as the Agency failed to adequately consider the science available for the review. The Agency, without explanation, failed to assess key studies published after the PM ISA cutoff date. As a result, the Agency has not ensured that its air quality criteria actually reflect the latest scientific knowledge as required by the CAA.

For all of these reasons, the current PM NAAQS review process has been flawed, riddled with arbitrary and capricious decisions, and is unlawful. The Administrator's reliance on the recommendations of some members of the CASAC is also unlawful, arbitrary and capricious, and an abuse of discretion.

This proposal is further unlawful because it would retain a standard that fails to protect public health with an adequate margin of safety as required by the Clean Air Act. If EPA refuses to reopen the NAAQS review process, the Agency must at least propose a revised standard.

B. The Scientific Evidence Demands that EPA Must Promulgate a More Protective Standard.

NGO commenters agree with the conclusions of the EPA Policy Assessment and of the IPMRP that the latest science indicates the current $PM_{2.5}$ standards do not protect public health — including the health of sensitive populations — with an adequate margin of safety. The coherent and robust body of evidence includes a number of important epidemiologic studies with unprecedentedly large numbers of subjects and correspondingly increased power that show positive statistically significant associations with exposure to $PM_{2.5}$ at levels allowed by the current NAAQS. In some cases these effects persist even in truncated analyses that, in cohort studies, exclude concentrations exceeding the current annual standard and in short-term studies, exclude concentrations exceeding the 24-hour standards. The strongest associations are with the most serious adverse effects: total mortality, cardiovascular mortality, and cardiovascular and respiratory morbidity, all of which the ISA determined to be causal or likely causal. Both EPA's expert staff and the IPMRP found that this body of evidence strengthens the conclusions and reduces uncertainties as compared to the evidence from the previous review. IPMRP Advice at B-21; Policy Assessment at 3-43.

This evidence is strongly supported by the controlled human exposure and animal toxicity studies, which support the biological plausibility of the observed associations, strengthening the overall weight of evidence in reaching conclusions on causality. Further evidence of record supporting both causality and the concomitant need to revise the standards is provided by the emerging studies examining health benefits of reduced $PM_{2.5}$ concentrations, including accountability and intervention studies as well as other studies using quasi-experimental and modern causal inference methods.

The weight of evidence and the risk assessment, as well as the Act's command to provide requisite protection with an adequate margin of safety—which includes the obligation to act without waiting for resolution of every imaginable uncertainty—mandate a decision to revise. The risks are disproportionately greater for vulnerable populations for whom the Act mandates protection, and EPA has failed to consider or explain how retaining the current standards will provide requisite protection and an adequate margin of safety to sensitive populations.

In considering the level of a potential revised annual primary standard, NGO Commenters are informed by the analysis and conclusions of EPA's expert staff in the policy assessment, and guided by the advice from the IPMRP, EPA must also consider the results of a number of powerful new accountability studies and other causal inference studies published after the cutoff date for the ISA. These studies strongly suggest that reductions of $PM_{2.5}$ that start at levels near to or below the level of the current standards down to 10 ug/m^3 and below are causally associated with significant public health benefits, and that a standard of 10 ug/m^3 would not protect public health with an adequate margin of safety. Given the evidence, we believe the science indicates an annual standard level of 8 ug/m^3 is requisite to protect public health, with an adequate margin of safety.

This level is supported considering only the evidence EPA has considered. Several US and Canadian studies reported significant associations between PM2.5 and health effects at mean levels at or below 9.6 ug/m3 (PA Figures 3-7, 3-8) including two U.S. studies that that found associations with when all data greater than the current standards (Di et al. 2017) or greater than 10 ug/m3 (Shi et al.,2016) were removed (PA at 105). Our recommended level of 8 ug/m3 is below the long-term mean in Di et al 2016 and just below the mean of the long-term air quality distribution in the Shi et al. (2016), See Policy Assessment at 3-105. This analysis that excluded levels above 10 ug/m3 indicates that the bulk of adverse effects are not disproportionately associated with the higher end of the air quality distributions, and therefore offers support to using a level below the mean of the long-term data as the basis for establishing the level of the annual standard. See Policy Assessment at 3-55, 3-77 and 3-105. Both the EPA expert staff and the IPMRP agree that the evidence of record supports an annual level of 8 ug/m3. Policy Assessment at 3-113; IPMRP Advice at B-14; see also IPMRP Advice at B-28 ("the Panel unanimously finds a scientific basis for 8 ug/m3 as being the lower bound of annual ranges for which there is strong weight of scientific evidence of adverse effects").

NGO Commenters further recommend strengthening the protection afforded by the 24-hour standard. As the IPMRP Panel noted, "there are numerous studies that find adverse effects at levels well below the current standard, within a range of 30 ug/m^3 to 25 ug/m^3." IPMRP Advice at B-31 (referring to the Canadian studies Weichenthal et al. 2016 a and b, and to the Medicare cohort studies Di et al., 2017b and Shi et al. 2016). The Panel further found that "[e]ven with an annual level in the range of 10 ug/m^3 to 8 ug/m^3, a 24-hour standard at 30 ug/m^3 may not be protective of acute health effects that could occur with sub-daily exposures", particularly in areas that meet the annual standard and are subject to seasonally high peak levels, for example in areas with widespread use of wood for heating. Both Di et al. and Shi et al. also show statistically significant effects when the distributions are truncated to remove all days with concentrations of 30 ug /m^3 and higher (30 ug/m^3 for Shi et al.; 25 ug/m^3 for Di et al.). Policy Assessment at 3-70. These studies indicate the need for revision of the standard, as the IPMRP found.

Finally, NGO Commenters agree that "[t]he level of the coarse PM standard should be revised downward," as the IPMRP recommended, "consistent with the recommended downward revision of the 24-hour primary $PM_{2.5}$ standard, to at least maintain, if not increase, the current level of public health protection to coarse particles." IPMRP Advice at 2.

In any case, the agency cannot validly finalize this proposal. To do so would be not only unlawful, but an abdication of the agency's obligation to follow the law and provide all Americans the requisite protection with an adequate margin of safety from harmful fine particle pollution.

X. EPA's Secondary PM Standards Proposal Is Entirely Unsupported by Science or Policy Rationales and Fails to Protect Public Welfare

A. EPA's Legal Obligations in Setting and Reviewing the Secondary Standard

The CAA requires EPA to set and periodically revise secondary ambient air quality standards that protect public welfare, 42 U.S.C. §§ 7408(a), 7409(a)-(b), and

> [S]pecify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.

42 U.S.C. § 7409(b)(2).

Pursuant to section 109(d) of the Clean Air Act, "[t]o ensure that the NAAQS take account of the current science"[289] EPA must complete a thorough review of the standards "at least once"[290] every five years. *Id.* § 7409(d)(1). During this review, EPA must revise the criteria and standards or promulgate new standards as appropriate. *Id.* The secondary ("welfare") standards "shall specify a level of air quality the attainment and maintenance of which . . . is requisite to protect the public welfare from any known or anticipated adverse effects."[291] Effects on welfare include impacts 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 well-being, whether caused by transformation, conversion, or combination with other air pollutants."[292] Senator Muskie, one of the prime architects of the Act, in speaking about the amendments for public welfare during the Senate debates, noted that the protections for public welfare "are especially important because some pollutants may have serious effects on the environment at levels below those where health effects may occur" and will be set to be "protective against any know or adverse environmental effects." Legislative History of Clean Air Act Amendments of 1970 at 227 (Senate Debate on S. 4358, Sept. 21, 1970). The congressionally mandated "ongoing, periodic review and revision process set up by Congress . . . ensure[s] that regulatory guidelines and standards which protect human safety and welfare are kept abreast of rapid scientific and technological developments"[293] and that "as the contours and texture of scientific knowledge change . . . EPA's NAAQS review necessarily changes as well."[294] The CASAC is chartered to offer recommendations on the secondary as well as the primary NAAQS.

B. Particulate Matter Welfare Effects

"The term 'particulate matter' is a shorthand for a variety of substances that form particles in the ambient air. So-called 'fine particles'—the kind of particulate pollution at issue in this case—are produced mainly by automobiles and power plants."[295] Visibility in many areas throughout the country is deteriorated by $PM_{2.5}$ and is unquestionably unacceptable to the general public. Fine particulate matter is a primary driver of haze and visibility impairment and negatively affects many ecosystem functions. Regional haze obscures the stunning views in many of our prized

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289 *Nat'l Ass'n of Manfr.'s v. EPA*, 750 F.3d 921, 923 (D.C. Cir. 2014) ("To ensure that the NAAQS take account of current science, the Clean Air Act directs EPA to review the standards at least once every five years.") (citation omitted).
290 *Id.*
291 42 U.S.C. § 7409(b)(2); *Am. Farm Bureau Fed'n v. EPA,* 559 F.3d 512, 530 (D.C. Cir. 2009).
292 42 U.S.C. § 7602(h).
293 *Am. Lung Ass'n v. Browner*, 884 F. Supp. 345, 347 (D. Ariz. 1994)
294 *Mississippi v. EPA*, 723 F.3d 246, 255–56 (D.C. Cir.), *amended and superseded on reh'g,* 744 F.3d 1334 (D.C. Cir. 2013); *see also* discussion and caselaw cited above.
295 *Nat'l Ass'n of Manfr.'s,* 750 F.3d at 923 (referencing *Am. Farm Bureau Fed'n*, 559 F.3d at 515).

national parks and wilderness areas.[296] Despite progress in reducing haze causing pollution, not a single one of the 156 designated "Class I" areas have achieved the statutory goal of natural visibility conditions. Visibility impairing pollution travels far and wide, for example in the Grand Canyon, 33% of the haze pollution found there originated from particle pollution generated in California. Beyond the confines of our "protected" Parks and Wilderness Areas, impaired visibility adversely affects the enjoyment, wellbeing, and welfare of people everywhere, as the familiar remote, rural, and urban scenes they're familiar with begin to fade from view.

The current secondary PM standards are based on consideration of the protection provided by the standards for visibility. While the Act's regional haze requirements apply to the Class I areas and focus on visibility, those requirements apply only in Class I areas, as compared to the secondary particulate matter NAAQS requirements, which apply to ambient air throughout the country.

Fine particle pollution is made of many different compounds, which are all independently harmful to ecosystems. $PM_{2.5}$ can be directly deposited on land and in the water, causing damage from acidification, eutrophication, deposition of toxic metals and organic compounds, and changes in soil and water chemistry. When deposited on plants, it can affect their ability to metabolize and photosynthesize correctly.

Fine particles entering aquatic ecosystems can affect all organisms both directly and through bioaccumulation. Similar to mercury, fish, frogs, snails, and other aquatic life can absorb PM, and as these animals are consumed the particulate matter travels up the food chain.[297] With each step up, the PM concentration increases, ultimately to fish-eating predators including eagles, osprey, otters, pelicans, and grizzly bears. Those concentrations of PM have harmful health effects on our wildlife.

Fine PM is also a significant component of acid rain. When nitrogen and sulfur secondary particles dissolve in rain and cloud water they contribute to the devastating effects of acid rain on our ecosystems, particularly in the eastern U.S. and in the Rocky Mountains at high elevations where ecosystems are more fragile and acidic cloud water can be more prevalent. There are numerous negative ecosystem effects of acid deposition like depletion of soil nutrients, aluminum mobilization, and acidification in waters that lead to accelerated plant die-off and

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[296] Congress has also taken actions to establish public lands that are set aside for specific uses intended to provide benefits to the public welfare including lands that are to be protected so as to conserve not only the scenic value, but also the natural vegetation and wildlife within such areas for the enjoyment of future generations, (*i.e.*, in additional to national parks and wilderness areas, forests and wildlife refuges).
[297] Danny Hartono et al. (2017). "Impacts of Particulate Matter ($PM_{2.5}$) on the Behavior of Freshwater Snail *Parafossarulus Striatulus*," *Scientific Reports* 7 (644), https://doi.org/10.1038/s41598-017-00449-5 (suggesting that high $PM_{2.5}$ deposition in water bodies, associated with acidification and some metals, can have an adverse effect on aquatic organisms).

depletion of oxygen, slower plant growth and damage to leaves and overall decreases in species diversity.

Additionally, $PM_{2.5}$ plays an important role in longer-distance pollution transport. The formation of secondary $PM_{2.5}$ from gaseous precursors like sulfur dioxide, nitric acid and ammonia helps transport these S and N pollutants and deposit them far from their sources. If emissions of any of these reactive gaseous precursors were decreased, local concentrations of $PM_{2.5}$ would decrease and downwind deposition of S and N would also decrease.

The collective effects of fine particulate matter on our ecosystems and on the experience of visitors to natural areas are extensive and deeply problematic for the health and public enjoyment of our national parks–places that bring in enormous economic benefits to surrounding communities and behold values of our democracy in safeguarding our natural, cultural, and historic heritage.[298]

C. The Administrator's Attempt to Rely on Advice from the CASAC is Arbitrary

As discussed above, CASAC formally requested of the Administrator the provision of expert advice, to enable it to properly conduct its review of the secondary standards and the effects of PM on visibility impairment, climate, and materials. The Administrator failed to provide those experts to advise CASAC. And CASAC also therefore admitted that the "breadth and diversity of evidence to be considered" for the PM NAAQS review "exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals." Thus, the CASAC lacked the expertise to assess the adequacy and basis of existing, new, or revised national ambient air quality standards, and communicated that lack of expertise to the Administrator, who nevertheless relied on CASAC's recommendations regarding the secondary standard. The Administrator's knowing failure to consider CASAC's unsuitability to render such advice, and instead blindly rely on the CASAC's statements, is arbitrary and capricious.

First, in taking into account the PA's evaluation of the policy-relevant information in the ISA and quantitative analyses of air quality related to visibility impairment, the Administrator also relies on "*the CASAC's advice and recommendations*, as reflected in discussions of the drafts of the ISA and PA at public meetings and in the *CASAC's letters to the Administrator*." Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094, 24,127 (proposed Apr. 30, 2020) (emphasis added). Second, "in reaching proposed conclusions on the current secondary PM standards, the Administrator takes into account policy relevant evidence-

[298] *See also*, Bay Area Air Quality Management District, Understanding Particulate Matter: Protecting Public Health in the San Francisco Bay Area, (Nov. 2012), *available at* https://www.baaqmd.gov/~/media/Files/Planning%20and%20Research/Plans/PM%20Planning/ParticulatesMatter_Nov%207.ashx.

based and quantitative information-based considerations, *as well as advice from the CASAC*." *Id.* 24,135 (emphasis added). Third, Section IV.D.2 describes advice received from the CASAC on the secondary standards, with no caveats regarding the members' expertise. Fourth, the proposal explains that "[a]s part of its review of the draft PA, *the CASAC has provided advice* on the adequacy of the current secondary PM standards. In its comments on the draft PA, the CASAC concurs with staff's overall preliminary conclusions that it is appropriate to consider retaining the current secondary PM standards without revision (Cox, 2019a)." *Id.* 24,137 (emphasis added). Fifth, even though the CASAC indicated it needed assistance in evaluating the visibility and materials effects, it nevertheless offered that it ''finds much of the information . . . on visibility and materials effects of $PM_{2.5}$ to be useful, while recognizing that uncertainties and controversies remain about the best ways to evaluate these effects'' (Cox, 2019a, p. 13 of consensus responses)." *Id.* 24,137 (alteration in original). Sixth, in opining on evidence and whether the standards should be changed EPA's proposal indicates they offered "[w]hen considering the overall body of scientific information for PM-related effects on visibility, materials, and climate, *the CASAC agrees* that 'the available evidence does not call into question the protection afforded by the current secondary PM standards and concurs that they should be retained' (Cox, 2019a, p. 3 of letter)." *Id.* 24,137.

The Administrator's ultimate proposal fails to acknowledge in any way the CASAC's unfitness, as he explains merely that "[h]is conclusions on the secondary standards are consistent *with advice from the CASAC*, which agrees 'that the available evidence does not call into question the protection afforded by the current secondary PM standards' and recommends that the secondary standards 'should be retained' (Cox, 2019a, p. 3 of letter)." *Id.* 24,139 (emphasis added).[299]Moreover, the terse and high-level nature of CASAC's comments on the secondary standards is further evidence of their unfitness. Additionally, the ISA, PA, and proposal omit significant recent scientific studies, which are discussed below. These recent scientific studies are not mentioned by the CASAC, which is yet another reason for the Administrator to discount their advice. Finally, as discussed elsewhere in our comments, when one compares the detailed advice provided by the IPMRP, the CASAC's lack of fitness to provide meaningful advice is further evident.

D. The Administrator failed to provide a reasoned explanation regarding uncertainties, thus the proposal is arbitrary and capricious

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[299] The Administrator reiterates this same point in specifying the standards he proposes retaining. Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094, 24,139 (proposed Apr. 30, 2020) ("Thus, based on his consideration of the evidence and analyses for PM-related welfare effects, as described above, and *his consideration of CASAC advice on the secondary standards*, the Administrator proposes to retain those standards (*i.e.,* the current 24-hour and annual $PM_{2.5}$ standards, 24-hour PM10 standard), without revision." (emphasis added)).

EPA merely mentions uncertainty in a handful of places, and does so without providing reasoned analysis. EPA's proposal lacks "clear and cogent reasons"[300] to support the Administrator's assertion that there are "attendant uncertainties and limitations"[301] regarding the scientific and technical information, which supports a determination that the current standards "protect against known and anticipated adverse effects on public welfare."[302] EPA cannot rely on general claims of scientific uncertainty to justify its inaction and merely mention uncertainties to avoid its statutory obligations.[303]

First, although EPA acknowledges "the $PM_{2.5}$ monitoring network has an increasing number of continuous FEM monitors reporting hourly $PM_{2.5}$ mass concentrations," which could be used for tracking visibility, EPA fails to consider using the network. EPA suggests unspecified "uncertainties"[304] are why the monitoring network is not considered. Contrary to the Administrator's statement that he will base his decision on a consideration of the "range and magnitude of uncertainties inherent,"[305] he provides no reasoned explanation for his refusal to consider using the monitoring network.[306] Because the proposal lacks any explanation of what the uncertainties are regarding the monitoring network, the public is unable to review and comment on this issue.

Second, the proposal merely restates uncertainties from the last review regarding public preference studies, with the Administrator rubber-stamping the prior work and concluding that the prior uncertainties support retaining the 24-hour standard.[307] For example, EPA provides no explanation for why studies conducted in the past represent today's preferences.[308] Furthermore, without explaining what different methods were used and why the methods "potentially" influenced responses, EPA asserts the methods used in the studies create uncertainty.[309] Additionally, EPA fails to provide an analysis of the range of U.S. population represented by the studies and the range and magnitude of the uncertainty.[310] Furthermore, EPA offers no

300 *Nat. Res. Def. Council, Inc. v. Adm'r, U.S. E.P.A.,* 902 F.2d 962, 987–88 (D.C. Cir. 1990).
301 Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094, 24,139 (proposed Apr. 30, 2020).
302 *Id.*
303 *Nat. Res. Def. Council, Inc. v. Adm'r, U.S. E.P.A.,* 902 F.2d 962, 987–88 (D.C. Cir. 1990); *see also* discussion and caselaw cited above.
304 Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094, 24,135-36 n.64 (proposed Apr. 30, 2020).
305 *Id.* at 24,137.
306 *Murray Energy Corp. v. EPA*, 936 F.3d 597, 619 (D.C. Cir. 2019)
307 Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094, 24,138 (proposed Apr. 30, 2020).
308 *Id.*
309 Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094, 24,138 (proposed Apr. 30, 2020).
310 *Id.*

explanation as to why the population surveyed is not representative. EPA also claims the "types of scenes being viewed"[311] in the studies may also "not capture the full range of visibility preferences"—and once again, EPA fails to provide an analysis of the range and magnitude of uncertainty this presents. Finally, EPA asserts that there are factors that were not considered in the preference study methods that would impact judgments in the studies.[312] Again, EPA fails to discuss a level of uncertainty associated with this alleged concern regarding the factors. EPA treats uncertainties as an on/off switch. EPA lists a bunch of uncertainties and based on the list proposes to do nothing to revise standards.

Given the correlation between the preference studies—as seen in recent important scientific studies ignored by EPA—EPA's allegations that the prior studies are impacted by uncertainties fail. As discussed below, the recent scientific work successfully assimilates the prior studies and identifies the failure of the current secondary standards to protect public welfare.

Without agreeing to what EPA appears to suggest are insurmountable uncertainties that prohibit it from revising the standard, we agree with recommendations from the IPMRP and the agency should "inquire if further protection is warranted until the uncertainties are resolved."[313] "The 'what if nothing is done' question is never explored to explore how large or small the consequences might be from retaining the current standard[s]." The Clean Air Act requires EPA to follow a precautionary principle in setting secondary standards. Such standards must protect against "any" adverse effects to welfare, both "known" and "anticipated."[314] "A safe minimum standard would call greater emphasis on protection of the environment, visibility here . . . ."[315] Contrary to the Administrator's proposal, uncertainty does not provide an offramp to do nothing, "the Clean Air Act "demand[s] regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable" because "[a]waiting certainty will often allow for only reactive, and not preventive, regulation."[316]

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[311] *Id.*
[312] *Id.* ("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.")
[313] Independent Particulate Matter Review Panel, Comment Letter on EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter at C-20 (Oct. 22, 2019).
[314] *Id.* (citing Kriebel, David et al. (2001). "The Precautionary Principle in Environmental Science." *Environmental Health Perspectives*, 109(9): 871-76, https://ehp.niehs.nih.gov/doi/abs/10.1289/ehp.01109871).
[315] IPMRP Comments at C-20 (citing Bishop, R.C. (1978). "Endangered Species and Uncertainty: The Economics of a Safe Minimum Standard. *American Journal of Agricultural Economics* 60(1): 10-18, https://doi.org/10.2307/1240156).
[316] *Ctr. for Biological Diversity v. EPA*, 749 F.3d 1079, 1090 (D.C. Cir. 2014) (citing *Ethyl Corp. v. EPA*, 541 F.2d 1, 25 (D.C. Cir. 1976)) (alterations in original); *see also Coal. for Responsible Regulation, Inc. v. EPA,* 684 F.3d 102, 122 (D.C. Cir. 2012); *Lead Indus. Ass'n v. EPA,* 647 F.2d 1130, 1155 (D.C. Cir. 1980).

E. EPA's failure to consider best practices in preference studies constitutes a failure to consider an important part of the problem in making its proposal

EPA fails to consider the "latest scientific information" on best practices in preference studies and to apply those concepts in further study.[317] For example, Johnston and others discuss best practices in the conduct of an economic preference study to evaluate public welfare gains and losses and the use of focus groups in the design of such studies.[318] Additionally, the American Association for Public Opinion Research issued its "Best Practices for Survey Research," which includes the recommendation that:

> All questions should be pretested to ensure that questions are understood by respondents, can be properly administered by interviewers or rendered by web survey software and do not adversely affect survey cooperation.[319]

In sum, EPA's proposal fails to consider the best practices research in this review. Rather, EPA merely reviews what has been done, and rather than applying criteria developed by the experts in the field of preference studies, applies a hodge-podge of its own criteria. Moreover, as discussed elsewhere, despite having the tools to conduct new studies (or retain contractors to do so), failed to conduct studies to supplement the earlier efforts using best practices. Finally, EPA fails to identify and plan for future work implementing best practices.

F. EPA's analysis of visibility effects is based on outdated data

As required by the Act, EPA's evaluation should "most represent state-of-the-art measurement techniques,"[320] and as presented by the IPMRP in our detailed comments, it does not. As noted by the IPMRP:

> The analysis of visibility effects is mainly based on outdated (2005-2008 vs. 2011-2014) data and doesn't provide new information that might influence evaluation of light extinction and visibility. To

[317] As discussed extensively above, EPA did not comply with Section 108's requirement that the scientific criteria include the "latest scientific information" relevant.

[318] Johnston, Robert J. *et al.* (2017). "Contemporary Guidance for Stated Preference Studies." *Journal of the Association of Environmental and Resource Economists* 4(2): 319-405, https://www.journals.uchicago.edu/doi/pdfplus/10.1086/691697.

[319] Am. Ass'n for Pub. Opinion Research, *Best Practices for Survey Research*, https://www.aapor.org/Standards-Ethics/Best-Practices.aspx#best6.

[320] Letter from IPMRP to Administrator Wheeler, at C-30 (Oct. 22, 2019), *available at* https://ucs-documents.s3.amazonaws.com/science-and-democracy/IPMRP-FINAL-LETTER-ON-DRAFT-PA-191022.pdf.

> achieve consistent and objective quantification of regional haze, the Regional Haze Rule (Section 308 of Protection of Visibility, 40 CFR Part 51, Subpart P, Sections 51.300-51.309) uses $PM_{2.5}$ chemical components to estimate particle light extinction (Watson 2002).[321] Information on spatial interpolation of average light extinction by major chemical component for the most recent period (e.g., 2015-2017) should be compared with that from the last review to provide some perspective on overall changes.[322]

EPA fails to address the effects of visibility from changes in $PM_{2.5}$ composition over the past decade, as "the organic mass (OM) to OC ratio increased across the network after 2011, highest in the east during summer, unrelated to the influence of particle bound water."[323] As recommended by the IPMRP, it is unclear if EPA reanalyzed the "three versions of IMPROVE light extinction algorithms (Malm et al., 1994;[324] Pitchford et al., 2007;[325] Lowenthal and Kumar, 2016)[326] [that] should provide IMPROVE 2015-2017 reconstructed light extinction coefficients (b_{ext}, Mm^{-1}) by chemical components with monthly average $PM_{2.5}$ concentrations, [and whether EPA] . . . compare[d] with those of 2005-2008 period."[327] Furthermore, it appears EPA failed to consider recent work that involved modifications and improvements to the U.S. IMPROVE carbon analysis protocol and hardware.[328]

> The revised IMPROVE algorithm (Pitchford et al, 2007) uses different scattering coefficients for the large and small sulfate,

321 John G. Watson, Critical review: Visibility: Science and regulation. Journal of the Air & Waste Management Association, 52, 628-713 (2002), *available at* http://www.tandfonline.com/doi/pdf/10.1080/10473289.2002.10470813.
322 IPMRP at C-29 (internal footnote supplied).
323 *Id.* at C-29, citing J. L. Hand et al., Trends in remote $PM_{2.5}$ residual mass across the United States: Implications for aerosol mass reconstruction in the IMPROVE network. Atmospheric Environment, 203, 141-152 (2019), *available at* https://doi.org/10.1016/j.atmosenv.2019.01.049.
324 William. C. Malm et al., Spatial and seasonal trends in particle concentration and optical extinction in the United States. Journal of Geophysical Research, 99, 1347-1370 (1994), *available at* https://doi.org/10.1029/93JD02916.

325 Marc Pitchford et al., Revised algorithm for estimating light extinction from IMPROVE particle speciation data. Journal of the Air & Waste Management Association, 57, 1326-1336 (2007), *available at* https://doi.org/10.3155/1047-3289.57.11.1326.
326 Douglas H. Lowenthal & Naresh Kumar, Evaluation of the IMPROVE Equation for estimating aerosol light extinction. Journal of the Air & Waste Management Association, 66, 726-737 (2016), *available at* https://doi.org/10.1080/10962247.2016.1178187.
327 IPMRP at C-29 (internal footnotes supplied).
328 Judith C. Chow et al., Optical Calibration and Equivalence of a Multiwavelength Thermal/Optical Carbon Analyzer, Aerosol and Air Quality Research, 15: 1145–1159 (2015), *available at* https://doi.org/10.4209/aaqr.2015.02.0106.

> nitrate, and OM concentrations. The 20 μg/m^3 cut-off was selected to separate the large vs. small components. Owing to the nationwide reduction in $PM_{2.5}$ mass and sulfate concentrations, the '20 μg/m^3' cut-off in the revised IMPROVE algorithms (Pitchford et al., 2007; Lowenthal and Kumar, 2016) may no longer be applicable. A reexamination with concentration levels more relevant to current air quality should be used to develop a more representative IMPROVE light extinction algorithm.[329]

Additionally, there are several scientific studies with data that can be used to assess PM impacts and trends, which EPA should take into consideration during this review.

> Starting with $PM_{2.5}$ filter samples from January 2016, the IMPROVE network reports seven wavelength (i.e., 405-980 nm) optical measurements along with the OC and EC analysis (e.g., Chen et al, 2015;[330] Chow et al, 2015; 2018; 2019[331]) that demonstrate the impact of BrC during [a] fire episode. These data should be used by EPA to address changes in OM/OC ratios; develop revised IMPROVE algorithm; improve emissions inventory estimates; and provide data for climate assessment.[332]

In evaluating visibility impairment EPA's PA focuses on "locations meeting the current 24-hour $PM_{2.5}$ and PM_{10} standards," 85 Fed. Reg. at 24,135, and concludes that since all the locations considered meet the current standards—'all is fine.' EPA arbitrarily skews its analysis to develop information that misses the boat. The Act requires that EPA evaluate the NAAQS to see whether the standard is requisite to protect public welfare from any known or anticipated adverse effects. Apparently, EPA concluded *at the start* of its analysis the current standards are not in need of revision, then ignored significant information available since the last review, and based on that flawed process the Administrator proposes no revisions to the standards. EPA treats its analysis as if it were developing a demonstration that a nonattainment area is meeting the NAAQS and

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329 IPMRP at C-29.
330 L.-W. A. Chen et al., Multi-wavelength optical measurement to enhance thermal/optical analysis for carbonaceous aerosol. Atmospheric Measurement Techniques, 8, 451-461 (2015), *available at* http://www.atmos-meas-tech.net/8/451/2015/amt-8-451-2015.html.
331 Judith C. Chow et al., Optical Calibration and Equivalence of a Multiwavelength Thermal/Optical Carbon Analyzer, Aerosol and Air Quality Research, 15: 1145–1159, 2015 (2015), *available at* https://doi.org/10.4209/aaqr.2015.02.0106. Judith C. Chow et al., Separation of brown carbon from black carbon for IMPROVE and CSN $PM_{2.5}$ samples. JOURNAL OF THE AIR & WASTE MANAGEMENT ASSOCIATION, 68, 494-510 (2018), *available at* https://doi.org/10.1080/10962247.2018.1426653. Judith C. Chow et al., Obtaining more information from existing filter samples in PM speciation networks. EM, 23, 15-19 (2019), *available at* https://www.researchgate.net/publication/332878240.
332 IPMRP at C-30 (internal footnotes supplied).

should be designated attainment; contrary to its approach here, EPA is supposed to follow an analysis of scientific rigor to inform the policy it sets. Our comments as well as other information presented to EPA from the IPMRP clearly shows that the public welfare is negatively impacted by particulate matter. The information does not show the proposed NAAQS are requisite to protect public welfare from any known or anticipated adverse effects. Thus, EPA must stop obfuscating its analysis and follow the Act's mandates.

G. EPA's Proposal is Unlawful Because the Scientific Evidence Shows the Current Standard is Not Requisite to Protect Public Welfare from any Known or Anticipated Adverse Effects

Currently available scientific evidence clearly shows the current annual and 24-hour secondary standards fail to protect public welfare adequately and appropriately from known or anticipated effects. As explained by the IPMRP, the current secondary annual and 24-hour PM NAAQS, which the Administrator proposes to leave unchanged, are substantially weaker standards than revisions to the standards evaluated by EPA staff and supported by CASAC in the last several PM NAAQS reviews.[333] Despite substantial and significant scientific evidence, which clearly demands revisions, for the sixth time EPA's proposal fails to follow the Act's mandate to protect the public welfare from any known or anticipated adverse effects associated with particulate matter in the ambient air. As discussed above, EPA must heed the advice of the IPMRP.

EPA's proposal "recognizes that visibility impairment can have implications for people's enjoyment of daily activities and for their overall sense of well-being. Therefore, as in previous reviews [the Administrator] considers the degree to which the current secondary standards protect against PM-related visibility impairment."[334] As detailed in our comments, the Administrator's proposal unlawfully and arbitrarily concludes that "the current level of

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[333] Comments of the IPMRP at C-94. The same IPMRP that recently published, "The Need for a Tighter Particulate-Matter Air-Quality Standard." *New England Journal of Medicine*, June, NEJMsb2011009. https://doi.org/10.1056/NEJMsb2011009, also found that the current secondary $PM_{2.5}$ standards were not adequate to protect against adverse effects on public welfare. For example, in the 1997 review, EPA staff considered a secondary PM2.5 annual mean of 15 and secondary 24-hr of 50, 98th percentile, which were more stringent than the primary and secondary NAAQS at that time, but not more stringent than the current primary and secondary NAAQS. In the 1987 review, EPA staff considered a 3-month seasonal mean PM2.5 2ndary in the range of 8 to 25 - which, at the low end, would have been more stringent than the current NAAQS. Letter from Morton Lippon, Chair, Clean Air Act Scientific Advisory Committee, to Administrator Lee Thomas, Review of the NAAQS for Particulate Matter: Assessment of Scientific and Technical Information (Dec. 16, 1986), *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/F03A1FC219CC87C9852573280066958D/$File/NAAQS+MATTER++++++++CASAC-87-010_87010_5-23-1995_302.pdf.

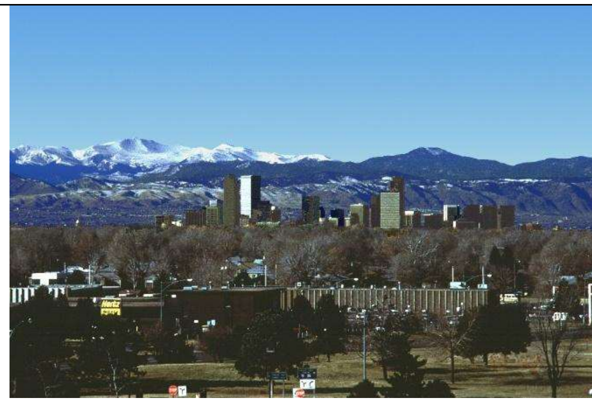
[334] Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094, 24,137 (proposed Apr. 30, 2020).

protection provided by the secondary PM standards as being requisite to protect against known and anticipated adverse effects on public welfare."[335]

To visually illustrate the inadequateness of the current standards, we provide the following images and photographs. The first set of images in Figure 1 are generated from the WinHaze model and compare the image of a clear day view to images of the same view modified to apply the current secondary NAAQS standards.[336] "The figure (worst visibility, 30.09 dv) models the visual air quality effects of 35 µg/m3 of $PM_{2.5}$ (composed of equal parts organic matter, ammonium sulfate and ammonium nitrate at 50% RH). This mix of pollutants at the level of the current daily $PM_{2.5}$ NAAQS results in light extinction of 202.71 Mm-1—or 30.09 dv—basically the upper end of the 20 to 30 dv range suggested in the final 2011 PM Policy Assessment Draft ("PAD") and rubber stamped in the current PAD. So clearly, PM light extinction at 30 dv (90th percentile) offers no protection beyond that provided by the current NAAQS. Looking at these photos, "does anyone really believe this is an adequate level of visibility protection?"[337] The modeled image (20.15 dv) shows a similar mix of PM2.5 species at 15 µg/m3. Coincidentally this results in visibility impairment of 20.15 dv—the low end of the range considered in the 2012 review.

[335] *Id.* at 24,319.
[336] Comments of the IPMRP at C-94 to 95 (images created from WinHaze, *available at* http://vista.cira.colostate.edu/Improve/winhaze/).
[337] *Id.* at C-95.

Figure 1. Winhaze Images Showing Visual Air Quality Effects of Current Welfare Standards.

Air	Photo
Clear Day View	
$PM_{2.5}$ **1 year** **15.0 µg/m^3** (annual mean, averaged over 3 years)	
$PM_{2.5}$ **24 hours** **35 µg/m^3** (98th percentile, averaged over 3 years)	

Our next set of images compare photographs from the Camnet Network (www.hazecam.net) paired with nearby IMPROVE VIEWS data for Boston (Figure 2) and Newark/New York (Figure 3). Attachment A to our comments contains images for all the locations listed in Table 1. IMPROVE data was accessed online using a VIEWS 2.0 data query, where total light extinction, and standard visual range (SVR) data were calculated using the new IMPROVE algorithm.[338] Photos are instantaneous examples of the visibility on a day and the IMPROVE data are 24-hour averages.

Table 1. Camnet and IMPROVE Monitoring Sites.

Camet			Viewpoint (km)		IMPROVE		
Location	Latitude	Longitude	Furthest	Target	Location	Latitude	Longitude
Baltimore	39.18	-76.46	17.70	17.70	Baltimore (BALT1)	39.2547	-76.7093
					Frostberg (FRRE1)		
Blue Hills	42.212	-71.112	43.45	14.48	Quabbin Summit (QURE1)	42.2985	-72.3346
Boston	42.47	-70.91	30.58	17.7	Quabbin Summit (QURE1)	42.2985	-72.3346
Brigantine	39.465	-74.4492	12.07	12.07	Brigantine (BRIG1)	39.465	-74.4492
Burlington	44.48	-73.20	57.94	6.84	Proctor Maple Research Forest (PMRF1)	44.5284	-72.8688
Hartford	41.8214	-73.2973	28.97	11.27	Mohawk Mtn (MOMO1)	41.8214	-73.2973
Mt. Washington	43.975	-71.135	40.72	35.41	Great Gulf Wild (GRGU1)	44.3052	-71.2177

338 Attachment A to Comments, Images from the Camnet Network Paired with Nearby IMPROVE VIEWS Data (June 27, 2020).

New York/ Newark	40.733	-74.157	12.87	12.87	New York City (NEYO1)	40.8161	-73.9019

Figure 2. Camnet photos under different air quality conditions in Boston.

Location	Photo	Photo and Air Quality Information
Boston		Image Date/Time: 8/9/2002 11 EST 24-hour Averages: *Quabbin IMPROVE* Aerosol extinction (dv): 6.4 Total light extinction (dv): 11.0 $PM_{2.5}$ Concentration ($\mu g/m^3$): 3.0 Standard Visual Range (km): 135
		Image Date/Time: 8/3/2002 12 EST 24-hour Averages: *Quabbin IMPROVE* Aerosol extinction (dv): 19.1 Total light extinction (dv): 20.6 $PM_{2.5}$ Concentration ($\mu g/m^3$): 9.4 Standard Visual Range (km): 50
		Image Date/Time: 7/22/2002 11 EST 24-hour Averages: *Quabbin IMPROVE* Aerosol extinction (dv): 25.1 Total light extinction (dv): 26.0 $PM_{2.5}$ Concentration ($\mu g/m^3$): 16.9 Standard Visual Range (km): 29
		Image Date/Time: 7/1/2002 12 EST 24-hour Averages: *Quabbin IMPROVE* Aerosol extinction (dv): 29.8 Total light extinction (dv): 30.3 $PM_{2.5}$ Concentration ($\mu g/m^3$): 24.0 Standard Visual Range (km): 19

Figure 3. Camnet photos under different air quality conditions in Newark/New York.

Location	Photo	Photo and Air Quality Information
Newark/ New York		Image Date/Time: 8/8/2009 11 EST 24-hour Averages: Aerosol extinction (dv): 9.8 Total light extinction (dv): 13.9 $PM_{2.5}$ Concentration ($\mu g/m^3$): 4.1 Standard Visual Range (km): 107
		Image Date/Time: 7/24/2009 12 EST Source: www.hazecam.net 24-hour Averages: Aerosol extinction (dv): 17.2 Total light extinction (dv): 19.1 $PM_{2.5}$ Concentration ($\mu g/m^3$): 7.5 Standard Visual Range (km): 60
		Image Date/Time: 7/27/2009 11 EST Source: www.hazecam.net 24-hour Averages: Aerosol extinction (dv): 23.2 Total light extinction (dv): 24.3 $PM_{2.5}$ Concentration ($\mu g/m^3$): 14.7 Standard Visual Range (km): 35
		Image Date/Time: 8/05/2009 13 EST Source: www.hazecam.net 24-hour Averages: Aerosol extinction (dv): 26.6 Total light extinction (dv): 27.4 $PM_{2.5}$ Concentration ($\mu g/m^3$): 19.5 Standard Visual Range (km): 26

Given the extreme degree of visibility impairment shown in the above images where PM2.5 levels meet the current standard, EPA cannot rationally claim that the standard protects the public welfare from any known or anticipated adverse impacts.

Moreover, it is arbitrary and contrary to the requirements of the Act for EPA to retain the level of the annual secondary standard for $PM_{2.5}$. It appears EPA may retain the secondary standard to claim the secondary *differs* from the primary standard; and thus, comports with the court's decision in *American Farm Bureau Federation*.[339] Such an assertion is unreasonable as the annual secondary standard for $PM_{2.5}$ has no meaning because it is less stringent that the primary standard.

Furthermore, EPA failed to consider new and significant scientific information about visibility effects. Although there is a wealth of information on visibility, EPA fails to fully consider scientific information regarding possible alternatives for the indicator, averaging time, form, and level of possible alternative visibility-based welfare standards, discussed below. Contrary to EPA's assertions, currently available evidence does not support retaining the current secondary standards without revision.

The secondary particulate NAAQS standards are supposed to protect public welfare and EPA must protect all effects on welfare, which "seem to encompass everything imaginable."[340] EPA's proposal only considers particulate matter effects in three areas: visibility, materials, and climate.[341] The agency's efforts in all three areas were notably minimal. Furthermore, EPA's proposal focuses solely on fine PM, totally ignoring coarse PM. The trend data shows that coarse PM is increasing, which is of concern as it too effects public welfare. EPA failed to show the proposed standards are requisite to protect public welfare from any known or anticipated adverse effects. Finally, EPA omitted from its review PM effects on ecosystems.

H. The Visibility Elements Are Not Scientifically and Technically Justified and Does Not Represent the Current State of the Science.

1. EPA's single level approach does not protect across all areas

[339] *Am. Farm Bureau Fed'n v. EPA,* 559 F.3d 512, 531 (D.C. Cir. 2009).
[340] *Envtl. Def. v. EPA*, 489 F.3d 1320, 1325 (D.C. Cir. 2007) (quoting *Envtl. Def. Fund, Inc. v. EPA*, 898 F.2d 183, 190 (D.C. Cir. 1990) (citing 42 U.S.C. § 7409(b)(2), which requires NAAQS "requisite to protect the public welfare")).
[341] Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094. 24,095 n.1 (proposed Apr. 30, 2020) ("Ecological effects associated with PM, and the adequacy of protection provided by the secondary PM standards for those effects, are being addressed in the separate review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM.").

EPA's proposes single NAAQS levels for the both the annual and 24-hour standards across the entire country, which suggests that there is a single level of visibility, expressed in terms of absolute light extinction or deciviews, that is uniformly applicable to all areas, across different time increments and acceptable to everyone. EPA provides no basis for its proposed decision.

EPA's proposal suggests it considered "the information that is newly available,"[342] EPA proposal fails to do so. For example, the use of 'acceptable' visibility as EPA applies in recounting prior preference studies,[343] is a fundamentally flawed policy concept.[344] As the IPMRP explains:

> What is acceptable in an urban area with a certain baseline visibility may not be acceptable in a rural area with a higher baseline of visibility. This is not just a dichotomy between urban and rural residents. Urban residents may expect greater visibility when they travel to a rural area for vacation, and rural residents may consider urban visibility a forgone condition. An additional question is whether the visibility standard should be higher in some locations such is already the case in Class I visibility areas, national parks and wilderness areas.[345]

In sum, individual preferences will vary depending on what one is looking at and where one is located. EPA's proposal lacks consideration of new studies in this area.

The recent studies demonstrate that while people in a particular area may rate a certain visibility level acceptable (expressed as a certain, fixed level of light extinction), this does not mean that they would not realize a welfare gain from further improvements in visibility.[346] One level of light extinction is not appropriate for protecting visibility in urban and rural areas across the U.S. Indeed, EPA staff working on secondary NAAQS for SO2 and NOx in the current and previous

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342 *Id.* 24,129. Furthermore, EPA's suggestion that "in this review" EPA is acting "similarly," is incorrect. *Id.* As EPA notes, in the prior review EPA relied on public comments to inform its selection. In this review, EPA ignored public comments submitted by the IPMRP, which shared detailed information regarding new scientific studies.

343 *Id.* at 24,138.

344 IMRP Comments at C-18.

345 *Id.*

346 *Id.* at B-34 (citing Boyle, Kevin J. et al. (2016). Valuing Shifts in the Distribution of Visibility in National Parks and Wilderness Areas in the United States." *Journal of Environmental Management* 173: 10-22, https://doi.org/10.1016/j.jenvman.2016.01.042; Haider, Wolfgang et al. (2019). "Climate Change, Increasing Forest Fire Incidence, and the Value of Visibility: Evidence from British Columbia." *Canadian Journal of Forest Research* 49(999): 1242-55, https://doi.org/10.1139/cjfr-2018-0309; Yao, Liuyang et al. (2018). "Evaluating Willingness to Pay for the Temporal Distribution of Different Air Quality Improvements: Is China's Clean Air Target Adequate to Ensure Welfare Maximization?" *Canadian Journal of Agricultural Economics* 67(2): 215-32, https://doi.org/10.1111/cjag.12189); *see also id.* at C-19 ("[EPA's] conclusion is based on flawed logic because an implicit premise of the report is that there a[re] no societal benefits beyond what some small and incomplete studies found as acceptable.").

rounds of NAAQS reviews developed innovative ways of considering consistent national standards, which would be regionally modified by local conditions. This approach also addresses perceived effects on visibility, which vary by time of day, regional landscape features, scenic viewing distances, and other factors. EPA is aware that different factors influence preferences, but the agency fails to consider them in revising the standard, instead characterizes them as "uncertainties"[347] and suggests relying on them as basis to do nothing yet again in this round.

2 .EPA fails to consider the alternative ("contrast of distance") methodology

EPA's proposal incorrectly asserts that:

> Since the time of the last review, no new visibility preference studies have been conducted in the U.S. Similarly, there is little newly available information regarding acceptable levels of visibility impairment in the U.S. [348]

As identified by the IPMRP, EPA's analysis totally ignores the "important recent meta-analysis of these available visibility preference studies conducted by William Malm and colleagues," which "addresses the limitations with the concept that there is any specific level of light extinction that is universally acceptable."[349] EPA fails to mention, much less consider this important body of research.[350] It was arbitrary and capricious for EPA to rely on and draw

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347 Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094. 24,138 (proposed Apr. 30, 2020).

348 *Id.* at 24,131. Elsewhere in the proposal, EPA makes similar unfounded assertions: "Given the lack of new information to inform a different visibility metric, the metric used in the PA is that defined by the EPA in the last review as the target level of protection for visibility (discussed above in section IV.A.1): A PM2.5 visibility index with a 24-hour averaging time, a 90th percentile form averaged over 3 year, and a level of 30 dv (U.S. EPA, 2020, section 5.2.1.2)." *Id.* at 24,135 n.63.

349 Comments of IPMRP at B-34 ; Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094. 24,135 (proposed Apr. 30, 2020).

350 Malm, William C. et al. (2011). "Which Visibility Indicators Best Represent a Population's Preference for a Level of Visual Air Quality?" Paper 2011-A-596-AWMA, Air & Waste Management Ass'n. 104th Annual Conference, Orlando, FL (June 21-24, 2011), enclosed and *available at* http://www.proceedings.com/13671.html; Malm, William C. (2013). "What Level of Perceived Visual Air Quality Is Acceptable?" Project 13-C-01-01, https://www.firescience.gov/projects/13-C-01-01/project/13-C-01-01_Malm_Acceptable_Levels_Report_3.pdf; Malm, William C. "Visibility: The Seeing of Near and Distant Landscape Features (2016), https://www.elsevier.com/books/visibility/malm/978-0-12-804450-6; Malm, William C et al. (2019). "Which Visibility Indicators Best Represent a Population's Preference for a Level of Visual Air Quality?" *Journal of the Air & Waste Management Association* 169(2):145-61, https://doi.org/10.1080/10962247.2018.1506370; Molenar, J. V. et al. (2012). "Effect of Clouds on the Perception of Regional and Urban Haze." Paper presented at the Specialty Conference on Aerosol and Atmospheric Optics: Visibility and Air Pollution, Whitefish, MT, enclosed and *available at* http://www.proceedings.com/17145.html.

conclusions from just the four studies. As EPA's analysis fails to consider the new research, it is contrary to the Act's requirement that EPA conduct a "thorough review" of the air quality criteria for particulate matter, and that such criteria "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public … welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." 42 U.S.C. §§ 7408(a)(2), 7409(d)(1).

The new studies ignored by EPA:

> Evaluated a large number of visibility preference indicators and found that the apparent contrast of distant, prominent but not necessarily dominant, scene elements was a much better and more consistent predictor of "acceptable" visibility, than any specific level of light extinction. Across all the currently available visibility preference studies, as the apparent contrast of distant, prominent scene elements approached an apparent contrast level of about -0.04 (i.e. very little contrast), 50% of respondents found the visibility unacceptable. In simpler terms, as the visual range approaches the distance of distant scenic elements, people everywhere find the visibility unacceptable.[351]

While EPA may assert that some of these studies are beyond the ISA cut-off date of January 2018, as discussed elsewhere in these comments, EPA has already considered studies after that date and is prohibited from cherry-picking some studies while barring consideration of others of the same vintage. Moreover, EPA was clearly aware of Malm's work when the draft ISA was released, and at one point intended to consider the work before the studies were apparently struck from consideration and ignored.[352]

EPA must evaluate these new studies as they suggest that replacing the current indicator with the contrast of distant scenic elements would be a significant improvement and more accurately

[351] Comments of the IPMRP at B-34.

[352] EPA appears to be aware of Malm's recent work, as reference to it appeared in an earlier version of the ISA. The IPMRP notes that in reviewing the draft ISA "[t]here appears to be a reference to Malm's work in the executive summary: 'There have been no recent visibility preference studies; however, a recent meta-analysis demonstrates that scene-dependent haze metrics better account for preference compared to only using the deciview scale as a metric.' However, any of this recent work seems to be missing from the Integrated Synthesis or Chapter 13." *Id.* at C-92. Furthermore, Malm et al.'s research, papers, and presentations have been going on for many years—further evidence of EPA's arbitrary action.

evaluate public preferences. The IPMRP further suggested the methodology EPA can use to develop viewing distances across different areas and regions.[353]

3. EPA fails to consider public benefits of improved visibility

As identified by the IPMRP,[354] "the framing of the policy from a welfare perspective using 'acceptable,' by default, leads to the conclusion that no further protection is required. From a welfare perspective, the question is never posed to ask if welfare would be enhanced if protection was increased."[355] EPA fails to consider public benefits of improved visibility. While a certain percentage of people may rate a certain level of visibility as acceptable, this does not imply that they would not realize a welfare gain from further improvements in visibility.[356] In short, the question is never posed or answered to consider if there are public benefits, improved welfare, for enhancing visibility beyond the acceptable level. This is flawed logic and inconsistent with the Act's review requirements. Under the statute, the question must be whether the level of $PM_{2.5}$ pollution allowed by the standard is requisite to protect against *any* known or anticipated adverse effect on public welfare from visibility impairment. The answer to that question requires focusing not on whether some people view a given degree of visibility impairment as "acceptable," but whether the level of $PM_{2.5}$ pollution allowed and attendant visibility impairment adversely affect people's welfare compared to what it would be if such pollution and impairment were reduced or eliminated. EPA's conclusion to accept the current standards "is based on flawed logic because an implicit premise of the report is that there are no societal benefits beyond what some small and incomplete studies found as acceptable."[357] And that conclusion also flouts the statutory mandate to protect against *any* adverse effects on welfare.

4. The 24-hour averaging time neglects scientific advancements and the proposed monitoring fails to demonstrate a relationship with visibility

EPA's continued reliance on outdated methods to monitor and measure visibility impairment is misplaced. EPA falsely concludes there is a "lack of new information to inform a

[353] *Id.* at B-34 ("It would be a relatively straightforward GIS exercise to characterize typical average and/or maximal viewing distances across different urban/suburban/rural areas and regions.").
[354] *Id.* at C-18.
[355] *Id.* at C-20.
[356] Boyle, Kevin J. et al. (2016). "Valuing Shifts in the Distribution of Visibility in National Parks and Wilderness Areas in the United States." *Journal of Environmental Management* 173: 10-22, https://doi.org/10.1016/j.jenvman.2016.01.042; Haider, Wolfgang et al. (2019). "Climate Change, Increasing Forest Fire Incidence, and the Value of Visibility: Evidence from British Columbia." *Canadian Journal of Forest Research* 49(999): 1242-55, https://doi.org/10.1139/cjfr-2018-0309; Yao, Liuyang et al. (2018). "Evaluating Willingness to Pay for the Temporal Distribution of Different Air Quality Improvements: Is China's Clean Air Target Adequate to Ensure Welfare Maximization?" *Canadian Journal of Agricultural Economics* 67(2): 215-32, https://doi.org/10.1111/cjag.12189).
[357] Comments of the IPMRP at C-19.

different visibility metric"[358] and proposes to continue use of the 24-hour averaging time. EPA once again ignores science and new information. As noted by the CASAC in 2006, "the CASAC and its monitoring subcommittees have repeatedly commended EPA's initiatives promoting the introduction of continuous and near-continuous PM measurements in various aspects of its monitoring strategy."[359] EPA's proposal to retain the 24-hour averaging time, and use of filters that allow no shorter than 24-hours of data, is not appropriate for protecting visibility because it is not the timeframe over which one perceives impairment. One does not experience a view all-at-one 24-hour period. When viewing a scenic vista, or experiencing a multi-day stay at an urban park or mountain destination one does not 'see' 24-hours at once. PM emissions can and do affect visibility over just a few hours and therefore selecting a shorter averaging time is necessary to capture the impact and experience of the public. Additionally, EPA fails to explain how a 24-hour standard is appropriate in urban areas where visibility during daylight hours is much more important.[360]

There are significant issues with the coverage, accuracy, and relationship of the filter samples to the standard. The CSN network samples, which are collected only every third day, at best, leave two-thirds of the days unmonitored. As the IPMRP identified to EPA, based on recent studies using the filter-based IMPROVE algorithm requires certain assumptions, essential to the accuracy of the data, that are not always met.[361] EPA's failure to consider these recent studies[362] is unreasonable and will result in continued use of flawed data. Finally, the filters collect all data over the entire 24-hour time period. Visibility is not seen over one entire 24-hour period, and therefore the data is not representative of visibility and impairment, which are on much shorter timeframes.[363]

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358 Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094. 24,136 n.63 (proposed Apr. 30, 2020).
359 Clean Air Sci. Advisory Comm., EPA-CASAC-LTR-06-002, Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter, cover letter at 5 (Mar. 21, 2006) (citing Hopke, March 1, 2002; Henderson, April 20, 2005). There are hundreds of PM monitors and EPA fails to explain why they cannot either by used or adapted for use for the secondary standards. Moreover, other federal agencies track and research visibility, and EPA fails to consider or explain why partnering with other agencies is not an option to supplement existing monitors) (e.g., Federal Aviation Association, discussion below on federal family, and use of satellite information).
360 IPMRP Comments at C-91.
361 *Id*. at C-89 (explaining that the assumptions for the following are not always met: "the degree of sulfate ammoniation, chemical form(s) of nitrate, the varying relationships between measured OC and POM mass, etc"); *see also* Hand, J. L. et al. (2019). "Trends in Remote $PM_{2.5}$ Residual Mass across the United States: Implications for Aerosol Mass Reconstruction in the IMPROVE Network." *Atmospheric Environment* 203: 141-52,https://doi.org/10.1016/j.atmosenv.2019.01.049; Prenni A. J. et al. (2019). "An Examination of the Algorithm for Estimating Light Extinction from IMPROVE Particle Speciation Data." *Atmospheric Environment* 214: 116880, https://doi.org/10.1016/j.atmosenv.2019.116880.
362 Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094. 24,130 (proposed Apr. 30, 2020).
363 IPMRP Comments at C-89.

Moreover, EPA fails to explain why retaining the current method using every third day 24-hour, filter-based reconstructed extinction indicator is better than the options offered by the IPMRP,[364] and advocated by EPA staff and CASAC in previous NAAQS reviews (as discussed above). The IPMRP provided suggestions to modify and improve the light extinction indicator, which EPA also needs to consider.[365] Finally, EPA's proposal is inconsistent with prior reviews conducted for other pollutants because it fails to consider applying different weights in evaluating indicator averaging times and concentrations.[366]

5. EPA's continued reliance on the current methods to monitor and measure visibility impairment is misplaced[367]

EPA needs to evaluate use of continuous $PM_{2.5}$ mass data, as suggested by the IPMRP, and as recommended by EPA staff and supported by CASAC in the three PM NAAQS reviews prior to this one.[368] The quality of the data has improved in accuracy and could be reported in near-real time. Contrary to EPA's assertion that there are no criteria and methods EPA can use,[369] the existing continuous $PM_{2.5}$ network can be used, which would provide much more coverage as explained by the IPMRP.[370] Unlike the current approach, such data would more directly relate to human perception of impaired visibility.[371] It appears EPA may have considered using this network, however, EPA fails to fully explain, particularly in light of the IPMRP analysis and prior NAAQS reviews, its rationale for rejecting this approach. Moreover, EPA has authority and resources to develop methods and require use of these or other monitors for the secondary standards. Congress mandated review of the NAAQS every five years, and EPA's failure to examine current science, technology and networks, and rely on outdated, inaccurate and unrepresentative data as a surrogate is simply unreasonable.

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[364] The IPMRP provides various options and considerations, which EPA should evaluate including: PM light extinction; use a fixed, long-term average RH to remove the natural variability from the regulation; impose an RH screen (eliminating hours with RH < 70%) on the PM data (as is done with urban visibility standards in Phoenix and Denver); the fact that use of the continuous PM data for secondary NAAQS regulatory purposes would lead to closer scrutiny, improved QA and better data quality. *Id.* at C88-91.
[365] *Id.* at C-90 ("[U]se the filter-based speciation data to calculate regional monthly or seasonal species composition + f(RH) factors to adjust the continuous $PM_{2.5}$ data to (slightly) better extinction estimates - which could then be considered on a sub-daily basis, much more relevant to human perception, and could be publicly reported from a much larger network in near-real time.").
[366] For example, in revising the ozone standards, the Administrator
[367] Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094. 24,130 (proposed Apr. 30, 2020).
[368] Comments of the IPMRP at C-91.
[369] Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094. 24,130 (proposed Apr. 30, 2020).
[370] Comments of the IPMRP at C-89.
[371] *Id.* at C-91.

6. EPA's proposal to retain the 30 dv level for the standard is arbitrary, capricious, and not technically supported

EPA proposes retaining the 30 dv level, asserting that it reflects "the highest degree of visibility impairment judged to be acceptable by at least 50% of study participants in the available visibility preference studies"[372] and fails to consider the recent important research studies by Malm et al. that provide meta-analysis of visibility preference studies, which clearly shows that the 30 dv level "is clearly unacceptable to the majority of respondents in all 5 study areas."[373]

7. EPA's 90th percentile form is based on a false equivalency, fails to collect data on two-thirds of the days, and totally ignores more than 30 days each year

The 90th percentile form is not appropriate for protecting visibility. The 90th percentile form is too low and would result in 36 days being excluded annually. This means that visibility could be worse than the standard on 36 days each year, but presumes the public only finds it objectionable when this happens on 37 or more days per year (further averaged over three years).[374] EPA's proposal asserts the following supports continued use of the 90th percentile form:

> [T]hat the Regional Haze Program targets the 20 percent most impaired days for improvements in visual air quality in Federal Class I areas and that the median of the distribution of these 20 percent worst days would be the 90th percentile . . . that strategies that are implemented so that 90 percent of days would have visual air quality that is at or below the level of the standard would reasonably be expected to lead to improvements in visual air quality for the 20 percent most impaired days.[375]

EPA asserts that using the 90th percentile for the secondary NAAQS would be consistent with the approach taken in the Regional Haze Program. This is a "false equivalency."[376] The Regional Haze Rule focuses on improving conditions on the worst days, which is why the 90th percentile is used. Applying the same "percentage as a NAAQS form has exactly the opposite effect"—it completely ignores the 36 worst visibility days, excusing them from being tracked and improved.[377] EPA fails to explain how averaging the form over three years is protective of visibility. The public does not perceive visibility in three-year averages. Therefore, providing for

[372] Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094. 24,138 (proposed Apr. 30, 2020) (citation omitted).
[373] Comments of the IPMRP at C-93.
[374] *Id.* at C-94.
[375] Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094. 24,129 (proposed Apr. 30, 2020).
[376] Comments of the IPMRP at C-94.
[377] *Id.*

a three-year standard is simply not protective of visibility and public welfare. Additionally, while over the years the forms of the various secondary standards that have been considered and recommended by EPA staff and/or CASAC have varied, the 98th percentile was commonly recommended.[378] EPA's proposal lacks consideration of the 98th percentile. Even if EPA wanted to follow the regional haze approach, the question is to first identify the worst impaired days and then require pollution on those days be reduced.

I. EPA ignored important meta-analysis scientific studies and significant modeling advancements

Contrary to the Act's requirement in section 108(a), EPA's proposed criteria fail to "accurately" reflect "the latest scientific knowledge." 42 U.S.C. § 7408(a). As discussed above, EPA ignores important meta-analysis scientific studies. EPA proposes retaining the 30 dv level, asserting that it reflects "the highest degree of visibility impairment judged to be acceptable by at least 50% of study participants in the available visibility preference studies."[379] EPA suggests that the only new information on preference studies was the single new study by Smith (2013), which is incorrect. EPA "disregards important new work in this area, which clearly shows a convergence of results across many different urban areas when the visual air quality is expressed in terms of the contrast of the most distant landscape features."[380] "This important work was entirely omitted from the draft ISA and from the draft PA"[381] and EPA's proposal fails to consider and discuss important research studies that provide meta-analysis of visibility preference studies. These studies, conducted by William Malm and colleagues (Malm et al., 2011, 2019; Malm, 2013, 2016; Molenar and Malm, 2012)[382] addresses the limitations with the concept that there is any specific level of light extinction that is universally acceptable. These studies further show that

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[378] *Id.*
[379] Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 24,094. 24,138 (proposed Apr. 30, 2020).
[380] Comments of the IRMRP at C-92.
[381] *Id.* at B-34.
[382] *Id.*; Malm, William C. et al. (2011). "Which Visibility Indicators Best Represent a Population's Preference for a Level of Visual Air Quality?" Paper 2011-A-596-AWMA, Air & Waste Management Ass'n. 104th Annual Conference, Orlando, FL (June 21-24, 2011), *available at* *http://www.proceedings.com/13671.html*; Malm, William C. (2013). "What Level of Perceived Visual Air Quality Is Acceptable?" Project 13-C-01-01, https://www.firescience.gov/projects/13-C-01-01/project/13-C-01-01_Malm_Acceptable_Levels_Report_3.pdf; Malm, William C. "Visibility: The Seeing of Near and Distant Landscape Features (2016), https://www.elsevier.com/books/visibility/malm/978-0-12-804450-6; Malm, William C et al. (2019). "Which Visibility Indicators Best Represent a Population's Preference for a Level of Visual Air Quality?" *Journal of the Air & Waste Management Association* 169(2):145-61, J. V. Molenar and William C. Malm (2012). "Effect of Clouds on the Perception of Regional and Urban Haze." Paper presented at the Specialty Conference on Aerosol and Atmospheric Optics: Visibility and Air Pollution, Whitefish, MT, *available at* *http://www.proceedings.com/17145.html* (Molenar).

the 30 dv level is clearly unacceptable to the majority of respondents in all public preference studies considered by EPA.[383]

EPA's failure to acknowledge the Malm and Molenar studies during this review is truly perplexing, as more than ten years ago it was EPA's CASAC that suggested statistical analysis of the visibility preference studies, which resulted free tools to easily conduct visibility preference studies.[384] Free tools – easily implemented at low cost - that EPA fails to use. In the subsequent two years after CASAC's suggestion and statistical analysis by EPA's contractor, in response to years of complaints about difficulties, expense of the visibility preference studies, and delay,[385] Molenar and Malm presented research papers and developed a new protocol.[386] The new protocol was tested, worked, and importantly included the use of clouds, which they found are important to the view, especially for scenes with only close features.[387] Below is a discussion on the use of clouds in the WinHaze model. In sum, EPA fails to provide any explanation of these tools and this important work, and has ignored the recent studies. Thus, the proposal fails reflect the Act's requirement that air quality criteria "accurately" reflect "the latest scientific knowledge." 42 U.S.C. § 7408(a).

Malm's recent meta-analysis evaluated a large number of visibility preference indicators and found that the apparent contrast of distant, prominent but not necessarily dominant, scene elements was a much better and more consistent predictor of "acceptable" visibility, than any

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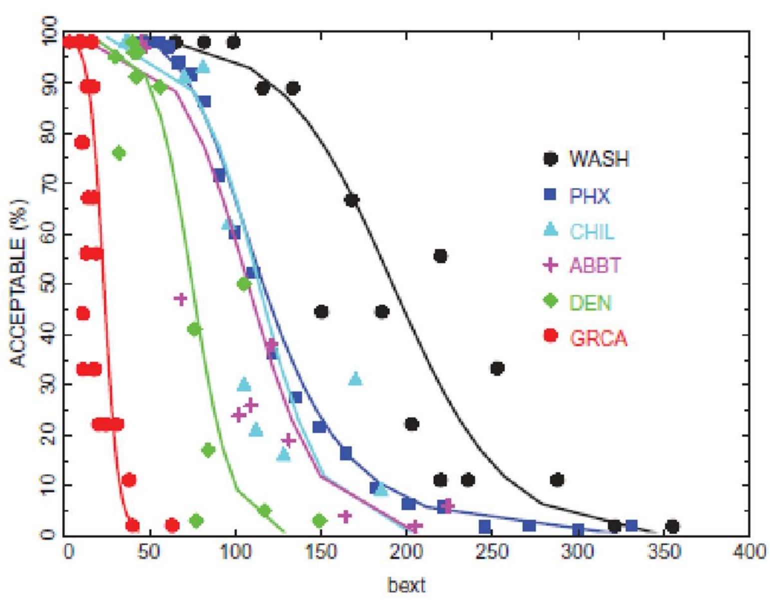
[383] *Id.* (citing Malm, William C et al. (2019). "Which Visibility Indicators Best Represent a Population's Preference for a Level of Visual Air Quality?" *Journal of the Air & Waste Management Association* 169(2):145-61, https://doi.org/10.1080/10962247.2018.1506370) .
[384] CASAC members suggested using data from the four studies available at the time to identify methods for statistical analysis. The four preference studies conducted at time involved observers that were shown images (e.g., prints, projected slides, or displayed on a monitor) or varying visual air quality (VAQ), and prints showing three to five levels of VAQ were presented simultaneously. Observers were asked to rate VAQ on a numerical scale, and/or is VAQ was acceptable or unacceptable. "On the basis of the CASAC comments and the information available in the previous Stratus Report (Stratus Consulting, 2009), EPA concluded it was appropriate to conduct further statistical analyses on the available urban visibility preference studies. Subsequently, EPA asked Stratus Consulting to re-examine the data from these studies and identify several methods for statistical analyses along the lines CASAC members suggested." Leland Deck and Megan Lawson, Stratus Consulting, Inc., to Vicki Sandiford, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Memorandum on Statistical analysis of existing urban visibility preference studies (Feb. 3, 2010) at 1, *available at* https://www3.epa.gov/ttn/naaqs/standards/pm/data/20100203logitanalysismemo.pdf. EPA's consultant assembled a master data set of 19,280 observations from the original data, and applied statistical analysis models and conducted hypothesis testing with the four-city data.
[385] A that point the preference study efforts had been going on for ten years. It is now ten year later, and EPA has yet to explain why no further studies have been conducted, despite having the "free tools," which would require minimum resources to implement.
[386] Molenar at 3.
[387] *Id.* at 28.

specific level of light extinction. Figure 4 "plots percent acceptability against absolute light extinction in dv. Note that at the 50% acceptability levels in all 5 studies are bounded by a range of extinction between about 20 and 30 dv. This was the basis for suggesting this range in the 2012 review . . . a level which is clearly unacceptable to the majority of respondents in all 5 study areas."[388] In describing the importance of Malm's work, the IPMRP further explains that:

> Across all the currently available visibility preference studies, as the apparent contrast of distant, prominent scene elements approached an apparent contrast level of about -0.04 (i.e. very little contrast), 50% of respondents found the visibility unacceptable. In simpler terms, as the visual range approaches the distance of distant scenic elements, people everywhere find the visibility unacceptable.[389]

So, in addition to demonstrating the current standard does not protect public welfare, this work provides a clear roadmap for EPA to use in establishing a more stringent standard. EPA can readily determine regional scene characteristics across the U.S. since it would be a relatively straightforward GIS exercise to characterize typical average and/or maximal viewing distances across different urban/suburban/rural areas and regions.[390] We agree with the IPMRP that EPA needs to perform this exercise in revising the secondary standards.

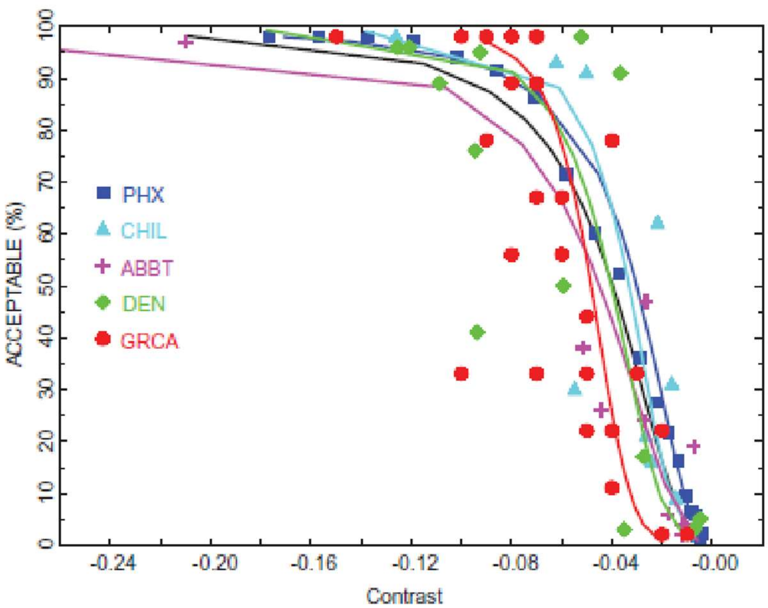
Figure 4. Percent Acceptability Levels and Atmospheric Extinction.



[388] *Id.* at C-93.
[389] *Id.*at B-34.
[390] *Id.* at B-35.

Figure 5, below, plots percent acceptability results from the same five studies against the apparent contrast of "a distant, prevalent, but not necessarily dominant, feature," which shows a remarkable consistency at a contrast of about -0,04 across many diverse types of study areas.[391] Therefore, the public trend finds decreased visibility unacceptable as prominent, distant landscape features begin to disappear.

Figure 5. Percent acceptability levels plotted against apparent contrast of distant landscape features.[392]



"Another important recent related technological development is the ability to incorporate clouds into the Winhaze model."[393] As discussed above, the Winhaze model generates images showing visibility impairment using different scenes. EPA also fails to consider this work, which has been available for many years. [394] This is important work because "[f]or cities in relatively flat terrain

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[391] Comments of the IPMRP atC-91 (explaining that "[t]his contrast threshold of about -0.04 basically occurs as the visual range nears the distance of prominent distant scenic elements"). In addition to Malm's more recent study using this figure, similar information was presented in his December 2013 report. Malm, William C. (2013). "What Level of Perceived Visual Air Quality Is Acceptable?" Project 13-C-01-01, at 19, https://www.firescience.gov/projects/13-C-01-01/project/13-C-01-01_Malm_Acceptable_Levels_Report_3.pdf.

[392] Malm, William C et al. (2019). "Which Visibility Indicators Best Represent a Population's Preference for a Level of Visual Air Quality?" *Journal of the Air & Waste Management Association* 169(2):145-61, at 157, https://doi.org/10.1080/10962247.2018.1506370)

[393] Comments of the IPMRP at C-92 to 93.

[394] *Id.* at C-94 to 95 (citation omitted). Molenar and Malm, first shared this work in 2012. Molenar, J. V. et al. (2012). "Effect of Clouds on the Perception of Regional and Urban Haze." Paper presented at the

which lack distant landscape features, clouds often are the most distant scenic attribute. As they begin to disappear, viewers tend to find the degradation of visibility unacceptable, at lower levels of light extinction than they would viewing cloud-free scenes."[395]

Figure 6, below, contains four images generated by adaptions to the WinHaze model showing: (a) cloud-free and (b) cloud-added images under near-Rayleigh conditions (particle-free atmosphere). Notably, images (c, d) correspond to where 50% of study participants found the visibility level to be unacceptable.[396] If EPA expanded Malm's research across the country to include multiple urban/suburban areas, we believe it would be even more clear that—contrary to assertions by EPA in its proposal—people in many diverse regions would likely find visibility impairment of 30 dv to be unacceptable.[397] Indeed, it's not only troubling that EPA ignored this important work on clouds, but had EPA followed the Act's mandate to consider recent scientific work, EPA's efforts should have expanded Malm's research across the country and used it "as a basis for setting a consistent national standard, which could vary geographically depending on local scene characteristics."[398]

Specialty Conference on Aerosol and Atmospheric Optics: Visibility and Air Pollution, Whitefish, MT, *available at* http://www.proceedings.com/17145.html.

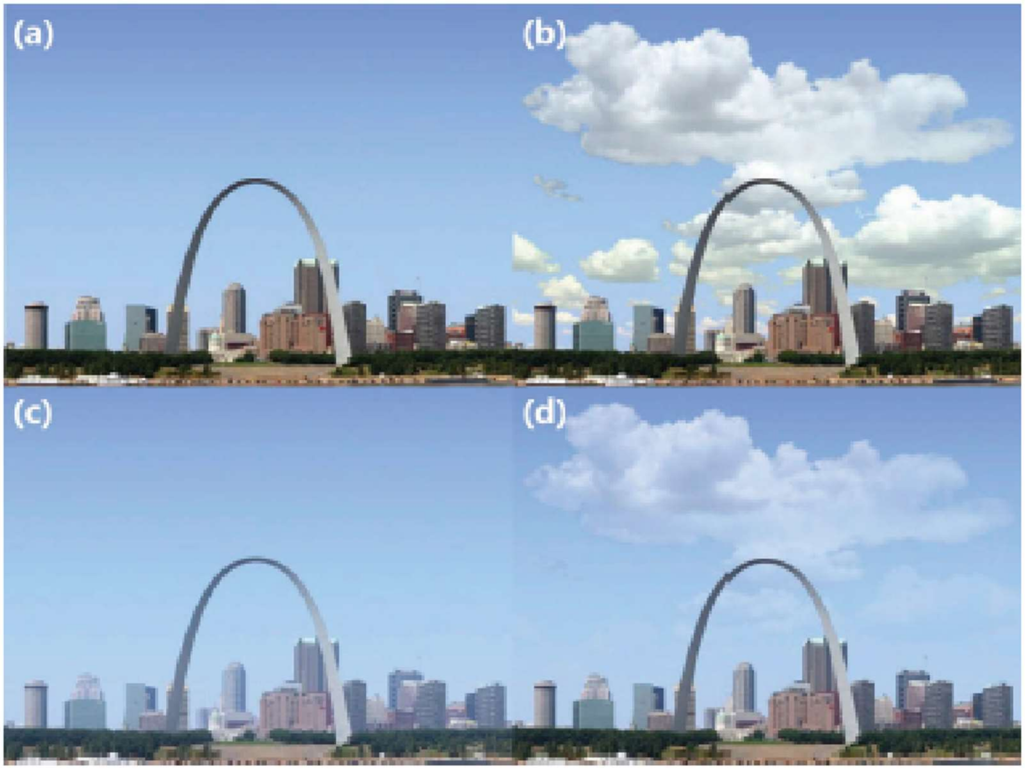
[395] Comments of the IPMRP at C-94 to 95 (citation omitted).

[396] Malm, William C et al. (2019). "Which Visibility Indicators Best Represent a Population's Preference for a Level of Visual Air Quality?" *Journal of the Air & Waste Management Association* 169(2):145-61, at 158, https://doi.org/10.1080/10962247.2018.1506370).

[397] *Id.* at C-93.

[398] *Id.*

Figure 6. Expanding WinHaze to Include Clouds in the Public's Perceptibility.



In light of this recent research, EPA's assertions regarding "uncertainties and limitations"[399] underlying the old public preference studies is unavailing.

Furthermore, during the last several PM NAAQS reviews, EPA has lamented the limited number of surveys of public preference or acceptability for different visibility levels in different areas.[400] Recent developments of the WinHaze model, including the ability to add clouds to scenic or urban views make it possible to conduct large public surveys in many areas at relatively low cost.[401] EPA arbitrarily fails to acknowledge this important body of scientific work; much less

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[399] As discussed earlier in our comments.

[400] Leland Deck and Megan Lawson, Stratus Consulting, Inc., to Vicki Sandiford, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Memorandum on Statistical analysis of existing urban visibility preference studies (Feb. 3, 2010), *available at* https://www3.epa.gov/ttn/naaqs/standards/pm/data/20100203logitanalysismemo.pdf.

[401] Indeed, as discussed elsewhere, the IPMRP shared recent scientific and technical studies in public survey work. They also shared information on best practices, which EPA ignored, American Association for Public Opinion Research, Best Practices for Survey Research, *available at* https://www.aapor.org/Standards-Ethics/Best-Practices.aspx#best6 (contains detailed recommendations on how to produce the best survey possible); Reg Baker et al., Evaluating Survey Quality in Today's Complex Environment, American Association for Public

use the tools it provides to support much needed revisions to the secondary PM NAAQS. EPA needs to stop complaining about lack of data and resources—and do its job.

J. EPA failed to consider the public welfare gains from improvements to visibility.

Additionally, contrary to the Act's requirements, EPA neither poses nor answers the question as to whether there are "net public benefits, improved welfare, for enhancing visibility beyond the acceptable level."[402] Since the last assessment numerous research studies considered the benefits of improved visibility.[403]

- *Boyle et al., 2016*, provides an approach for estimating the economic benefits of different distributional changes as the worst environmental conditions are removed. The proposed approach is illustrated by examining shifts in visibility at Class I visibility areas (National Parks and wilderness areas). In this application the paper shows that people value shifts in the distribution of visibility and place a higher value on the removal of a low visibility day than on the addition of a high visibility day. They found that respondents would pay about $120 per year in the Southeast U.S. and about $80 per year in the Southwest U.S. for improvement programs that remove the 20% worst visibility days.[404] Important findings that support more stringent standards.

- *Haider et al.*, 2019, considered that "climate change may increase the occurrence and severity of forest fires, leading to worsening wildfire seasons." Noting that "more frequent burn events would have various effects due to increased haze and smoke, including a greater incidence of impacts on human health and reduced or impaired visibility." They studied an area in Canada, which like many in the U.S., "prides itself on panoramic mountain and city views, [and that] individuals may be willing to pay to address deteriorating visibility conditions arising from wildfires or other sources." The studies' authors recognized that "studies consistently show that any attempt to ask individuals how much they are willing to pay to improve local visibility will be

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Opinion Research, available at https://www.aapor.org/Education-Resources/Reports/Evaluating-Survey-Quality.aspx.

402 Dr. Boyle comments at C-18.

403 As Dr. Boyle points out in his comments, compromised visibility can also affect property values Margaret A. Walls et al., Is what you see what you get? The value of natural landscape views, Land Economics, 91 (1): 1-19 (Feb. 2015), *available at* http://le.uwpress.org/content/91/1/1.full.pdf+html. Boyle comments at C-18. *See also*, Taeyun Jeong et al., A comparative study on the value of scenic views between an inland and a coastal city in Korea, Pacific Rim Property Research Journal (2019), 25:2, 101-124.

404 Kevin J. Boyle et al., Valuing shifts in the distribution of visibility in national parks and wilderness areas in the United States, Journal of Environmental Management, 173: 10-22 (2016), *available at* https://doi.org/10.1016/j.jenvman.2016.01.042.

confounded with the benefits of improving local health conditions," which they confirmed when they "included the consideration of health effects and found that these two attributes were indeed linked." Their study "used a discrete choice experiment to estimate the value of potential improvements in local visibility in the Lower Fraser Valley . . . [and applied the results] to estimate the value of damages from visibility disruptions related to wildfire smoke from 2002 to 2018 in the Lower Fraser Valley."[405] The results from this study are useful given the similarities between the areas studied and those in the U.S., as well as the fact that the authors were successful in isolating visibility from health impacts in studying how the public values visibility.

- *Yao et al. (2019)*,[406] recognizes that preference analyses seeking to determine the public's value for air quality improvements often estimate willingness to pay (WTP) for days at a specified minimum quality threshold (e.g., days with clean air), but do not consider the temporal distribution of pollution levels below this threshold. Their paper developed a choice experiment designed to evaluate WTP for a more complete distribution of air quality improvements, including the number of days per year at multiple air quality levels. Results from a linearly constrained mixed logit model demonstrate that average household WTP for improving a lightly polluted, moderately polluted, heavily polluted, or severely polluted day to a clean air day increased as the amount of pollution increased. These results show that WTP depends not only on the total number of clean air days, but on the total distribution of pollution levels across all days of the year.[407] This study further emphasizes the need for EPA to consider all days of the year, rather than one of every three and ignoring more than 30.

Compromised visibility can also affect property values, and EPA also fails to consider the economic effects of scenic views on property values. For example, the recent study by Walls et al. (2015) found that views of natural areas and green space may have value quite apart from access to those lands.[408] Using 25 years of home sales data from St. Louis County, Missouri, and modern geographic information system tools to measure views, they estimated a hedonic property fixed-effects model that captures the effects of changing land cover on house sale prices. Unlike previous studies, their approach minimizes bias from omitted variables and uniquely captures changes over time. In addition to their findings on the value of views apart

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405 Wolfgang Haider et al., Climate change, increasing forest fire incidence, and the value of visibility: evidence from British Columbia, Canada. Canadian Journal of Forest Research, 49 (999): 1242-1255 (2019), *available at* https://doi.org/10.1139/cjfr-2018-0309.

406 Liuyang Yao et al., Evaluating willingness to pay for the temporal distribution of different air quality improvements: Is China's clean air target adequate to ensure welfare maximization? Canadian Journal of Agricultural Economics, 67 (2): 215-232 (2019), *available at* https://doi.org/10.1111/cjag.12189.

407 *Id.*

408 Margaret A. Walls et al., Is what you see what you get? The value of natural landscape views, Land Economics, 91 (1): 1-19 (Feb. 2015), *available at* http://le.uwpress.org/content/91/1/1.full.pdf+html.

from access, they future found that forest views negatively affect home prices, whereas farmland views have positive effects. EPA's proposal only considers the preference studies, and clearly the two main findings from this study demonstrate the need for EPA to take its findings into account, as they show the public values views extend far beyond EPA's narrow focus.[409]

Finally, reduced visibility has negative impacts to tourism, regardless of the area of the country visited. For example, the recent 2018 research study at 33 National Parks found that each increase of 1 part per billion in ozone concentration (which harms human health and visibility) is associated with a 2 percent decrease in monthly visitation during peak summer periods.[410] This study shows that increased pollution results in reduced visitation and therefore reduced tourist dollars. EPA failed to take impacts to tourism into account in evaluating the secondary standard. The impact of PM to tourism in our National Parks and other land management by federal and state agencies should have been part of EPA's consideration - it wasn't. EPA's missed opportunities to work with its counterparts in the federal family and gain valuable scientific and technical knowledge to evaluate NAAQS revisions is discussed below.

EPA's assessment neglects to include *any* studies on the public benefits and improved welfare for enhancing visibility. EPA must consider these as well other studies in its current assessment, and meaningfully consider enhancing visibility beyond what it incorrectly asserts is an acceptable level.

K. EPA failed to adequately consider the effect of PM on materials

Although EPA's proposal explains that "the current evidence continues to support the conclusion from the last review that there is a causal relationship between PM deposition and materials effects," 85 Fed. Reg. at 24,133, EPA fails to specify a level of air quality to protect against adverse effects from PM on materials. The overarching conclusion from the studies EPA discusses is clear: the current PM welfare standards fail to protect materials from the effects of PM. EPA acted arbitrarily in summarily dismissing the data as "insufficient to conduct quantitative analyses for PM effects on materials in the current review." *Id.* at 24,135. Furthermore, we disagree with EPA's assertion that new scientific studies "provide limited new data for consideration in this review." *Id.* at 24133. For example, there is evidence on the cost of

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409 There are undoubtedly many more studies on this topic. It seems EPA failed to search for any studies on this topic at all, as we can locate no information in the docket on this topic. *See also*, Jay Mittal and Sweta Byahut, Scenic landscapes, visual accessibility and premium values in a single family housing market: A spatial hedonic approach, Environment and Planning B: Urban Analytics and City Science 0(0) 1–18 (2017), *available at* https://journals.sagepub.com/doi/10.1177/2399808317702147.
410 David Keiser et al., "Air Pollution and Visitation at U.S. National Parks," Science Advances Vol. 4, No. 7 (July 18, 2018), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6051738/.

soiling from air pollution (e.g., *Besson et al.*, 2017[411]; *Grøntoft et al.*, 2019[412]), and while these studies were conducted outside the U.S., the materials studied are also in the U.S. and thus the results should be fully considered by EPA.

- *Besson el al.* found that the effect of soiling on PV systems negatively impacts the energy production and that the phenomenon is highly dependent on the environmental context and conditions of operation. Indeed dirt, dust, and other air contaminants are site-specific and their accumulation on PV modules depends on the installation configuration. This study, conducted over a period of two and half years, focused on analyzing power production and soiling losses of three photovoltaic technologies, monocrystalline, polycrystalline, and thin-film Si. Further analyzing the seasonality of soiling rates, the study determined a yearly trend for soiling. Using the yearly soiling trend, the authors developed a link between economical parameters and the cleaning pattern applied.[413]

- Contrary to EPA's assertion that "no quantitative relationships have been established between characteristics of PM or the frequency of cleaning or repainting that would help to inform the EPA's understanding of the public welfare implications of soiling," *Id.* at 24,135, *Grøntoft et al.* estimated maintenance-cleaning costs, cost savings and cleaning interval increases for structural surfaces and windows in Europe obtainable by reducing the air pollution. The study considered a hypothetical 50% reduction in the air pollution to determine savings in these cleaning costs. The study further observed that the reduction in the air pollution, from 2002–2005 until 2011–2014, probably increased the cleaning interval for white painted steel with ~100% (from 12 to 24 years), representing reductions in the single intervention cleaning costs from 7 to 4%/year (= % of one cleaning investment, per year during the cleaning interval) and for the modern glass with ~65% (from 0.85 to 1.3 years), representing reductions in the cleaning cost from 124 to 95%/year. The cleaning cost reductions, obtainable by a 50% reduction in air pollution, would have been ~3 %/year for white painted steel and ~60%/year for the modern glass, representing ~100 and 50% additional cleaning interval increases. These potential

[411] P. Besson, et al., Long-Term Soiling Analysis for Three Photovoltaic Technologies in Santiago Region, IEEE Journal of Photovoltaics, 7 (6): 1755-1760 (2017), *available at* https://www.ing.uc.cl/publicaciones/long-term-soiling-analysis-for-three-photovoltaic-technologies-in-santiago-region/.

[412] Terje Grøntoft et al., Cleaning costs for European sheltered white painted steel and modern glass surfaces due to air pollution since the year 2000. Atmosphere, 10 (4): 167 (2019), *available at* https://doi.org/10.3390/atmos10040167.

[413] P. Besson, et al., Long-Term Soiling Analysis for Three Photovoltaic Technologies in Santiago Region, IEEE Journal of Photovoltaics, 7 (6): 1755-1760 (2017), *available at* https://www.ing.uc.cl/publicaciones/long-term-soiling-analysis-for-three-photovoltaic-technologies-in-santiago-region/.

> cleaning cost savings are significantly higher than previously reported for the weathering of Portland limestone ornament and zinc monuments.[414]

Furthermore, as discussed below, EPA failed to consider other recent work on how the accumulation of soiling on photovoltaic (PV) modules affects PV systems.

The Administrator fails to provide a basis for many assertions in the proposal. For example, his proposed conclusion that "with respect to non-visibility welfare effects, the Administrator considers the evidence for PM-related impacts on . . . materials and concludes that it is generally appropriate to retain the existing secondary standards . . . ." 85 Fed. Reg. at 24,139. There is nothing in the proposal that explains how the current standard is appropriate to protect materials from the effects of PM. The Administrator further asserts, without citing which studies, that the new evidence is primarily from studies conducted outside the U.S. *Id.* By not providing references to which studies he refers to, the public cannot comment on this assertion. Additionally, the Administrator indicates that in his judgment, apparently all the scientific information in the current review remains insufficient to quantify, with confidence, the public welfare impacts of ambient PM on materials. *Id.* The Administrator has to do more than share his proposed conclusion - his merely saying so does not make it so. *Murray Energy Corp. v. EPA*, 936 F.3d 597, 619 (D.C. Cir. 2019) ("We defer to EPA's judgment that the available evidence is too uncertain only when the agency reasonably explains its decision."); *see also* discussion and caselaw cited above. Several studies included quantification methodology, and EPA fails to explain why it ignores the following:

- For example, EPA notes that "[c]orrosion of stone and the decay of stone building materials by acid deposition and sulfate salts were described in the 2009 ISA . . . [and] [s]ince that time, advances have been made on the quantification of degradation rates and further characterization of the factors that influence damage of stone materials." 85 Fed. Reg.. at 24,134. But EPA fails to explain why the quantification of information from those studies is not useful to revise the standards.

- Additionally, EPA explains that "[c]ontinued efforts to develop dose-response curves for soiling have led to some advancements for modern materials," *id.,* but fails to explain why it does not consider any of the dose-response curves in revising the secondary standards.

- Finally, EPA notes that "[s]ince the last review, damage functions for a wide range of building materials (*i.e.,* stone, aluminum, zinc, copper, plastic, paint, rubber, stone) have

[414] Grøntoft, T., Verney-Carron, A. and Tidblad, J., Cleaning costs for European sheltered white painted steel and modern glass surfaces due to air pollution since the year 2000. Atmosphere, 10 (4): 167 (2019), *available at* https://doi.org/10.3390/atmos10040167.

been developed and reviewed (Brimblecombe and Grossi, 2010)," *id.* at 24,135, however, the agency fails to explain why it cannot use the new damage function information to revise the standards.

EPA's proposal further dismisses research studies on soiling, which is the result of PM accumulation on an object. EPA provides broad-sweeping characterizations as to why the 31 studies[415] included in its evaluation "provide limited new data for consideration," simply noting that they are primarily from studies conducted outside of the U.S. and are "on buildings and other items of cultural heritage and at concentrations greater than those typically observed in the U.S." 85 Fed. Reg.. at 24,133 (referencing U.S. EPA, 2019, section 13.4). The ISA lacks clarity as to which studies EPA is discounting, and merely indicates "[t]here is new information on the soiling process, types of materials, such as glass, and dose-response and damage functions described below. Most of the recent work on this topic has been conducted outside of the U.S. on buildings and other items of cultural heritage."[416] EPA identifies only one that was conducted outside the U.S. in a "severely polluted" city.[417] Of the remaining studies, many of which were conducted in the U.S., EPA fails to identify those that it dismisses from consideration. It is further unclear which studies collected data outside the U.S., as EPA's proposal and ISA are silent as far as characterizing studies in the U.S. or outside the U.S. Moreover, EPA dismisses studies on all "buildings" that are "outside the U.S." The studies cover a wide range of building structures, and it is unreasonable for EPA to dismiss them all without providing details to distinguish why each study is ignored. EPA provides no rationale to explain why the studies are not relevant in the U.S. Moreover, it is unclear why items of cultural heritage are dismissed. The U.S has historical buildings and structures including those of Native American heritage as well as those preserved by our National Park System that EPA should consider and must protect. Therefore, it is unreasonable and arbitrary for EPA's proposal to conclude that "sufficient evidence is not available to conduct a quantitative assessment of PM mass or component-related soiling and corrosion effects." 85 Fed. Reg. at 24,135.

Based on these faulty and unsupported assumptions, the Administrator proposes that "there is insufficient information at this time to support a distinct national ambient standard based on materials impacts." *Id.* at 24,139. Moreover, the Administrator fails to take into consideration in proposing his decision to do nothing -- information in his own proposal finds that "[s]oiling is

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[415] Barca et al., 2010; Smith et al., 2008; Kloppmann et al., 2011, France; de Oliveira et al., 2011; Worobiec et al., 2010; Ozga et al., 2011; Lanzon and Garcia-Ruiz, 2010; Alfaro et al., 2012; Mooers et al., 2016; Casati et al., 2015; Chabas et al., 2015; Lau et al., 2008; Liu et al., 2015; Sabbioni et al., 1998; Haneef et al., 1993; Johansson et al., 1988; Sanjurjo Sanchez et al., 2009; Sabbioni et al., 1998; Saiz-Jimenez, 1993; Cultrone et al., 2000; Viles and Gorbushina, 2003; Sanjurjo-Sanchez and Alves, 2012; Hussey et al., 2017; Abderrezek and Fathi, 2017; Radonjic et al., 2017; Besson et al., 2017; Boyle et al., 2017; Javed et al., 2017; Walwil et al., 2017; Quan and Zhang, 2017; and Rosso et al., 2016.
[416] ISA at 13-78.
[417] *Id.* at 13-79 (referencing Liu et al. (2015)).

the result of PM accumulation on an object that alters its optical characteristics or appearance . . . [and] these soiling effects can . . . result in . . . irreversible damage to the surface." *Id.* at 24,133. Irreversible damage means the function provided by the surface of the material is lost. The Administrator does not consider the irreversible damage. Related to irreversible damage to the surface of materials are the rates at which the materials degrade. As EPA explains in its proposal - and Administrator fails to take into account - Brimblecombe et al., 2009, predicts that PM-attributable damage will result in "potentially higher degradation rates for polymeric materials, plastic, paint, and rubber due to increased oxidant concentrations and solar radiation." *Id.* at 24135. From these studies and others considered by EPA, the Administrator is clearly aware of the irreversible damage and degradation to the surface of materials attributable to PM, and yet in failing to proposed a standard that covers materials, he ignores the Act's requirement to set a standard "requisite to protect the public welfare from any known or anticipated adverse effects." 42 U.S.C. § 7409(b)(2).

L. EPA's proposal is inconsistent with the overarching recommendations of the panel of scientists EPA had previously appointed to assist CASAC in its deliberations.

In addition to the specific recommendations from the IPMRP outlined above, "[b]ased on the scientific evidence, the [IPMRP] finds that the current welfare standards are not requisite to protect the public welfare from known and anticipated adverse effects from reduced visibility."[418]

The IPMRP further recommended – which EPA also ignored – that "[a] second draft of the PA should systematically address these issues while taking into account the implications of revisions to the 24-hour $PM_{2.5}$ standard recommended by the [IPMRP], which would have co-benefits with respect to visibility effects."[419] As discussed above, the IPMRP is not only well-qualified to provide these recommendations but also shared with EPA extensive analysis and supporting documentation, which EPA ignored.

M. EPA failed to consider research studies and data from and coordinate with the Federal Family, in coming to its secondary standards proposal.

The federal land managers (USFS, NPS, FWS, BLM) have identified visibility and other PM public welfare effects on Air Quality Related Values[420] and other impacts to the lands they are

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[418] IPMRP at 5.
[419] *Id.*
[420] The identification, monitoring and assessment of AQRVs with regard to an adverse effect is an approach used for assessing the potential for air pollution impacts from pending permit actions in Class I areas. An adverse impact is recognized by the National Park Service as one that results in diminishment of the Class I or Class II area's national significance or the impairment of the ecosystem structure or functioning, as well as impairment of the quality of the visitor experience. Federal land managers (FLMs)

responsible for managing. Inconsistent with other NAAQS assessments,[421] EPA's proposal fails to consider information from members of the Federal family, which in addition to the federal land managers include: Bureau of Indian Affairs, Department of Defense, Department of Energy, Department of Interior (U.S. Geological Survey), Department of Transportation and Federal Highway Administration, National Aeronautics and Space Admiration, National Oceanic and Atmospheric Administration, National Science Foundation, Tennessee Valley Authority, USDA (Cooperative State Research, Education and Extension Service), and USDA (U.S. Forest Service Research and Development).[422] EPA's proposal fails to evaluate considerations with regard to public welfare significance on the lands managed by the Federal family. As identified by the federal land managers, depending on the extent and severity, PM effects impact the public welfare in scenic and/or recreational areas, particularly in areas with special protection, such as Class I areas. Indeed, there is nothing in EPA's proposal to indicate it searched for recent studies and data, much less consulted with members of the federal family. We note several recent studies of interest.[423] Additionally, the U.S. National Laboratories also conduct research on PM effects.

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make such adverse impact determinations on a case-by-case basis, using technical and other information which they provide for consideration by permitting authorities. Bureau of Land Management, Air Resources Technical Report for Oil and Gas Development – New Mexico, Oklahoma, Texas and Kansas, 18-22 (March 2018), *available at* https://www.blm.gov/sites/blm.gov/files/AR_Tech_Report_2018.pdf.

421 For example, in the ozone NAAQS revision, EPA considered a dataset from the U.S. Forest Service Forest Health Monitoring/Forest Inventory and Analysis biomonitoring network program. 80 Fed. Reg. 65,292, 65,371 (Oct. 26, 2015). The Forest Service maintains numerous databases as part of its Forest Inventory and Analysis Nation Program, and there is no evidence that EPA considered any of this information in the PM analysis. U.S. Forest Service, Forest Inventory and Analysis National Program, *available at* https://www.fia.fs.fed.us/tools-data/index.php.

422 Led by NOAA, representatives of the federal family met over a seven-month period in late 2001 through the spring of 2002, and developed the "Strategic Plan for Particulate Matter." The Plan described the broad elements of an interagency research plan to focus the resources of member agencies addressing the most pressing needs of this public health and welfare issue. (cont.)
The report "lays out a conceptual framework that integrates discipline specific research in a risk assessment - risk management context. It summarizes current understanding, highlights recent accomplishments, and identifies some of the key information gaps in science to support public policy on PM. It highlights a set of policy relevant science questions and the intended impacts of ongoing Federal research to answer these questions. Science on this subject is rapidly evolving and periodic updates of this working document are anticipated." at 2, Particulate Matter Research Coordination Working Group, Air Quality Research Subcommittee of the Committee on Environment and Natural Resources, NOAA Aeronomy Laboratory, Strategic Plan for Particulate Matter, (2002), *available at* https://www.esrl.noaa.gov/csl/aqrs/reports/srppm.pdf. EPA's proposal fails to mention any coordinated planning like this.

423 Bethany K. Kunz et al., Dust Control Products at Hagerman National Wildlife Refuge, Texas: Environmental Safety and Performance. Transportation Research Record, 2472(1), 64–71 (2015), *available at* https://doi.org/10.3141/2472-08. Roger W. Surdahl et al., Stabilization and Dust Control at the Buenos Aires National Wildlife Refuge, Arizona, Transportation Research Record, 1989–1(1), 312–321 (2007), *available at* https://doi.org/10.3141/1989-37. Richard L. Reynolds et al., Concentrations of mineral aerosol from desert to plains across the central Rocky Mountains, western United States, Aeolian Research, Volume 23, 21-35 (2016), *available at* https://doi.org/10.1016/j.aeolia.2016.09.001.

For example, the Argonne National Laboratory recently issued a final report that modeled dust levels associated with solar development.[424] This study was not considered by EPA and it is unclear why not given its contents clearly contain information relevant to EPA's review.[425]

Furthermore, EPA's PM proposal is inconsistent with other analyses where the agency considered the pollutant's effects in areas with special federal protections and lands set aside by states, tribes, and public interest groups to provide similar benefits to the public welfare. 80 Fed. Reg. at 65,377. For example, in reaching his conclusion regarding the need for revision of the secondary ozone standard in the 2008 review, the Administrator took note of ''a number of actions taken by Congress to establish public lands that are set aside for specific uses that are intended to provide benefits to the public welfare, including lands that are to be protected so as to conserve the scenic value and the natural vegetation and wildlife within such areas, and to leave them unimpaired for the enjoyment of future generations." 73 Fed. Reg 16,436, 16,496 (Mar. 27, 2008). Unlike the ozone assessment, here the Administrator fails to take into consideration the "clear public interest in and value of maintaining these areas in a condition that does not impair their intended use." 80 Fed. Reg. at 65,377.

Finally, while EPA considers IMPROVE data, EPA neglects to consider information and studies from the agencies and organizations that manage IMPROVE's cooperative measurement effort. Notably, the effort is managed by the Steering Committee that consists of representatives from EPA, NPS, USFS, FWS, BLM, NOAA, four organizations representing state air quality organizations (NACAA, WESTAR, NESCAUM, and MARAMA), and three Associate Members: Arizona DEQ, Environment Canada, and the South Korea Ministry of Environment.[426] Certainly those managing the IMPROVE effort have experience and suggestions on much needed improvements.

N. EPA must consider the adverse ecological effects from PM

EPA's proposal only considers the "*non-ecological* public welfare effects associated with PM and pertaining to the presence of PM in ambient air," 85 Fed. Reg. at 24,126-7, explaining that:

[424] Y.-S. Chang et al., Modeling of Dust Levels Associated with Potential Utility-Scale Solar Development in the San Luis Valley-Taos Plateau Study Area, United States, (2016), *available at* https://www.osti.gov/biblio/1351306 (research study by the Argonne National Laboratory prepared for Bureau of Land Management that modeled dust levels during the construction and operational phases of solar facilities, identifying ways to decreased wind-blown dust generation, estimating cumulative impacts during operations and exploring whether there would be associated adverse health impacts for nearby resident from dust levels, including arsenic contaminated dust).

[425] Furthermore, as discussed above, EPA entirely ignored two lines of significant research regarding public surveys and use of clouds in the WinHaze model that involved members of the federal family.

[426] IMPROVE Program Overview, *available at* http://vista.cira.colostate.edu/Improve/improve-program/.

> Ecological effects associated with PM, and the adequacy of protection provided by the secondary PM standards for those effects, are being addressed in the separate review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and PM. *Id.* at 24,095.

EPA notes that while its "2012 decision on the adequacy of the secondary PM standards was based on consideration of the protection provided by those standards for visibility and for the non-visibility effects of materials damage, climate effects and ecological effects," for the current review, EPA decided the ecological effects would be considered separately. *Id.* at 24,127 (citing U.S. EPA, 2016, Chapter 1, section 5.2; U.S. EPA, 2020, Chapter 1, section 5.1.1).[427] EPA fails to provide any logical explanation for this decision, examine any scientific evidence or perform any risk assessments to evaluate PM's ecological welfare effects. Moreover, EPA fails "to show that compliance with statutory mandated deadlines is impossible or infeasible … [EPA's] [e]xcuses for delay must go beyond the general proposition that further study and analysis of materials will make final agency action better … because further study will always make everything better, and it is always easier to do something with more rather than less time." *Am. Lung Ass'n v. Browner*, 884 F. Supp. 345, 347 (D. Ariz. 1994) (internal references omitted).

As described above, the Clean Air Act requires secondary NAAQS to "specify a level of air quality the attainment and maintenance of which ... 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 Act further explains that "[a]ll language referring to effects on welfare includes, but is 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 well-being. *Id.* § 7602(h). Finally, the Act states that, not later than December 31, 1980, and on five-year reviews thereafter,[428] the Administrator "shall make such revisions in such ... [primary and secondary national ambient air quality] standards ... as may be appropriate." *Id.* § 7409(d)(1).

The statute is clear that the definition of welfare expressly includes ecosystem effects (soils, water, crops, vegetation, animals, wildlife, weather).[429] EPA's proposed deferral of a required final action, would effectively amount to a decision to take no action to revise the NAAQS. EPA cites no authority for evading review during this cycle. EPA's proposal to evade review is also "inconsistent with Congress' goal of carefully monitoring polluting emissions into the ambient air." *Nat. Res. Def. Council v. EPA*, 902 F.2d 962, 984 (D.C. Cir. 1990) (citing H.R.REP. No. 294, at 182)(separate opinion of Wald, J.). Furthermore, during the last review EPA found that

[427] Indeed, as discussed above, EPA has considered ecological effects in all prior reviews.
[428] *Environmental Defense Fund v. Thomas*, 870 F.2d 892, 897-98 n. 1 (2d Cir. 1989) (Sec. 109(d)(1) requires EPA to decide whether to revise standards "within the stated deadlines").
[429] Moreover, EPA's proposal fails to consider several other welfare factors (and hazards to transportation, effects on economic values and on personal comfort and well-being).

that, as discussed below, "the body of the evidence is sufficient to infer a likely causal relationship between deposition of PM and a variety of effects on individual organisms and ecosystems," and new studies only continue to support and strengthen EPA's finding. In the prior review of secondary NAAQS for NOx and SOx, EPA likewise found that existing NAAQS "do not provide adequate protection for ecosystems that are sensitive to aquatic acidification and that effects to these ecosystems are ongoing from ambient deposition of oxides of nitrogen and oxides of sulfur." 77 Fed. Reg. 20,218, 20,240 (Apr. 3, 2012). EPA further found that "there is sufficient evidence to conclude that ambient deposition under the current secondary standards is causing or contributing to terrestrial acidification as well as nutrient enrichment in sensitive ecosystems." *Id.* Moreover, EPA explained that:

> [T]he ISA has established that the major effects of concern for this review of the oxides of nitrogen and sulfur standards are associated with deposition of nitrogen and sulfur caused by atmospheric concentrations of oxides of nitrogen and sulfur. The current standards are not directed toward depositional effects, and none of the elements of the current NAAQS—indicator, form, averaging time, and level—are suited for addressing the effects of nitrogen and sulfur deposition. Additionally, although the proportion of total nitrogen loadings associated with atmospheric deposition of nitrogen varies across locations, the ISA indicates that atmospheric nitrogen deposition is the main source of new anthropogenic nitrogen to most headwater streams, high elevation lakes, and low-order streams. Atmospheric nitrogen deposition contributes to the total nitrogen load in terrestrial, wetland, freshwater and estuarine ecosystems that receive nitrogen through multiple pathways.

Id. EPA's final action summarized the data that clearly demonstrated these effects are seen across the country.[430] Moreover, EPA explained that it is confident that there is

[430] "There are expansive data to indicate that the levels of deposition under the current standards are not sufficient to prevent adverse effects in ecosystems. With regard to aquatic acidification, recent data indicate that in the Adirondacks and Shenandoah areas, rates of acidifying deposition of oxides of nitrogen and sulfur are still well above pre-acidification (1860) conditions. Forty-four percent of Adirondack lakes and 85 percent of Shenandoah streams evaluated exceed the critical load for an ANC of 50 μeq/L, and have suffered loss of sensitive fish species. With regard to terrestrial acidification, the REA evaluated a small number of sensitive areas as case studies and showed the potential for reduced growth. When the methodology was extended to a 27-state region, similar results were found to indicate the potential for growth effects in sensitive forests. Nitrogen deposition can alter species composition and cause eutrophication in freshwater systems. In the Rocky Mountains, for example, current deposition levels, which are within the range associated with ambient nitrogen oxide levels meeting the current standard, are known to cause changes in species composition in diatom communities indicating impaired water quality. With regard to terrestrial nutrient enrichment, most terrestrial ecosystems in the United States are nitrogen-limited, and therefore they are sensitive to perturbation caused by nitrogen additions. Under recent conditions, nearly all of the known sensitive mixed conifer forest ecosystems receive total nitrogen deposition levels above the ecological benchmark for changes in lichen species. In addition, in

> [S]ufficient robust science to conclude that aquatic acidification is ongoing in sensitive ecosystems, that ambient deposition of oxides of nitrogen and oxides of sulfur are causative in many ecosystems nationwide and that the current standards are neither appropriate in form nor adequate in level to protect against such effects.[431]

Nevertheless, while EPA's prior review concluded "there is sufficient evidence to conclude that ambient deposition under the current secondary standards is causing or contributing to terrestrial acidification as well as nutrient enrichment in sensitive ecosystems," EPA did nothing to ensure the secondary NAAQS are requisite to protect "ecosystems that are sensitive to aquatic acidification." Evidence of ongoing aquatic acidification continues as the current secondary standards are not requisite to protect the adverse effect on public welfare.

For example, atmospheric deposition of nitrogen is one of the main sources of pollution affecting water quality in the Chesapeake Bay and contributing to persistent eutrophication in the estuary.[432] EPA's Chesapeake Bay Program reports that ammonia emissions account for an increasing amount of the total nitrogen from atmospheric deposition entering the Bay and its tidal rivers.[433] Livestock and poultry generate airborne ammonia[434], which also contributes to the formation of PM.[435] In recent years, the total amount of poultry produced on the Delmarva

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Coastal Sage Scrub ecosystems in California, nitrogen deposition exceeds the benchmark above which nitrogen is no longer a limiting nutrient, leading to potential alterations in ecosystem composition." *Id.*

[431] *Id.* at 20241.

[432] *See* U.S. EPA, Chesapeake Bay Total Maximum Daily Load for Nitrogen, Phosphorus, and Sediment, at ES-3 (Dec. 2010), *available at* https://www.epa.gov/chesapeake-bay-tmdl/chesapeake-bay-tmdl-document ("Most of the Chesapeake Bay and its tidal waters are listed as impaired because of excess nitrogen, phosphorus and sediment. These pollutants cause algae blooms that consume oxygen and create 'dead zones' where fish and shellfish cannot survive, block sunlight that is needed for underwater Bay grasses, and smother aquatic life on the bottom.").

[433] U.S. EPA, Chesapeake Bay Program, "Atmospheric Deposition of Nitrogen in the Chesapeake", at slides 7, 39, 58 (Oct. 2017), https://www.chesapeakebay.net/channel_files/25651/atmo_dep_webinar_draft_11-1-17.pdf ("Reduced nitrogen species (largely agricultural sources) in deposition are increasing").

[434] *See, e.g.*, Siefert, R.L., J.R. Scudlark, A.G. Potter, K.A. Simonsen, and K.A. Savidge. 2004. Characterization of Atmospheric Ammonia Emissions from a Commercial Chicken House on the Delmarva Peninsula. *Environmental Science and Technology*. 38, 2769-2778.

[435] *See* Battye, W., V. P., Aneja and W. H., Schlesinger (2017), Is nitrogen the next carbon?, *Earth's Future*, *5*,894–904, doi:10.1002/2017EF000592 ("Anthropogenic reactive nitrogen produces multiple impacts at local, regional, and global scales. Emissions of NH3 and NOx contribute to the formation of fine particulate matter (PM2.5)"); Behera, S.N., Sharma, M., Aneja, V.P. et al. Ammonia in the atmosphere: a review on emission sources, atmospheric chemistry and deposition on terrestrial bodies, *Envtl. Science and Pollution Research* 20, 8092–8131 (2013), *available at* https://doi.org/10.1007/s11356-013-2051-9 ("Recent studies have indicated that NH3 emissions have been increasing over the last few decades on a global scale. This is a concern because NH3 plays a

peninsula has increased,[436] prompting questions about whether ammonia emissions and their resulting nitrogen deposition are sufficiently managed to meet the pollution reduction goals of the Chesapeake Bay Total Maximum Daily Load (TMDL)[437] and water quality standards in local waterbodies.[438] A 2018 study contributes to evidence showing that the role of ammonia emissions in formation of PM is significant.[439] EPA's decision to ignore ecological impacts of PM and its precursors in this review of the NAAQS fails to fulfill the Agency's obligations under the CAA and the Chesapeake Bay TMDL.

Moreover, EPA's assertion that the ecosystem effects are being addressed in a separate review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur and, belatedly, PM, appears to be yet another attempt by the agency to evade meaningful review and establish protective secondary PM NAAQS. As explained above, EPA foot-dragging has already been going on for more than 30 years. EPA's proposal to defer is analogous to pure agency muteness, which, unless ecosystem effects are considered in this review, amounts to a final decision not to revise.[440] *Nat. Res. Def. Council,* 902 F.2d at 987–88.

O. EPA illegally and arbitrarily failed to consider the effects of PM on the ecosystem, which are numerous and diverse

EPA fails to consider the adverse effects of PM on the various components of the ecosystem, which are numerous and diverse. Atmospheric particulate matter (PM) is a heterogeneous material and it exerts most effects on vegetation and ecosystems by virtue of the mass loading of its chemical constituents.[441] Despite EPA's prior conclusions regarding the effect of PM on the ecosystem, EPA fails to consider these effects in this review. For example, in addition to other

significant role in the formation of atmospheric particulate matter, visibility degradation and atmospheric deposition of nitrogen to sensitive ecosystems.").

[436] *See, e.g.*, Delmarva Poultry Industry, "Facts and Figures" (last visited 6/28/2020), http://www.dpichicken.org/facts/facts-figures.cfm (noting a 7.1% increase in the number of chickens raised and 24% increase in pounds of poultry produced over ten years).

[437] U.S. EPA, Chesapeake Bay Total Maximum Daily Load for Nitrogen, Phosphorus, and Sediment (Dec. 2010), *available at* https://www.epa.gov/chesapeake-bay-tmdl/chesapeake-bay-tmdl-document.

[438] *See, e.g.,* Baker, J., Battye, W.H., Robarge, W., Arya, S.P., and Aneja, V.P. 2019. "Modeling and Measurements of Ammonia from Poultry Operations: Their Emissions, Transport, and Deposition in the Chesapeake Bay," *Science of the Total Environment* 706 (2020) 135290.

[439] *See* Jason Plautz, Piercing the Haze: Ammonia, a poorly understood smog ingredient could be key to limiting deadly pollution, *Science* (Sep. 13, 2018), https://www.sciencemag.org/news/2018/09/ammonia-poorly-understood-smog-ingredient-could-be-key-limiting-deadly-pollution.

[440] EPA cannot delay decisions regarding the ecosystem and other considerations regarding PM effects on welfare to avoid judicial review. *Sierra Club v. Gorsuch,* 715 F.2d 653, 659 (D.C. Cir. 1983); *Environmental Defense Fund v. Ruckelshaus,* 439 F.2d 584, 593 (D.C. Cir. 1971).

[441] D.A. Grantz et al., Ecological effects of particulate matter, Environment International 29 213–239 (2003), *available at* https://doi.org/10.1016/S0160-4120(02)00181-2.

determinations made by EPA and CASAC summarized elsewhere in our comments, EPA's 2013 review explained that based on the conclusion of the ISA,

> [E]cological evidence is sufficient to conclude that a causal relationship is likely to exist between deposition of PM and a variety of effects on individual organisms and ecosystems (U.S. EPA, 2009a, sections 2.5.3 and 9.4.7), and also noted that vegetation and other ecosystem components are affected more by particulate chemistry than size fraction.[442]

Additionally, EPA noted that the "most direct ecosystem effects associated with particulate pollution occur in severely polluted areas near industrial point sources (quarries, cement kilns, metal smelting) (U.S. EPA, 2009a, sections 9.4.3 and 9.4.5.7).[443] Since then, as explained below and in information considered by EPA as a part of its deferred effort to assess ecological systems as a part of this review, there is substantial scientific research available to characterize the nature and magnitude of effects of PM on the ecosystem.

As presented in EPA's prior review and recent studies, known and anticipated adverse effects from PM on the ecosystem are in three areas: vegetation and soils; acid rain; and water, aquatic systems, and wildlife, which we highlight as follows.

1. EPA Failed to Consider Adverse Effects of PM on vegetation and soils

- PM can affect plant life through direct deposition on surfaces, or indirectly through altered soil chemistry.
- When directly deposited onto vegetation, PM can affect the metabolism and photosynthesis of plants by blocking light, obstructing stomata apertures, increasing their temperature, and altering pigment and mineral content.
- Fine PM has been shown to enter the leaf through the stomata, penetrate the structure of the leaf, and alter its chemistry. Coarse PM can form a "crust" on the leaf, which reduces photosynthesis, damages the leaf tissues, inhibits new growth of the tissue, and reduces starch storage.
- Plant growth is negatively impacted by the presence of trace elements and heavy metals in soils, which can then enter the plant tissue. As the plants absorb heavy metals and other pollutants via PM deposition into the soil, this can have a biomagnification effect and negatively impact the health of the people or animals that eat them.
- Studies demonstrate that increased nitrogen deposition is negatively affecting native plant communities which are adapted to live in low-nitrogen environments. These changes have enhanced invasion of exotic plant species.

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[442] 78 Fed. Reg. 3086, 3203 (Jan. 15, 2013)
[443] *Id.*

- PM impacts soil recovery around former smelters and other industries, due to the continued presence of metals in the soil.

2. EPA Failed to Consider Adverse Effects of PM and Acid Rain

- Regions where a high percent of ambient PM2.5 is composed of secondary particles such as ammonium sulfate and ammonium nitrate (e.g., the eastern US) are more likely to experience greater negative impacts of acid rain. Acid rain has negative effects on soil, water (freshwater and saltwater), aquatic ecosystems, and building materials.
- On land, acid rain can damage trees, especially at higher elevations, where exposure to acid-heavy clouds and mist is greater.
- Acid dissolves and removes the nutrients in forest soils before trees and other plants can use them to grow. At the same time, acid rain causes the release of substances that are toxic to trees and plants, such as aluminum, into the soil.
- According to the National Parks Service, acid rain and snow are serious problems in the eastern U.S. and the Colorado Rockies. Many high elevation Sierra lakes have low buffering capacity (ability to cope with acid), so it is important to minimize any future acid deposition.
- According to the National Acid Precipitation Assessment Program Report to Congress (2011)[444] and the U.S. Environmental Protection Agency, numerous negative ecosystem effects are attributed to increased acid deposition, including:

    - Impaired visibility;
    - Acidification of lakes and streams, which has a cascading effect onto fish in terms of reductions in total population, hardiness of the fish, age distribution, and size;
    - Reduction in plankton biodiversity (specific to the western US);
    - Reduction in acid neutralizing capacity;
    - Decrease in pH (increase in acidity level), which can affect the ability of certain plant, insect and aquatic species to survive;
    - High levels of nitrates in water which are toxic to aquatic life;
    - Depletion in oxygen levels of the water from accelerated plant life/death;
    - Slower growth, injury or death of forests and plant species from altered soil chemistry, and/or damage to leaves or plant organs;
    - Increases in atmospheric nitrogen deposition, which tends to decrease species diversity (particularly in alpine plant communities); and
    - Degrading effects on built structures and monuments, particularly those made of limestone, marble, lime mortars and carbonate-cemented sandstone.

[444] D.A. Burns et al., U.S. EPA Clean Air Markets Div., *National Acid Precipitation Assessment Program Report to Congress 2011: An Integrated Assessment*, National Science and Technology Council (2011), available at https://www.sciencebase.gov/catalog/item/55d5da75e4b0518e3546a50e.

3. EPA Failed to Consider Adverse Effects of PM on water, aquatic systems, and wildlife

- Some components of anthropogenic (manmade) PM such as trace metals have a particularly damaging effect on ecosystems, including mercury, a significant trace metal component of PM that moves readily through ecosystems; as well as pesticides and polyaromatic hydrocarbons (PAHs). Once deposited, these pollutants may travel through the snow pack and feed into the water system. Deposition of PM containing these compounds has been found in the Sierra Nevada mountains in California, the major source of the state's water supply;
- Physiological responses of fish to higher pollutant levels include increased mortality rates, chromosomal damage, retarded growth and development, and disruption of normal biological functions, including reduced stamina for swimming and maintaining positions in streams;
- An increase in concentrations of certain heavy metals such as aluminum, nickel, cadmium, copper, and mercury can poison fish and shellfish, and those who prey upon fish/shellfish. Deposition of PM on land and water can have a range of negative impacts on ecosystems and wildlife from the bottom of the food chain to the top, due to the process of bio-magnification or bioaccumulation;
- Atmospheric deposition of sulfur and nitrogen compounds can cause significant ecosystem effects such as acidification, eutrophication, and changes in soil and water chemistry;
- Air pollutants deposited in the aquatic environment can damage the broader ecosystem. To the extent that PM is deposited in water and then absorbed by fish, frogs, snails and other marine life, these then travel up the food chain, increasing in concentration with each step up the ladder, to fish-eating predators including bald eagles, osprey, otters, pelicans, and grizzly bears;
- Acidification of soils, lakes and streams can result in changes in community structure, biodiversity, reproduction, and decomposition;
- Due to wet deposition, the pollutants in PM2.5 can enter aquatic ecosystems and affect aquatic organisms; and
- Documented impacts in some refuges include stressed trees, acidified streams, and reduction in species of fish and other aquatic life in affected waters.

P. EPA failed to consider any recent studies regarding adverse PM effects on ecosystems

Significant new scientific evidence exists regarding adverse PM effects on ecosystems and the other evaded welfare factors, which EPA must consider during this cycle.[445] The emissions, transport, chemical reactions with and deposition of soil have various important ecological implications.[446] “Wind erosion and associated dust emissions play a fundamental role in many ecological processes and provide important biogeochemical connectivity at scales ranging from individual plants up to the entire globe.”[447]

1. Summary of recent research on chemical reactions and particulate matter

Soil deposition provides an important source of base cations (BC), enhancing, equaling, and often exceeding BC supplied by weathering. Miller et al. (1993), assessed the response of forests to a changing chemical environment. Their measurements from a high-elevation forest ecosystem in the Adirondack mountains, New York, indicated that mineral weathering reactions contribute about 70% and soil cation-exchange reactions about 30% of annual strontium exports. Their strontium isotope data indicate that 50–60% of the strontium in the organic-soil-horizon exchangeable and vegetation cation pools has an atmospheric origin, reduction of atmospheric cation inputs coupled with continued strong-acid anion inputs may result in significant depletion

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[445] Many of these studies are also discussed in the recent CASAC letter. Letter from Dr. Louis Anthony Cox, Jr., Chair, to Administrator Andrew R. Wheeler, CASAC Review of the EPA’s Integrated Science Assessment for Oxides of Nitrogen, Oxides of Sulfur, and Particulate Matter – Ecological Criteria (Second External Review Draft – June 2018) (May 5, 2020). (CASAC May 2020). (Note: our reference to this letter in no way acknowledges that EPA has the authority to pursue ecological criteria for particulate matter in the delayed manner anticipated in that effort.) Furthermore, CASAC also submitted comments on the ecological criteria in 2017. Letter from Dr. Ana Diez Roux, Chair Clean Air Scientific Advisory Committee and Dr. Ivan J. Fernandez, Chair, CASAC Secondary NAAQS Review Panel for Oxides of Nitrogen and Sulfur, to Administrator E. Scott Pruitt, CASAC Review of the EPA’s Integrated Science Assessment for Oxides of Nitrogen, Oxides of Sulfur, and Particulate Matter – Ecological Criteria (First External Review Draft – February 2017)(Sept. 28, 2017), available at https://yosemite.epa.gov/sab/sabproduct.nsf/B69A024F25E04680852581A9005140F7/$File/EPA-CASAC-17-004_.pdf. EPA’s proposal fails to include any of this information.

[446] Jason. P. Field et al., The ecology of dust, Frontiers in Ecology and the Environment, 8: 423-430 (2010), *available at* https://doi.org/10.1890/090050.

[447] *Id*. (This study “provide[s] a general overview of the ecological importance of dust, examine complex interactions between wind erosion and ecosystem dynamics from the scale of plants and surrounding space to regional and global scales, and highlight specific examples of how disturbance affects these interactions and their consequences.”);Cox, 2020, A-51 - A-65 (Mr. Richard Poirot’s comments detail the concerns in this section).

of this cation reservoir.[448] Others recent investigations of these issues include: Draaijers et al. (1997)[449] and Kennedy et al. (1998).[450]

Ballantyne et al. (2011) studied remote oligotrophic surface waters in the western U.S. and found that soil deposition is increasing primary productivity.[451] The deposition of dust has recently increased significantly over some regions of the western U.S. and they explored how changes in dust deposition have affected the biogeochemistry of two alpine watersheds in Colorado, US. The increase in dust deposition combined with its enrichment in certain elements altered the biogeochemisty of these systems. Both lakes showed an increase in primary productivity as evidenced by a decrease in carbon isotopic discrimination; however, the cause of increased primary productivity varies due to differences in watershed characteristic. This study illustrates that alpine watersheds are excellent integrators of changes in atmospheric deposition, but that the biogeochemical response of these watersheds may be mediated by their physical (i.e. watershed area) and chemical (i.e.; underlying geology) properties. Watmough et al. (2014), researched industrial activities in the oil sands region of Alberta, Canada, which have resulted in greatly elevated emissions of SO2 and N (NOx and NH3). Notably, there are concerns over possible widespread ecosystem acidification.[452]

We are also concerned about the major ecological implications of increasing total phosphorus (TP) concentrations in oligotrophic lakes and streams in all U.S. regions, documented by Stoddard et al. (2016).[453] The increases were observed over the period 2000–2014, increasing TP concentrations appear to be ubiquitous, but their presence in undeveloped catchments suggests that they cannot be entirely attributed to either point or common non-point sources of TP.

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[448] Eric. K. Miller et al., Determination of soil exchangeable-cation loss and weathering rates using Sr isotopes, Nature, vol. 362, pp 438–441 (1993), *available at* https://www.nature.com/articles/362438a0.

[449] G. P. J. Draaijers et al., Base-cation deposition in Europe—part II. Acid neutralization capacity and contribution to forest nutrition, Atmospheric Environment, 31:24 pp. 4159-4168 (1997), *available at* https://doi.org/10.1016/S1352-2310(97)00253-7.

[450] M. J. Kennedy et al., Changing sources of base cations during ecosystem development, Hawaiian Islands. Geology, 26 (11): 1015–1018 (1998), *available at* https://doi.org/10.1130/0091-7613(1998)026<1015:CSOBCD>2.3.CO;2.

[451] A. P. Ballantyne et al., Biogeochemical response of alpine lakes to a recent increase in dust deposition in the Southwestern, US, Biogeosciences, 8, 2689-2706 (2011), *available at* https://doi.org/10.5194/bg-8-2689-2011.

[452] Shaun A. Watmough et al., The importance of atmospheric base cation deposition for preventing soil acidification in the Athabasca Oil Sands Region of Canada, Science of the Total Environment, 493: 1–11 (2014), *available at* https://doi.org/10.1016/j.scitotenv.2014.05.110.

[453] John L. Stoddard et al., Continental-Scale Increase in Lake and Stream Phosphorus: Are Oligotrophic Systems Disappearing in the United States?, Environmental Science & Technology, (7) 3409-3415 (2016), *available at* https://doi.org/10.1021/acs.est.5b05950.

Another area of concern is soil and sea salt, which react readily with nitric acid, leading to formation of coarse mode CaNO3 and NaNO3. The research by Lefer er al. (2001),[454] which studied summertime measurements of the atmospheric concentrations and aerodynamic size distributions of NH4 + and NO 3- and other major aerosol species were made between 1991 and 1996 at a rural site in central Massachusetts to examine the nature of aerosol chemistry at the Harvard Forest.

A study by Lee et al. (2008)[455] reports a comprehensive characterization of atmospheric aerosol particle properties in relation to meteorological and back trajectory data in the southern Arizona region, which includes two of the fastest growing metropolitan areas in the United States (Phoenix and Tucson). Multiple data sets (MODIS, AERONET, OMI/TOMS, MISR, GOCART, ground-based aerosol measurements) are used to examine monthly trends in aerosol composition, aerosol optical depth (AOD), and aerosol size. Fine soil, sulfate, and organics dominate $PM_{2.5}$ mass in the region. Trend analyses between 1988 and 2009 indicate that the strongest statistically significant trends are reductions in sulfate, elemental carbon, and organic carbon, and increases in fine soil during the spring (March–May) at select sites. These results can be explained by population growth, land-use changes, and improved source controls. While the research by Zhang et al. (2008)[456] size-segregated water-soluble inorganic ions, including particulate sulphate (SO_4^{2-}), nitrate (NO_3^-), ammonium (NH_4^+), chloride (Cl^-), and base cations (K^+, Na^+, Mg^{2+}, Ca^{2+}), during were measured using a Micro-Orifice Uniform Deposit Impactor (MOUDI) during fourteen short-term field campaigns at eight locations in both polluted and remote regions of eastern and central Canada. Seasonal contrasts in the size-distribution profiles suggest that emission sources and air mass origins were the major factors controlling the size distributions of the primary aerosols while meteorological conditions were more important for the secondary aerosols.

Brahney et al. (2013a)[457] evaluated potential changes in sources of calcium to the atmosphere including soil erosion, industrial emissions, forest fires, and sea-salt aerosols to determine the cause of rising atmospheric calcium deposition. Based on their evaluation, the most parsimonious explanation for increased Ca^{2+} deposition is an increase in mineral aerosol emissions from within the western U.S. This explanation is corroborated by independent

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[454] B. L. Lefer et al., Summertime measurements of aerosol nitrate and ammonium at a northeastern US site, J. Geophys. Res., 106, 20365–20378 (2001), *available at* https://agupubs.onlinelibrary.wiley.com/doi/pdf/10.1029/2000JD900693.
[455] Taehyoung Lee et al., Observations of fine and coarse particle nitrate at several rural locations in the United States. Atmospheric Environment, 42. 2720-2732 (2008), *available at* https://doi.org/10.1016/j.atmosenv.2007.05.016.
[456] L. Zhang, Characterization of the size-segregated water-soluble inorganic ions at eight Canadian rural sites, Atmos. Chem. Phys., 8, 7133–7151 (2008), *available at* https://doi.org/10.5194/acp-8-7133-2008.
[457] J. Brahney, et al., Increasing Ca^{2+}deposition in the Western US: The role of mineral aerosols, Aeolian Research (2013a), *available at* https://doi.org/10.1016/j.aeolia.2013.04.003.

evidence showing increases in the frequency of dust storms and low-visibility days across regions of the western U.S. Furthermore, their analysis indicates that the increase in mineral aerosol emissions is most likely due to (1) increased aridity and wind transport; and (2) increased area and intensity of upwind human activities. Changes in atmospheric dust concentrations can have important ecological implications through the contribution of acid neutralizing capacity to both precipitation and regions of deposition. Thus, increased dust emissions have the potential to ameliorate the detrimental effects of acid precipitation on terrestrial ecosystems, in addition to exacerbating the impacts of air quality on human health.

Additionally, the study by Allen et al. (2015)[458] involved inorganic aerosol composition that was measured in the southeastern United States, a region that exhibits high aerosol mass loading during the summer, as part of the 2013 Southern Oxidant and Aerosol Study (SOAS) campaign. They suggest the nitrate aerosol forms by multiphase reactions of HNO_3 and particles, reactions that are facilitated by transport of crustal dust and sea spray aerosol from a source within the United States. Finally, Bian et al. (2017)[459] performed an assessment of global particulate nitrate and ammonium aerosol based on simulations from nine models participating in the Aerosol Comparisons between Observations and Models (AeroCom) phase III. They noted that it is critical to correctly account for contributions of heterogeneous chemical production of nitrate on dust and sea salt, because this process overwhelmingly controls atmospheric nitrate production (typically > 80 %) and determines the coarse- and fine-mode distribution of nitrate aerosol.

2. Summary of recent research on airborne particulate matter, none of which were considered by EPA

Globally, more than 40% of the total aerosol nitrate is associated with crustal dust (Usher et al. 2003).[460] Thus, soil is an important, often dominant contributor to particulate nitrate deposition. Griffin et al. (2001) note that airborne soil is also an important source and transport host of bioaerosols, which cause or contribute to a variety of environmental effects.[461] Movement of soil particles in atmospheres is a normal planetary process. On Earth, desert soils moving in 2. the atmosphere are responsible for the orange hues in brilliant sunrises and sunsets. In severe dust

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[458] H. M. Allen et al., Influence of crustal dust and sea spray supermicron particle concentrations and acidity on inorganic NO3 aerosol during the 2013 Southern Oxidant and Aerosol Study, Atmos. Chem. Phys., 15, 10669–10685 (2015), *available at* https://doi.org/10.5194/acp-15-10669-2015.

[459] Huisheng Bian et al., Investigation of global particulate nitrate from the AeroCom phase III experiment, Atmos. Chem. Phys., 17, 12911-12940 (2017), *available at* https://doi.org/10.5194/acp-17-12911-2017.

[460] Usher et al., Reactions on mineral dust, Chem. Rev., 103, 4883–4939 (2003), *available at* https://doi.org/10.1021/cr020657y.

[461] Dale W. Griffin et al., Dust in the wind: Long range transport of dust in the atmosphere and its implications for global public and ecosystem health, Global Change and Human Health, Vol. 2 No. 1, pp 20-23 (2001), *available at* https://doi.org/10.1023/A:1011910224374.

storm events, millions of tons of soil may be moved across great expanses of land and ocean. An emerging scientific interest in the process of soil transport in the Earth's atmosphere is in the field of public and ecosystem health. Their article addresses the benefits and the potential hazards associated with exposure to particle fallout as clouds of desert dust traverse the globe.[462]

Shinn et al. (2000)[463] noted that the vitality of Caribbean coral reefs underwent a continual state of decline since the late 1970s, a period of time coincidental with large increases in transatlantic dust transport. It is proposed that the hundreds of millions of tons/year of soil dust that have been crossing the Atlantic during the last 25 years could be a significant contributor to coral reef decline and may be affecting other ecosystems. Benchmark events, such as near synchronous Caribbean-wide mortalities of acroporid corals and the urchin *Diadema* in 1983, and coral bleaching beginning in 1987, correlate with the years of maximum dust flux into the Caribbean. Besides crustal elements, in particular Fe, Si, and aluminosilicate clays, the dust can serve as a substrate for numerous species of viable spores, especially the soil fungus *Aspergillus*. *Aspergillus sydowii*, the cause of an ongoing Caribbean-wide seafan disease, has been cultured from Caribbean air samples and used to inoculate sea fans.

Research by Garrison et al. (2003),[464] followed Shinn's work and put forward a hypothesis that addresses the widespread distribution of coral diseases and lack of recovery on coral reefs, their report presents an overview of the atmospheric transport of African and Asian dust; reviews relevant background information and current research on airborne microorganisms, coral diseases, and atmospheric transport of chemical contaminants; and suggests causal mechanisms and strategic avenues of investigation. The National Park Service explains that these airborne dust impacts on marine environments are of significant concern to the National Park Service responsible for managing air quality at the Virgin Islands National Park.[465] The tradewinds blowing across the tropical Atlantic ocean bring millions of tons of dust from the Sahara and Sahel regions of Africa to the Caribbean every year. The dust that reaches the Caribbean limits visibility and research indicates that this dust also contains viable bacteria and fungi, nutrients, metals, and persistent organic pollutants (e.g., pesticides, PAHs, PCBs) (Garrison et al. 2003,

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[462] *See also*, James K. M. Brown et al., Aerial Dispersal of Pathogens on the Global and Continental Scales and Its Impact on Plant Disease, Science, Vol. 297, Issue 5581, pp. 537-541 (2002), *available at* https://science.sciencemag.org/content/297/5581/537.full.
[463] Eugene A. Shinn et al., African Dust and the Demise of Caribbean Coral Reefs,Geophys. Res. Lett., VOL. 27, NO. 19, pp 3029-3032 (2000), *available at* https://doi.org/10.1029/2000GL011599.
[464] Virginia. H. Garrison et al., African and Asian Dust: From Desert Soils to Coral Reefs, BioScience, Volume 53, Issue 5, 1, Pages 469–480 (2003), *available at* https://doi.org/10.1641/0006-3568(2003)053[0469:AAADFD]2.0.CO;2.
[465] National Park Service Series: Park Air Profiles, Virgin Islands National Park, available at https://www.nps.gov/articles/airprofiles-viis.htm.

Kellogg and Griffin 2006). A particular soil fungus detected, *Aspergillus sydowii*, causes sea fan disease and results in widespread coral mortality.[466]

Holmes et al. (2004)[467] noted that Saharan dust is persistently transported and deposited in ecosystems of the western Atlantic Ocean. This dust is an aggregate of clay and quartz particles cemented with iron oxides. Samples collected and analyzed from Mali (central Africa), the Azores, the Caribbean and the Eastern United States document the levels of minor and trace metals in the dust. Metal loadings, particularly the toxic elements—mercury and arsenic, are significantly higher than average crustal rocks. Over the past decade, the focus has been to understand the cycling of mercury in south Florida, but arsenic has received very little attention. Arsenic in the sediment deposited in the past decade in south Florida averages 14 mg/kg and appears to be correlated with aluminum, a proxy for dust. The largest available aerosol data set containing arsenic is the IMPROVE (Interagency Monitoring of Protected Visual Environments) data set. The average concentrations in aerosols collected during this program range from 17 mg/kg in the Virgin Islands to 79 mg/kg at Chassahowitzka, Florida. At Chassahowitzka, most of the As appears to be associated with organic carbon. If it is assumed that the concentrations in Mali dust and in the aerosols in the Virgin Islands are indicative of soil dust, then the higher values at Chassahowitzka may be derived from local or regional sources. A simple calculation indicates that African dust supplies about 25% of the arsenic deposited from aerosols in the southeastern United States. Comparison of the average yearly arsenic concentrations measured in the Virgin Islands and Everglades shows a negative relationship with the North Atlantic Oscillation (NAO). This relationship demonstrates the influence of climate on the transport and deposition of aerosols to the southeastern United States.

The efforts cited by the National Park Service by Kellogg et al. (2006)[468] look at desert winds that aerosolize several billion tons of soil-derived dust each year, including concentrated seasonal pulses from Africa and Asia. These transoceanic and transcontinental dust events inject a large pulse of microorganisms and pollen into the atmosphere and could therefore have a role in transporting pathogens or expanding the biogeographical range of some organisms by facilitating long-distance dispersal events. Huge dust events create an atmospheric bridge over land and sea, and the microbiota contained within them could impact downwind ecosystems.

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[466] The NPS coordinates with scientists from agencies including USGS and NASA to study the connections between atmospheric dust events and the health of coral reefs.
[467] C. W. Holmes et al., Atmospherically transported elements and deposition in the Southeastern United States: Local or transoceanic?. Applied Geochemistry, 19. 1189-1200 (2004), *available at* https://doi.org/10.1016/j.apgeochem.2004.01.015.
[468]Christina A. Kellogg et al., Aerobiology and the global transport of desert dust, Trends in Ecology and Evolution, Vol.21 No.11 (2006), *available at* https://doi.org/10.1016/j.tree.2006.07.004.

Such dispersal is of interest because of the possible health effects of allergens and pathogens that might be carried with the dust.[469]

The study by Haller et al. (2011)[470] presents measurements showing the presence of biological material within frequent dust storms in the western United States. Previous work has indicated that biological particles were enhancing the impact of dust storms on the formation of clouds. This paper presents multiple case studies, between April and May 2010, showing the presence of and quantifying the amount of biological material via an Ultraviolet Aerodynamic Particle Sizer during dust events. All dust storms originated in the Four Corners region in the western United States and were measured at Storm Peak Laboratory, a high elevation facility in northwestern Colorado. From an Aerodynamic Particle Sizer, the mean dust particle size during these events was approximately 1 μm, with number concentrations between 6 cm^{-3} and 12 cm^{-3}. Approximately 0.2% of these dust particles had fluorescence signatures, indicating the presence of biological material.

Related to Haller's research, Fröhlich-Nowoisky et al. (2016)[471] noted that aerosols of biological origin play a vital role in the Earth system, particularly in the interactions between atmosphere, biosphere, climate, and public health. Airborne bacteria, fungal spores, pollen, and other bioparticles are essential for the reproduction and spread of organisms across various ecosystems, and they can cause or enhance human, animal, and plant diseases. Moreover, they can serve as nuclei for cloud droplets, ice crystals, and precipitation, thus influencing the hydrological cycle and climate. The sources, abundance, composition, and effects of biological

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469 EPA's history and present day engagement with other agencies and governments on responses to these well-documented huge dust events make it nonsensical for the agency to now suggest that it is unaware and incapable of addressing these events. For example, regarding impacts to the U.S. environment and public welfare from neighboring countries, EPA works cooperatively with the Canadian and Mexican governments to study and explore solutions. Additionally, EPA, U.S.A.I.D. and other members of the Federal Family identified above devote resources to international capacity building to improve public health, welfare and the environment across the world. (e.g., EPA Office of International Cooperation and Tribal Affairs (OITA), which "leads EPA's international and tribal engagements, working across EPA's programs and regions to develop and implement policy and programs that protect U.S. public health and the environment." https://www.epa.gov/aboutepa/about-office-international-and-tribal-affairs-oita. As OITA's website explains, "[b]ecause pollution does not respect international boundaries, OITA works with other federal agencies and international organizations and individual countries to address bilateral, regional, and global environmental challenges and advance U.S. foreign policy objectives." In fact, OITA has numerous current and recent activities in Sub-Saharan Africa, including assistance in air quality management planning. https://www.epa.gov/international-cooperation/epa-collaboration-sub-saharan-africa.

470 A. Gannet Haller et al., Atmospheric bioaerosols transported via dust storms in the western United States, Geophys. Res. Lett., 38, L17801 (2011), *available at* https://doi.org/10.1029/2011GL048166.

471 Janine Fröhlich-Nowoisky et al., Bioaerosols in the Earth system: Climate, health, and ecosystem interactions, Atmospheric Research, 182:346–376 (2016), *available at* https://doi.org/10.1016/j.atmosres.2016.07.018.

aerosols and the atmospheric microbiome are, however, not yet well characterized and constitute a large gap in the scientific understanding of the interaction and co-evolution of life and climate in the Earth system. Their review presents an overview of the state of bioaerosol research, highlights recent advances, and outlines future perspectives in terms of bioaerosol identification, characterization, transport, and transformation processes, as well as their interactions with climate, health, and ecosystems, focusing on the role bioaerosols play in the Earth system.

Dust-related "Valley Fever" (*Coccidioides*) is well documented in dogs, cats and horses, and presumably affects other mammals as well. Tong et al. (2017)[472] noted that climate models have consistently projected a drying trend in the southwestern United States, aiding speculation of increasing dust storms in this region. Long-term climatology is essential to documenting the dust trend and its response to climate variability. They reconstructed long-term dust climatology in the western United States, based on a comprehensive dust identification method and continuous aerosol observations from the Interagency Monitoring of Protected Visual Environments (IMPROVE) network. They reported direct evidence of rapid intensification of dust storm activity over American deserts in the past decades (1988–2011), in contrast to reported decreasing trends in Asia and Africa. The frequency of windblown dust storms has increased 240% from 1990s to 2000s. This dust trend is associated with large-scale variations of sea surface temperature in the Pacific Ocean, with the strongest correlation with the Pacific Decadal Oscillation. They further investigated the relationship between dust and Valley fever, a fast-rising infectious disease caused by inhaling soil-dwelling fungus (Coccidioides immitis and C. posadasii) in the southwestern United States. The frequency of dust storms is found to be correlated with Valley fever incidences, with a coefficient (r) comparable to or stronger than that with other factors believed to control the disease in two endemic centers (Maricopa and Pima County, Arizona).

3. Summary on recent research on improvements in sampling particulate matter

Duniway et al. (2019)[473] reported on the design and efficacy of a new dry deposition sampler (Dry Deposition Sampling Unit (DSU)), a method that quantifies the gravitational flux of dust particles. The sampler can be used alone or within existing networks such as those employed by the National Atmospheric Deposition Program (NADP). Because the samplers are deployed sterile and the use of water to remove trapped dust is not required, this method allows for the recovery of unaltered dry material suitable for subsequent chemical and microbiological analyses. The samplers were tested in the laboratory and at 15 field sites in the western United

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[472] Daniel Q. Tong et al., Intensified dust storm activity and Valley fever infection in the southwestern United States, Geophys. Res. Lett., 44, 4304–4312 (2017), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6108409/.

[473] M. C. Duniway et al., Wind erosion and dust from US drylands: a review of causes, consequences, and solutions in a changing world. Ecosphere 10(3): e02650 (2019), *available at* https://doi.org/10.1002/ecs2.2650.

States. With respect to material retention, sampler performance far exceeded commonly used methods. Retrieval efficiency was >97% in all trials and the sampler effectively preserved grain size distributions during wind exposure experiments. Field tests indicated favorable comparisons to dust-on-snow measurement across sites (r^2 0.70, $p < 0.05$) and within sites to co-located aerosol data (r^2 0.57–0.99, $p < 0.05$). The inclusion of dust deposition and composition monitoring into existing networks increases spatial and temporal understanding of the atmospheric transport of materials and substantively furthers knowledge of the effects of dust on terrestrial ecosystems and human exposure to dust and associated deleterious compounds.

4. Recent studies on the impact of dust in the western U.S. ecosystems

The work by Brahney et al. (2013)[474] also considered if the atmospheric transport and deposition of aerosols has the potential to influence the chemistry and biology of oligotrophic alpine lakes. In recent decades, dust and nitrogen emissions to alpine ecosystems have increased across large areas of the western U.S., including Wyoming. They used sediment geochemistry and 87Sr/86Sr and 143Nd/144Nd isotopes to examine historical dust deposition rates to alpine lakes in the southwestern region of the Wind River Range, Wyoming. They evaluate the biological response using diatom fossil assemblages and sediment pigment concentrations. Sediment core analyses indicated that prior to a recent rise in dust flux, phosphorus concentrations and species composition were similar to those found in other alpine lakes in the region. Concomitant with a 50-fold increase in dust flux to the sediments circa 1940, sediment proxies revealed a two- to threefold increase in normalized sediment phosphorus content, an increase in the diatom-inferred total dissolved phosphorus concentration from 4 to 9-12 lg L21 , a tenfold increase in diatom production, and a relative increase in cyanobacteria abundance. The increase in dust influx during the 20th century appears to be due in part to human factors and demonstrates the potential for dust and other atmospheric pollutants to significantly alter remote aquatic ecosystems.

Clow et al. (2016)[475] noted that mountain snowpacks are a vital natural resource for ∼1.5 billion people in the northern Hemisphere, helping to meet human and ecological demand for water in excess of that provided by summer rain. Springtime warming and aeolian dust deposition accelerate snowmelt, increasing the risk of water shortages during late summer, when demand is greatest. While climate networks provide data that can be used to evaluate the effect of warming on snowpack resources, there are no established regional networks for monitoring aeolian dust deposition to snow. They tested the hypothesis that chemistry of snow, wet deposition, and aerosols can be used as a surrogate for dust deposition to snow and analyzed spatial patterns and temporal trends in inferred springtime dust deposition to snow across the Rocky Mountains,

[474] *Id.*

[475] David W. Clow et al., Increasing Aeolian dust deposition to snowpacks in the Rocky Mountains inferred from snowpack, wet deposition, and aerosol chemistry, Atmos. Environ., 146, 183–194 (2016), *available at* https://doi.org/10.1016/j.atmosenv.2016.06.076.

USA, for 1993–2014. Geochemical evidence, including strong correlations ($r2 \geq 0.94$) between Ca^{2+}, alkalinity, and dust concentrations in snow deposited during dust events, indicate that carbonate minerals in dust impart a strong chemical signature that can be used to track dust deposition to snow. Spatial patterns in chemistry of snow, wet deposition, and aerosols indicate that dust deposition increases from north to south in the Rocky Mountains, and temporal trends indicate that winter/spring dust deposition increased by 81% in the southern Rockies during 1993–2014. Using a multivariate modeling approach, they determined that increases in dust deposition and decreases in springtime snowfall combined to accelerate snowmelt timing in the southern Rockies by approximately 7–18 days between 1993 and 2014. Previous studies have shown that aeolian dust emissions may have doubled globally during the 20th century, possibly due to drought and land-use change. Climate projections for increased aridity in the southwestern U.S., northern Africa, and other mid-latitude regions of the northern Hemisphere suggest that aeolian dust emissions may continue to increase, compounding the risk that climate warming poses to snowpack water resources in arid/semi-arid regions of the world. [476]

The study by Hand et al. (2016)[477] focused on trends in the southwestern U.S. and noted that Particulate matter $(PM)_{2.5}$ dust concentrations (mineral particles with aerodynamic diameters less than 2.5 μm) typically peak in spring and early summer at rural and remote sites across the southwestern United States. Trend analyses indicate that springtime regional mean $PM_{2.5}$ dust concentrations have increased from 1995 to 2014, especially in March ($5.4\%\ yr^{-1}$, $p < 0.01$). This increase reflects an earlier onset of the spring dust season across the Southwest by 1 to 2 weeks over the 20-year time period. March dust concentrations were strongly correlated with the Pacific Decadal Oscillation index ($r = -0.65$, $p < 0.01$), which was mostly in its negative phase from 2007 to 2014, during which the region was drier, windier, and less vegetated. The positive spring trend and its association with large-scale climate variability have several important implications for visibility, particulate matter, health effects, and the hydrologic cycle in the region.

Follow-on research by Hand et al. (2017)[478] suggested that understanding the spatial and temporal variability in fine mineral dust (FD, mineral aerosols with diameters less than 2.5 μm) and coarse aerosol mass (CM, mass of aerosols with diameters between 2.5 and 10 μm) is

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[476] *See also* these related studies, Thomas H. Painter et al., Impact of disturbed desert soils on duration of mountain snow cover, Geophys. Res. Lett., 34, L12502 (2007), *available at* https://doi.org/10.1029/2007GL030284; and Louis A. Derry et al., Contributions from Earth's Atmosphere to Soil, Elements, Vol. 3. pp. 333-338 (2007), *available at* http://www.geo.cornell.edu/eas/PeoplePlaces/Faculty/derry-new/publications/derry-chadwick_elements_07.pdf.
[477] J. L. Hand et al., Earlier onset of the spring fine dust season in the southwestern United States, Geophys. Res. Lett., 43,4001–4009 (2016), *available at https://doi.org/10.1002/2016GL068519*.
[478] J. L. Hand et al., Spatial and seasonal variability in fine mineral dust and coarse aerosol mass at remote sites across the United States, J. Geophys. Res. Atmos., 122, 3080–3097 (2017), *available at* https://doi.org/10.1002/2016JD026290.

important for accurately characterizing and perhaps mitigating their environmental and climate impacts. The spatial and seasonal variability of ambient FD and CM was characterized at rural and remote sites across the United States for 2011–2014 using concentration and elemental chemistry data from the Interagency Monitoring of Protected Visual Environments (IMPROVE) aerosol monitoring network. FD concentrations were highest (and had ≥50% contributions to $PM_{2.5}$ mass) in the southwestern United States in spring and across the central and southeastern United States in summer (20–30% of $PM_{2.5}$ mass). CM was highest across the Southwest and southern Great Plains in spring and central United States in spring, summer, and fall (≥70% contributions to PM_{10} mass). Similar FD and CM seasonal variability was observed near source regions in the Southwest, but a seasonal decoupling was observed in most other regions, suggesting the contribution of nonlocal sources of FD or perhaps non-dust-related CM. The seasonal and spatial variability in FD elemental ratios (calcium, iron, and aluminum) was fairly uniform across the West; however, in the eastern United States a shift in summer elemental composition indicated contributions from nonlocal source regions (e.g., North Africa). Finally, long-term trend analyses (2000–2014) indicated increased FD concentrations during spring at sites across the Southwest and during summer and fall in the southeastern and central United States.

The recent work by Achakulwisut et al. (2017)[479] also contributes to additional understanding of the western region and notes that soil-derived particulate matter, also known as mineral dust, contributes to air quality degradation, visibility reduction, and public health risks in the western United States, where abundant arid lands serve as dust sources. Dust is also transported here from Asian deserts across the Pacific Ocean. Improved understanding of how meteorology influences airborne dust levels in the present day can help assess future changes due to human-caused climate change. Using statistical methods, they identify the key drivers of year-to-year changes in springtime dust across the West to be regional precipitation, temperature, and soil moisture. These drivers are in turn influenced by the El Niño–Southern Oscillation (ENSO) and Pacific Decadal Oscillation (PDO). Trans-Pacific transport of Asian dust also contributes to the observed dust variations. They find that dust levels have been increasing in southwestern regions between 2002 and 2015. This increase is associated with (1) regionally drier and warmer conditions associated with ENSO and PDO, (2) declines in soil moisture across North American deserts, and (3) stronger transport of Asian dust. With the U.S. Southwest projected to experience severe and persistent droughts in coming decades due to climate change, our results suggest that this region could also become increasingly dustier. Furthermore, with the onset of the springtime soil peak in the SW US is occurring earlier in the year, where - depositing on the snowpack - it may contribute to earlier snowmelt, adversely affecting hydrological cycles.

[479] Pattanun Achakulwisut et al., What controls springtime fine dust variability in the western United States? Investigating the 2002–2015 increase in fine dust in the U.S. Southwest, Journal of Geophysical Research: Atmospheres, 122:12,449 – 12,467 (2017), *available at* https://doi.org/10.1002/2017JD027208.

Neff et al. (2005, 2008)[480] also studied soils in the western U.S., with a focus on Utah They noted that many soils in southeastern Utah are protected from surface disturbance by biological soil crusts that stabilize soils and reduce erosion by wind and water. When these crusts are disturbed by land use, soils become susceptible to erosion. Their study compared a never-grazed grassland in Canyonlands National Park with two historically grazed sites with similar geologic, geomorphic, and geochemical characteristics that were grazed from the late 1800s until 1974. They showed that, despite almost 30 years without livestock grazing, surface soils in the historically grazed sites have 38–43% less silt, as well as 14– 51% less total elemental soil magnesium, sodium, phosphorus, and manganese content relative to soils never exposed to livestock disturbances. Using magnetic measurement of soil magnetite content (a proxy for the stabilization of far-traveled eolian dust) they suggest that the differences in magnesium, sodium, phosphorus, and manganese are related to wind erosion of soil fine particles after the historical disturbance by livestock grazing. Historical grazing may also lead to changes in soil organic matter content including declines of 60–70% in surface soil carbon and nitrogen relative to the never-grazed sites. Collectively, the differences in soil carbon and nitrogen content and the evidence for substantial rock-derived nutrient loss to wind erosion implies that livestock grazing could have long-lasting effects on the soil fertility of native grasslands in this part of southeastern Utah. This study suggests that nutrient loss due to wind erosion of soils should be a consideration for management decisions related to the long-term sustainability of grazing operations in arid environments.

5. Recent studies on the spatial and seasonal variability in urban and rural aerosol concentrations on a continental scale

Hand et al. (2012)[481] used speciated aerosol composition data from the rural Interagency Monitoring for Protected Visual Environments (IMPROVE) network and EPA's urban/suburban Chemical Speciation Network (CSN), which were combined to evaluate and contrast the $PM_{2.5}$ composition and its seasonal patterns at urban and rural locations throughout the United States. They examined the 2005–2008 monthly and annual mean mass concentrations of $PM_{2.5}$ ammonium sulfate (AS), ammonium nitrate (AN), particulate organic matter (POM), light-absorbing carbon (LAC), mineral soil, and sea salt from 168 rural and 176 urban sites. Urban and rural AS concentrations and seasonality were similar, and both were substantially higher in the eastern United States. Urban POM and LAC concentrations were higher than rural concentrations and were associated with very different seasonality depending on location. The

[480] J. C. Neff et al., Multidecadal impacts of grazing on soil physical and biogeochemical properties in southeast Utah, Ecol. Appl., 15, 87–95 (2005), *available at* https://doi.org/10.1890/04-0268; J. C. Neff et al., Increasing Aeolian dust deposition in the western United States linked to human activity, Nat. Geosci., 1(3), 189–195 (2008), *available at* https://www.nature.com/articles/ngeo133.
[481] J. L. Hand et al., Seasonal composition of remote and urban fine particulate matter in the United States, J. Geophys. Res. Vol. 117, D05209 (2012), *available at* https://doi.org/10.1029/2011JD017122.

highest urban and rural POM and LAC concentrations occurred in the southeastern and the northwestern United States. Wintertime peaks in AN were common for both urban and rural sites, but urban concentrations were several times higher, and both were highest in California and the Midwest. Fine soil concentrations were highest in the Southwest, and similar regional patterns and seasonality in urban and rural concentrations suggested impacts from long-range transport. Contributions from sea salt to the $PM_{2.5}$ budget were non-negligible only at coastal sites. This analysis revealed spatial and seasonal variability in urban and rural aerosol concentrations on a continental scale and provided insights into their sources, processes, and lifetimes.

6. Recent studies on the human-dust cycle interactions impact on ecosystems

The Webb et al. (2018)[482] research covered anthropogenic land use and land cover change, including local environmental disturbances, moderate rates of wind-driven soil erosion and dust emission. These human-dust cycle interactions impact ecosystems and agricultural production, air quality, human health, biogeochemical cycles, and climate. While the impacts of land use activities and land management on aeolian processes can be profound, the interactions are often complex and assessments of anthropogenic dust loads at all scales remain highly uncertain. Here, they critically reviewed the drivers of anthropogenic dust emission and current evaluation approaches. Then they identified and described opportunities to: (1) develop new conceptual frameworks and interdisciplinary approaches that draw on ecological state-and-transition models to improve the accuracy and relevance of assessments of anthropogenic dust emissions; (2) improve model fidelity and capacity for change detection to quantify anthropogenic impacts on aeolian processes; and (3) enhance field research and monitoring networks to support dust model applications to evaluate the impacts of disturbance processes on local to global-scale wind erosion and dust emissions.

Finally, as noted by the CASAC, it is important that EPA's analysis include the soil or "crustal material" component of PM because it is typically the largest component of coarse particle mass ($PM_{10-2.5}$), and larger particles dry deposit more efficiently than small ones. Airborne soil could be a significant source of cations (Ca+, Mg++, K+, Na+, etc.) that may partially buffer acidifying deposition. Furthermore, it is the one component of PM that appears to be increasing - at least in some regions and seasons, which we noted above EPA fails to address. While most other components of PM (SO4, NO3, NH4, POM, EC) are decreasing over time in most regions, soil has not recently decreased anywhere and so is becoming a proportionately larger contributor to PM in most U.S. regions. Absolute concentrations of fine soil and coarse mass (presumably mostly soil) and wet deposition of soil-related elements are increasing in several regions in the western U.S., especially during the spring.

[482] Nicholas P. Webb et al., Quantifying Anthropogenic Dust Emissions, Earth's Future, 6: 286295 (2018), *available at* https://doi.org/10.1002/2017EF000766.

In sum, this is but a small fraction of the wealth of new scientific and technical information available since the last review. EPA must fully consider all new scientific information as it lacks authority to defer action beyond the statutorily mandated five-year cycle and a final decision that evades welfare factors is incomplete, arbitrary, and unlawful.

Q. The Administrator's reliance on CASAC recommendations for his decision on the secondary standards is unwarranted and unreasonable in light of the assessment and recommendations by the PM Panel and Prior CASACs, as well as the scientific evidence

The Administrator references advice from CASAC as part of the bases for his proposed decisions. 85 Fed. Reg. at 24,127 ("The Administrator's rationale also takes into account the PA's evaluation of the policy-relevant information in the ISA and quantitative analyses of air quality related to visibility impairment and the CASAC's advice and recommendations, as reflected in discussions of the drafts of the ISA and PA at public meetings and in the CASAC's letters to the Administrator."); 85 Fed. Reg. at 24135 ("In reaching proposed conclusions on the current secondary PM standards, the Administrator takes into account policy relevant evidence-based and quantitative information-based considerations, as well as advice from the CASAC. … Section IV.D.2 describes advice received from the CASAC on the secondary standards"). As discussed extensively above, CASAC lacks the range and depth of expertise to provide advice on the secondary standards.

Therefore, while the CASAC provided advice to the agency in several areas regarding the adequacy of and revisions to the secondary standards, that advice is not entitled to any weight in this review. For example, the Administrator needs to discount advice provided as part of its review of the draft PA, where the CASAC opined on the adequacy of the current secondary PM standards, for in addition to lacking the expertise, the following statements were conclusory, not supported by the scientific evidence, and counter to the IPMRP and prior CASAC recommendations:

- The CASAC concurs with staff's overall preliminary conclusions that it is appropriate to consider retaining the current secondary PM standards without revision (Cox, 2019a). 85 Fed. Reg. at 24,137.

- The CASAC ''finds much of the information . . . on visibility and materials effects of PM2.5 to be useful, while recognizing that uncertainties and controversies remain about the best ways to evaluate these effects'' (Cox, 2019a, p. 13 of consensus responses). 85 Fed. Reg. at 24,137.

- When considering the overall body of scientific information for PM-related effects on visibility, materials, and climate, the CASAC agrees that ''the available evidence does not call into question the protection afforded by the current secondary PM standards and concurs that they should be retained'' (Cox, 2019a, p. 3 of letter). 85 Fed. Reg. at 24,137.

Moreover, the Administrator inappropriately relies on advice from the ill-suited CASAC members in the proposed notice. For example:

- He asserts that his conclusions on the secondary standards are consistent with advice from the CASAC, which agrees ''that the available evidence does not call into question the protection afforded by the current secondary PM standards'' and recommends that the secondary standards ''should be retained'' (Cox, 2019a, p. 3 of letter). 85 Fed. Reg. at 24,139.

- The Administrator proposes to retain those standards (*i.e.,* the current 24-hour and annual PM2.5 standards, 24-hour PM10 standard), without revision, in part based on his consideration of CASAC advice on the secondary standards. 85 Fed. Reg. at 24,139.

XI. Conclusion and Summary of Recommendations

EPA's proposal to retain the current PM primary NAAQS cannot lawfully be finalized because it fails to satisfy the requirements of the Clean Air Act, and reflects arbitrary and capricious decision-making. EPA must reopen the review process to ensure that the Agency satisfies its statutory obligations, as the current NAAQS review process has been marred by critical process flaws that have rendered it unlawful and undermined the scientific basis for this proposed rule. EPA implemented significant changes that truncated the review process and deviated from past practice and the CASAC-approved IRP in ways that impaired the CASAC's ability to conduct its statutorily required external review. 42 U.S.C. § 7409(d). These changes included having CASAC review the draft PM PA before the PM ISA had been finalized, a procedure the full CASAC referred to as "unusual."[483] In addition to being unusual, this change subverted the logically sequential process intended to separate the science and policy considerations. EPA also refused to provide revised drafts of these documents for review, as contemplated by the IRP, despite prior experience showing that these documents often require substantial revisions. EPA's deviation from the IRP without a reasoned explanation was arbitrary and capricious, as was the Agency's implementation of a new schedule and process that failed to provide the CASAC an opportunity for meaningful scientific review.

Furthermore, even if EPA had provided CASAC an adequate review opportunity, the committee lacked the necessary expertise to conduct a meaningful scientific review. EPA unlawfully and arbitrarily excluded recipients of EPA grants from consideration for CASAC membership and

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[483] Clean Air Sci. Advisory Comm. EPA-CASAC-20-001, 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), (Dec. 16, 2019), https://yosemite.epa.gov/sab/sabproduct.nsf/E2F6C71737201612852584D20069DFB1/$File/EPA-CASAC-20-001.pdf.

disbanded the PM Panel previously assembled to assist CASAC in its review by providing additional expertise. Despite a request from CASAC, EPA declined to reinstate the expert PM Panel, and instead created a smaller panel of consultants who were incapable of providing the necessary assistance to CASAC. The unbalanced composition of CASAC, which for this review included only one academic research scientist, and the lack of NAAQS review experience among most of the members, further contributed to CASAC's inability to conduct a meaningful external review of the NAAQS documents. For these reasons, the Administrator's reliance on some CASAC members' recommendations in the Proposal is unlawful, arbitrary and capricious, and an abuse of discretion.

EPA's truncated review process also resulted in a failure to reflect the latest scientific knowledge, as the Agency failed to adequately consider the science available for the review. The Agency, without explanation, failed to assess key studies published after the PM ISA cutoff date. As a result, the Agency has not ensured that its air quality criteria actually reflect the latest scientific knowledge as required by the CAA.

For all of these reasons, the current PM NAAQS review process has been flawed, riddled with arbitrary and capricious decisions, and is unlawful. The Administrator's reliance on the recommendations of some members of the CASAC is also unlawful, arbitrary and capricious, and an abuse of discretion.

A. Primary Standard

This proposal is further unlawful because it would retain a primary standard that fails to protect public health with an adequate margin of safety as required by the Clean Air Act. If EPA refuses to reopen the NAAQS review process, the Agency must at least propose a revised standard. NGO commenters agree with the conclusions of the EPA Policy Assessment and of the IPMRP that the latest science indicates the current $PM_{2.5}$ standards do not protect public health—including the health of sensitive populations—with an adequate margin of safety. The coherent and robust body of evidence includes a number of important epidemiologic studies with larger numbers of subjects with increased power that show positive statistically significant associations with exposure to $PM_{2.5}$ at levels allowed by the current NAAQS. In some cases these effects persist even in truncated analyses that, in cohort studies, exclude concentrations exceeding the current annual standard and in short-term studies, exclude concentrations exceeding the 24-hour standards. The strongest associations are with the most serious adverse effects: total mortality, cardiovascular mortality, and cardiovascular and respiratory morbidity, all of which the ISA determined to be causal or likely causal. Both EPA's expert staff and the IPMRP found that this body of evidence strengthens the conclusions and reduces uncertainties as compared to the evidence from the previous review. IPMRP Advice at B-21; Policy Assessment at 3-43.

This evidence is strongly supported by the controlled human exposure and animal toxicity studies, which support the biological plausibility of the observed associations, strengthening the overall weight of evidence in reaching conclusions on causality. Further evidence of record supporting both causality and the concomitant need to revise the standards is provided by the emerging studies examining health benefits of reduced $PM_{2.5}$ concentrations, including accountability and intervention studies as well as other studies using quasi-experimental and modern causal inference methods.

The weight of evidence and the risk assessment, as well as the Act's command to provide requisite protection with an adequate margin of safety—which includes the obligation to act without waiting for resolution of every imaginable uncertainty—mandate a decision to revise. The risks are disproportionately greater for vulnerable populations for whom the Act mandates protection, and EPA has failed to consider or explain how retaining the current standards will provide the requisite protection and an adequate margin of safety to sensitive populations.

In considering the level of a potential revised annual primary standard, NGO Commenters are informed by the analysis and conclusions of EPA's expert staff in the policy assessment, and guided by the advice from the IPMRP. EPA must also consider the results of a number of powerful new accountability studies and other causal inference studies published after the cutoff date for the ISA. These studies strongly suggest that reductions of $PM_{2.5}$ that start at levels near to or below the level of the current standards down to 10 ug/m3 and below are causally associated with significant public health benefits, and that a standard of 10 ug/m3 would not protect public health with an adequate margin of safety. Given the evidence, we believe the science indicates an annual standard level of 8 ug/m3 is requisite to protect public health.

This level is supported even considering only the evidence EPA has considered. Several US and Canadian studies reported significant associations between PM2.5 and health effects at mean levels at or below 9.6 ug/m3 (PA Figures 3-7, 3-8) including two U.S. studies that that found associations with when all data greater than the current standards (Di et al. 2017) or greater than 10 ug/m3 (Shi et al.,2016) were removed (PA at 105). Our recommended level of 8 ug/m3 is below the long-term mean in Di et al 2016 and just below the mean of the long-term air quality distribution in Shi et al. (2016), See Policy Assessment at 3-105. The analysis in Shi et al. that excluded levels above 10 ug/m3 indicates that the bulk of adverse effects are not disproportionately associated with the higher end of the air quality distributions, and therefore offers support to using a level below the mean of the long-term data as the basis for establishing the level of the annual standard. See Policy Assessment at 3-55, 3-77 and 3-105.

Both the EPA expert staff and the IPMRP agree that the evidence of record supports an annual level of 8 ug/m3. This level is based on U.S. and Canadian studies, and reflects the long-term mean of a key epidemiological study, Shi et al. 2016, as the analysis of truncated data in that study gives it added weight. Policy Assessment at 3-113; IPMRP Advice at B-14; see also IPMRP Advice at B-28 ("the Panel unanimously finds a scientific basis for 8 ug/m3 as being the lower bound of annual ranges for which there is strong weight of scientific evidence of adverse effects").

NGO commenters further recommend strengthening the protection afforded by the 24-hour standard. As the IPMRP Panel noted, "there are numerous studies that find adverse effects at levels well below the current standard, within a range of 30 ug/m3 to 25 ug/m3." IPMRP Advice at B-31 (referring to the Canadian studies Weichenthal et al. 2016 a and b, and to the Medicare cohort studies Di et al., 2017b and Shi et al. 2016). The Panel further found that "[e]ven with an annual level in the range of 10 ug/m3 to 8 ug/m3, a 24-hour standard at 30 ug/m3 may not be protective of acute health effects that could occur with sub-daily exposures", particularly in areas that meet the annual standard and are subject to seasonally high peak levels, for example in areas with widespread use of wood for heating. Both Di et al. and Shi et al. also show statistically significant effects when the distributions are truncated to remove all days with concentrations of 30 ug /m3 and higher (30 ug/m3 for Shi et al.; 25 ug/m3 for Di et al.). Policy Assessment at 3-70. These studies indicate the need for revision of the standard, as the IPMRP found.

Finally, NGO commenters agree that "[t]he level of the coarse PM standard should be revised downward," as the IPMRP recommended, "consistent with the recommended downward revision of the 24-hour primary PM2.5 standard, to at least maintain, if not increase, the current level of public health protection to coarse particles." IPMRP Advice at 2.

B. Secondary Standard

EPA's proposal to maintain the secondary annual and 24-hour NAAQS is unlawful and arbitrary as it is clearly not supported by the latest compelling scientific knowledge. EPA ignores meta-analysis visibility studies and computer model enhancements that clearly demonstrate that the level of the current standard is not requisite to protect public welfare from any known or anticipated adverse effects. Further evidence of the need to strengthen the secondary NAAQS is found in recent studies documenting public welfare gains from visibility improvement, as well as negative impacts to tourism when visibility is degraded. There are readily available continuous monitoring methods and an existing network that EPA can and should use to replace the outdated methods. Current monitoring methods cover less than a third of the year, collecting data only once every three days, ignoring more than 30 days of data annually, and relying on an equation that recent studies show is flawed.

The NGO commenters recommend that EPA consider readily available scientific information, which supports strengthening the level of the 24-hour and annual NAAQS and aligning the monitoring methods – in numeric standard and averaging time - with today's science to correlate with how the public perceives visibility. Based on its assessment of recent research, the IPMRP also recommended revisions similar to ours, including strengthening the secondary NAAQS.

EPA must consider all effects on welfare, including: soils, water, crops, vegetation, animals, wildlife, weather, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants. Contrary the Act's mandate to consider all welfare effects, EPA arbitrarily evades review by punting ecosystem considerations to a future review. EPA's foot-dragging to revise the secondary NAAQS has already been going on for more than 30 years. Thanks to methodology developed and now published in research studies, EPA has tools it should use to strengthen the NAAQS to ensure the standards are requisite to protect all aspects of public welfare from any known or anticipated adverse effects.

For all the foregoing reasons, EPA's proposal fails to comply with the Act's mandate to "specify a level of" particulate matter "the attainment and maintenance of which … is requisite to protect the public welfare from any known or anticipated adverse effects." The levels that EPA has specified are plainly not requisite to protect against known or anticipated adverse effects due to PM-related visibility impairment, and any EPA finding to the contrary would be arbitrary based on the evidence and analysis discussed above. As to all the other known and anticipated adverse welfare effects from PM pollution documented above, EPA has unlawfully and arbitrarily failed to specify any levels requisite to protect against such adverse effects.

C. Conclusion

In short, the agency cannot validly finalize this proposal. To do so would be not only unlawful, but an abdication of the agency's obligation to follow the law and provide all Americans the requisite protection with an adequate margin of safety from harmful fine particle pollution. If you have any questions about our comments, please feel free to reach out to any of the signatories below.

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