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ON THE RECONSIDERATION OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER

88 Fed. Reg. 5558 (Jan. 27, 2023)

EPA-HQ-OAR-2015-0072

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I. EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency ("EPA" or "the agency") must move expeditiously to finalize and implement a strengthened version of its proposed rule, Reconsideration of the National Ambient Air Quality Standards for Particulate Matter, 88 Fed. Reg. 5558 (Jan. 27, 2023). It is well established that fine particulate matter ("$PM_{2.5}$") air pollution kills and causes other severe health harms to people at levels below the current national ambient air quality standards ("standards" or "NAAQS") of 12 $\mu g/m^3$ for the annual standard and 35 $\mu g/m^3$ for the 24-hour standard. It is also well established that certain populations, like people of color—especially Black populations—and low-income communities bear a disproportionate share of the exposure to and health harms from $PM_{2.5}$ pollution.

Primary Standards. The combination of an annual standard no higher than 8 $\mu g/m^3$ and a 24-hour standard no higher than 25 $\mu g/m^3$ is necessary to protect public health with an adequate margin of safety, as the Clean Air Act requires. Any weaker standards would be unlawful and arbitrary. Importantly, EPA must set the standards to protect, with an adequate margin of safety, the health of sensitive subpopulations—like young children and older Black adults—not merely an average population. EPA declined to propose the needed standards, but is taking comment on more protective standards (8 $\mu g/m^3$ and 25 $\mu g/m^3$). These more protective standards would begin to close the unjust disparate public health burdens caused by $PM_{2.5}$ and would thus represent an important, though not the last, step toward finally achieving environmental justice.

Yet, EPA proposed only to strengthen the annual standard modestly, to 9-10 $\mu g/m^3$, and not to strengthen the 24-hour standard at all. Though the stronger end of EPA's proposal would mark an important, but limited, advance for public health and for somewhat narrowing inequitable disparate public health burdens of $PM_{2.5}$, the proposal is ultimately grossly inadequate. For example, EPA's proposal departs arbitrarily and unlawfully from the majority recommendations of the Clean Air Scientific Advisory Committee ("CASAC").

For the annual standard, EPA ignores important evidence that was before it, and turns the Act on its head by demanding an arbitrarily vague, but heightened, level of certainty, even though the Act's command for an adequate margin of safety means EPA is supposed to resolve lesser uncertainties in favor of protection. EPA further focuses on means and averages of $PM_{2.5}$ concentrations in ways that are contrary to the evidence and Act: its approach would leave **<u>un</u>**protected the people who experience the $PM_{2.5}$ concentrations at which EPA itself has the highest confidence in $PM_{2.5}$'s harmful effects. That outcome would perpetuate ongoing environmental injustice. Accordingly, EPA must finalize stronger standards, both under its own vision of its mission and under the Clean Air Act.

EPA's proposal to retain the 24-hour standard is also unlawful and arbitrary. The latest scientific evidence shows that the existing 24-hour standard fails to protect public health with an adequate margin of safety. The agency unreasonably and unlawfully interprets or dismisses the compelling weight of epidemiologic and controlled human exposure studies in favor of arbitrarily and illegally heavily weighing the results of its risk assessment, the utility of which is severely limited for the 24-hour standard, as the CASAC majority notes. Strengthening the 24-hour standard in combination with a strengthened annual standard provides significantly better protection against 2-hour and 4-hour peak exposures than leaving the standard unchanged. Fundamentally, the agency irrationally relies on the annual standard to do essentially all the work, even though strengthened versions of the two standards will work together to effectively control both long- and short-term harmful $PM_{2.5}$ concentrations, and a stronger 24-hour standard is requisite to provide adequate protection against short-term peaks even with an annual standard of 8 $\mu g/m^3$. The form of the 24-hour standard remains deeply flawed, too, and EPA also must consider strengthening it so that it no longer allows so many dangerous $PM_{2.5}$ spikes to persist. To meet the Clean Air Act's requirements and advance environmental justice, EPA must strengthen the 24-hour standard to no higher than 25 $\mu g/m^3$.

Secondary Standards. As well as harming human health, $PM_{2.5}$ causes serious environmental harms, and the secondary standards must finally be updated to protect against them. EPA is now on a judicially enforceable deadline to review the aspect of the secondary standards that is supposed to protect against the ecological harms particulate matter ("PM") causes. We do not concede that it is lawful or rational for EPA to split up its review of the secondary PM standards, but, given the timeline of that review, we focus here on other welfare harms PM causes, chiefly to visibility.

To rationally meet the Clean Air Act's mandate that secondary standards protect public welfare against any known or anticipated adverse effects, the secondary standards must be strengthened, which has not occurred since 2006 (and was done in an unlawful and arbitrary manner then). EPA's contrary proposal is unlawful and arbitrary. Instead, to protect against adverse effects on visibility, EPA must strengthen the 24-hour $PM_{2.5}$ standard to 25 μg/m^3. EPA's formulaic basis for declining to do so is inconsistent with the record and recommendations of experts, including CASAC. EPA provides no rational consideration of the annual $PM_{2.5}$ standard, and it too must be strengthened.

Air Quality Monitoring & Air Quality Index. If people and regulators don't know whether levels of $PM_{2.5}$ in the air are above or below the level of the standards, the standards cannot fully deliver their promised health protections. Effective, accurate air quality monitoring and timely provision of information to people about actual air quality conditions thus go hand-in-glove with standards. We accordingly generally support EPA's proposed changes to air quality monitoring network requirements and the air quality index, though we call for EPA to make certain key improvements to its proposal. We also are encouraged by EPA's request for comment on how to make use of air quality data resulting from new technologies. Real-world experience has shown that such data can help fill gaps in the regulatory monitoring network, making important information about air quality available to communities, especially overburdened ones, and helping make the promise of clean air real. EPA should encourage the generation and use of such data so that the data can make the most positive impact practicable.

Other Issues. Though implementation concerns cannot lawfully factor into EPA's standard-setting, we comment on several. Principally, we note how important it is for EPA to move swiftly to complete this rulemaking and to begin implementing strengthened standards through air quality designations that go into effect no later than the end of 2025. EPA must also ensure that illegal considerations, including those regarding impacts of emissions from exceptional events like prescribed fires, do not enter into the standard-setting process. Such events must be addressed in implementing the standards—not in setting them. And, though, again, implementation costs cannot be considered, we note that the benefits of stronger $PM_{2.5}$ standards will vastly outweigh the costs of implementing them. Indeed, existing and proposed rules, as well as cost-effective additional measures, will likely further reduce costs, as historically has been the case.

* * *

In sum, stronger standards are consistent with this EPA's priorities, are required by the Clean Air Act, and would yield real, necessary benefits. In particular, primary standards no higher than 8 μg/m³ (annual) and 25 μg/m³ (24-hour) have firm scientific and legal foundations and would mark important, concrete advances toward environmental justice. This Administration must not further delay them.

II. EPA'S LEGAL OBLIGATIONS IN SETTING AND REVIEWING 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 Elec. 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 for EPA's approval or disapproval 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.

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

The Clean Air Act provides a clear process for establishing the NAAQS. The first step 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), 7409.

Primary NAAQS must be set to be "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 adverse health effects from polluted air, but also those that are scientifically uncertain or that research has not yet uncovered. 88 Fed. Reg. at 5562.

Further, the statute makes clear that there are significant limitations on the discretion granted to EPA in setting 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 [A]ct, 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 substantive requirements is discussed in more detail below.

B. The Clean Air Act requires EPA to set primary NAAQS that protect public health, with an adequate margin of safety, including for at-risk populations

The Clean Air Act requires the primary NAAQS be set to ensure that <u>everyone</u> has access to clean, healthy air. As its congressional drafters stated, the 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 correctly 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 the people of this country 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]

1. EPA must establish NAAQS that protect vulnerable populations

Because EPA must set the NAAQS to provide an adequate margin of safety for all, the NAAQS must be set at a level that protects against adverse effects in vulnerable subpopulations, such as children, the elderly, pregnant women, the socially disadvantaged, and people with heart and lung disease and other pre-existing health conditions. The D.C. Circuit has repeatedly found that if a certain level of a pollutant

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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 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.").

"adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *American Lung*, 134 F.3d at 389 (citation omitted); *accord 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). Thus, EPA must build into the NAAQS an adequate margin of safety for these sensitive subpopulations. *See Am. Farm Bureau Fed'n*, 559 F.3d at 525-26.

The drafters of the 1970 Clean Air Act Amendments made clear that the millions of people 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 v. EPA*, 684 F.3d 803, 810 (D.C. Cir. 2012). NAAQS must "be set at a level at which there is 'an absence of adverse effect' on these sensitive individuals." *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980).

EPA agrees with the above, and notes that, where environmental justice factors implicate vulnerable or at-risk populations, the NAAQS review and revision process <u>must</u> incorporate those factors:

> In setting the NAAQS, EPA focuses on the health effects on population groups that are at higher risk of adverse health effects. Thus, the NAAQS are required to take certain environmental justice factors into account as part of the standard-setting process where those factors are consistent with consideration of at-risk populations.

EPA, Off. of Gen. Counsel, *EPA Legal Tools to Advance Environmental Justice* 15 (Pub. No. 360R22001, May 2022), https://www.epa.gov/system/files/documents/2022-05/EJ%20Legal%20Tools%20May%202022%20FINAL.pdf.

Put differently, due to the severe, inequitably distributed human harms particulate matter pollution causes, if EPA sets rational and lawful primary $PM_{2.5}$ standards, they will generate significant environmental justice benefits. *See* Richard L. Revesz, *Air Pollution and Environmental Justice*, 49 Ecology L.Q. 187, 189-90 (2022).

2. Where there is scientific uncertainty, EPA must take a protective approach to provide an adequate margin of safety

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*, 647 F.2d at 1154. 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. Indeed, the requirement for an adequate margin of safety "means the agency is to 'err on the side of caution.'" *Am. Petroleum Inst. v. EPA*, 684 F.3d 1342, 1352 (D.C. Cir. 2012) (quoting *Am. Farm Bureau*, 559 F.3d at 533); *accord, e.g.*, *Coal. of Battery Recyclers Ass'n*, 604 F.3d at 621; *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 369 (D.C. Cir. 2002) (Act requires "that the Agency err on the side of caution by setting primary NAAQS that 'allow an adequate margin of safety'" and "requires EPA to promulgate protective primary NAAQS even where…the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree'" (cleaned up)).

3. The only lawful consideration in setting NAAQS is the effect of the pollutant in the ambient 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 465-71; *Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1040-41 (D.C. Cir. 1999), *upheld in relevant part sub nom. Whitman*, 531 U.S. 457; *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. This principle was reaffirmed recently in *Murray Energy Corp. v. EPA*, 936 F.3d 597, 622-24 (D.C. Cir. 2019), where the D.C. Circuit held that EPA must set the primary NAAQS based exclusively on public-health considerations, without regard to "background" levels of the pollutant. "[A]ttainability and technological feasibility are not relevant considerations in the promulgation of NAAQS." *Id.* (cleaned up).

When the agency considers the public health and welfare benefits of a standard, however, it should not look at the standard in a vacuum. As explained above, EPA must set standards to protect sensitive populations. The factors that, in the real world, lead to sensitivities are complex and interrelated. Further, the Act commands EPA to include, "to the extent practicable," in the air quality criteria that form the basis for the NAAQS information on "those variable factors…which of themselves or in combination with other factors may alter the effects on public health" of the air pollutant under review, as well as on "the types of air pollutants which, when present in the atmosphere, may interact with [the pollutant under review] to produce an adverse effect on public health." 42 U.S.C. § 7408(a)(2)(A)-(B); *see also id.* § 7409(b), (d).

Thus, to meet the goals of the NAAQS program, EPA must also consider the cumulative impacts of PM on people who are exposed to a variety of pollutants, as is the case in most environmental justice or overburdened communities. EPA defines cumulative impacts as "the totality of exposures to combinations of chemical and non-chemical stressors and their effects on health, well-being, and quality of life outcomes," including "contemporary exposures to multiple stressors as well as exposures throughout a person's lifetime," and notes that such impacts "can be considered in the context of individuals, geographically defined communities, or definable population groups."[3]

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[3] EPA, Off. of Res. & Dev't, *Cumulative Impacts Research: Recommendations for EPA's Office of Research and Development* at vii (EPA/600/R-22/014a, Sept. 2022), https://www.epa.gov/system/files/documents/2022-09/Cumulative%20Impacts%20Research%20Final%20Report_FINAL-EPA%20600-R-22-014a.pdf.

As EPA notes in its recent addendum to EPA's Legal Tools to Advance Environmental Justice, "[i]n communities with environmental justice concerns and other underserved populations, the combined exposures to…stressors (i.e., cumulative impacts) often increases their vulnerability to new or ongoing environmental hazards, which can cause, perpetuate, or exacerbate disproportionate environmental and public health harms and risks."[4] Application of these concepts here supports stronger standards, given the known disproportionate exposures to and health harms of $PM_{2.5}$. Moreover, PM is composed of various compounds including sulfates, nitrates, carbonaceous aerosol, and metals, including lead, and EPA does not account for the exact chemical makeup of PM at the hyper-local level. Yet, each of these PM compounds on its own has multiple pathways of exposure. Thus, to ensure that the $PM_{2.5}$ NAAQS is truly protective of public health, particularly for overburdened communities, EPA must set the most protective scientifically supported standard to protect against negative cumulative exposures to or interactions from compounds like lead.

4. This CASAC panel's recommendations merit significant deference

Under the Clean Air Act, EPA is required to ensure that the NAAQS "accurately reflect the latest scientific knowledge." 42 U.S.C. § 7408(a)(2). To do so, Congress directed EPA to create the Clean Air Scientific Advisory Committee ("CASAC"), made up "of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies." *Id.* § 7409(d)(2)(A). As the D.C. Circuit has noted, "[h]istorically, EPA advisory committees have included academic scientists who, supported by EPA grants, conduct cutting-edge scientific and technical research important to the agency's statutory mission." *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 638 (D.C. Cir. 2020). But under the previous Administration, former Administrator Scott Pruitt announced a CASAC appointments policy that broke with decades of EPA practice and led to the

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[4] EPA, Off. of Gen. Counsel, *EPA Legal Tools to Advance Environmental Justice: Cumulative Impacts Addendum* 1 (Pub. No. 360R22002, Jan. 2023) (footnotes omitted), https://www.epa.gov/system/files/documents/2022-12/bh508-Cumulative%20Impacts%20Addendum%20Final%202022-11-28.pdf; *see also id.* at 6 (noting one way in which cumulative impacts should be considered in NAAQS-setting).

formation of a CASAC without the requisite scientific expertise to provide adequate review of the standards.[5] Multiple courts found this action an arbitrary and severe departure from Congress's goals in setting up the committee.[6]

In contrast to the previous Administration, current Administrator Michael S. Regan has made it a point to restore CASAC's scientific integrity by resetting the committee with a mix of new and previously serving members, reestablishing a larger PM-specific panel made up of true subject-matter experts across the range of pertinent considerations, and ensuring that appointees had requisite expertise in their fields without facing irrelevant barriers to appointment.[7] Thus, among other members, the current CASAC includes eminent scholars and researchers like:

- Dr. Elizabeth (Lianne) Sheppard, Rohm & Haas Endowed Professor in Public Health Sciences and of Environmental and Occupational Health Sciences, and Biostatistics at the University of Washington, who has not only served on CASAC before (2015-2018), but also has deep expertise in epidemiology, biostatistics and exposure assessments. Dr. Sheppard also serves as the Chair of CASAC.

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[5] Scott Pruitt, Adm'r, EPA, Strengthening and Improving Membership on EPA Federal Advisory Committees (Oct. 31, 2017), https://www.epa.gov/sites/default/files/2017-10/documents/final_draft_fac_directive-10.31.2017.pdf; Memorandum from Scott Pruitt, Adm'r, EPA, Strengthening and Improving Membership on EPA Federal Advisory Committees (Oct. 31, 2017), https://www.epa.gov/sites/default/files/2017-10/documents/final_draft_fac_memo-10.30.2017.pdf.

[6] *Physicians for Soc. Responsibility*, 956 F.3d at 647; *see Nat. Res. Def. Council v. EPA*, 438 F. Supp. 3d 220, 232 (S.D.N.Y. 2020).

[7] EPA, Press Release, Administrator Regan Directs EPA to Reset Critical Science-Focused Federal Advisory Committees (Mar. 31, 2021), https://www.epa.gov/newsreleases/administrator-regan-directs-epa-reset-critical-science-focused-federal-advisory; EPA, Press Release, EPA Announces Selections of Charter Members to the Clean Air Scientific Advisory Committee (June 17, 2021), https://www.epa.gov/newsreleases/epa-announces-selections-charter-members-clean-air-scientific-advisory-committee.

- Dr. Michelle L. Bell, the Mary E. Pinchot Professor of Environmental Health at the Yale University School of the Environment, whose work is based in epidemiology, biostatistics, and environmental engineering.
- Dr. Christina H. Fuller, Associate Professor of Environmental Health at Georgia State University, whose research in environmental health and justice is focused on exposure science and epidemiology, including air pollution exposure and health disparities.
- Dr. Mark Frampton, Professor Emeritus in Medicine in the Pulmonary and Critical Care Division of the University of Rochester Medical Center, who has not only worked as a physician, but has deep research experience on particle exposure on lung and cardiovascular functions.

Not only does the current CASAC have the experience to adequately advise EPA on the "latest scientific knowledge" on the public health and welfare effects of particulate matter, but the current CASAC is EPA's "most diverse panel since the committee was established."[8] As such, this CASAC's recommendations merit significant deference and great weight.

C. EPA must engage in reasoned decision-making

A fundamental precept of administrative law, a final rule must be the result of an agency's reasoned decision-making. The agency must have "weighed competing views, selected a [solution] with adequate support in the record, and intelligibly explained the reasons for making that choice."[9] A rule will be reversed if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law."[10] *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.* provides the seminal test for reasoned decision-making:

[8] EPA, Press Release, EPA Announces Selections of Charter Members to the Clean Air Scientific Advisory Committee.

[9] *FERC v. Elec. Power Supply Ass'n*, 577 U.S. 260, 295 (2016).

[10] *See* 42 U.S.C. § 7607(d)(9); 5 U.S.C. § 706(2); *see also Catawba County v. EPA*, 571 F.3d 20, 41 (D.C. Cir. 2009) (explaining that the same standard applies under both these provisions).

> [T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made. In reviewing that explanation, we must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.[11]

Especially because EPA is charged with "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," it "has the heaviest of obligations to explain and expose every step of its reasoning." *Am. Lung*, 134 F.3d at 392.

III. EPA'S PRIOR REVISIONS OF THE PRIMARY $PM_{2.5}$ NAAQS

As scientific knowledge about the harmful health effects of particulate matter air pollution has advanced, EPA has moved cautiously to update its standards. In 1997, after being sued over missing its deadline for reviewing the then-governing 1987 standards, *American Lung Ass'n v. Browner*, 884 F. Supp. 345 (D. Ariz. 1994), EPA dramatically revised the NAAQS for PM by adding two new standards specifically targeting $PM_{2.5}$. 62 Fed. Reg. 38,652 (July 18, 1997). The new revision increased protections from $PM_{2.5}$ by setting annual and daily standards with that pollutant as the indicator, separate from the standards for coarse particular matter ("PM_{10}"). The new standards—a 15 μg/m^3 annual standard and a 65 μg/m^3 24-hour standard—were added partially because of EPA's recognition that PM_{10} often has a different health effect than $PM_{2.5}$. 62 Fed. Reg. at 38,667.

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[11] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (cleaned up); *see also Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016) (similar).

Since EPA created the $PM_{2.5}$ standards, EPA has revised the annual and 24-hour standards once each. EPA's first, and only, revision of the 24-hour $PM_{2.5}$ standard occurred in 2006, the first time it reviewed the 1997 standards—and four years later than the Act commanded. At the time, EPA noted that compared to the previous review, there was a "stronger body of evidence now available on health effects related to both short- and long-term exposure to $PM_{2.5}$." 71 Fed. Reg. 61,144, 61,153 (Oct. 17, 2006). But, despite this evidence, EPA only revised the 24-hour standard down to 35 $\mu g/m^3$. *Id.* at 61,144. At the time, CASAC wrote to EPA to express its disappointment in the agency refusing to revise the annual standard despite "clear and convincing scientific evidence that significant adverse human-health effects occur in response to short-term and chronic particulate matter exposures at and below 15 $\mu g/m^3$, the level of the current annual $PM_{2.5}$ standard."[12] And after state and environmental petitioners challenged EPA's decision to not revise the annual standard in court, the D.C. Circuit found that "EPA did not adequately explain why an annual level of 15 $\mu g/m^3$ is sufficient to protect the public health while providing an adequate margin of safety." *Am. Farm Bureau Fed'n*, 559 F.3d at 528.

In late 2012, again later than the Act commanded review of the flawed 2006 decision, EPA finally revised the annual standard downward to 12 $\mu g/m^3$. In making this decision, EPA noted that the Clean Air Act requires the Administrator to set the standard at a level that "reduces risk sufficiently so as to protect public health, including the health of at-risk populations, with an adequate margin of safety." 78 Fed. Reg. 3086, 3161 (Jan. 15, 2013).

In 2020, some eight years after its last review, despite a growing body of evidence showing that the current standards are inadequate to protect public health, EPA decided to retain both the annual and 24-hour $PM_{2.5}$ standards at the levels that they were set in 2012 and 2006, respectively. 85 Fed. Reg. 82,684 (Dec. 18, 2020). EPA's decision relied on a flawed and illegal process that failed to meet the Clean Air Act's requirement that the agency consider "the latest scientific knowledge." 42 U.S.C.

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[12] Letter from CASAC to Stephen L. Johnson, Adm'r, EPA, re Clean Air Scientific Advisory Committee Recommendations Concerning the Final National Ambient Air Quality Standards for Particulate Matter 1 (EPA-CASAC-LTR-06-003, Sept. 29, 2006) (emphasis removed).

§ 7408(a)(2). This included an improperly constituted CASAC panel that by its own admission lacked the necessary expertise to adequately review the standards, and that failed to consider recent studies, like a 2018 meta-analysis of 53 cohort studies which found significant associations between $PM_{2.5}$ concentrations well below 12 μg/m^3 and mortality.[13] This study, which was presented to CASAC during its deliberations, went unmentioned in CASAC's letter and by the Administrator. Throughout the review process, CASAC ignored, and EPA failed to evaluate, published studies that were directly relevant to the NAAQS, including studies that focused on mortality[14] and reduced life expectancy,[15] showing that there were adverse health responses at levels well below the current NAAQS. The profound process issues, self-confessed inadequacy of the CASAC that was convened in that review, and the fundamental flaws in its majority recommendations are described in detail in several sets of comments already in the docket. *E.g.*, EPA-HQ-OAR-2015-0072-0973 at 8-34, 41-69. In light of these issues, the conclusions EPA reached in the 2020 review, as well as the majority CASAC's advice at the time, merit no deference in this reconsideration.

In June 2021, EPA finally acknowledged that "available scientific evidence and technical information indicate that the current standards may not be adequate to protect

[13] Vodonos, Alina, Yara Abu Awad, and Joel Schwartz. 2018. "The Concentration Response between Long-Term $PM_{2.5}$ Exposure and Mortality; A Meta-Regression Approach." Environmental Research 166 (October): 677-89. https://doi.org/10.1016/j.envres.2018.06.021.

[14] 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.

[15] 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; 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.

public health and welfare, as required by the Clean Air Act."[16] Yet EPA's career staff had already reached that conclusion. EPA, Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter 3-106 (EPA-452/R-20-002, Jan. 2020) ("2020 PA").

Indeed, EPA's acknowledgment understates the strength of the available evidence. In late 2012, Canada set its ambient air quality standards for $PM_{2.5}$ to be significantly stronger than EPA's current ambient air quality standards—and even stronger than the standards EPA proposes now, though within the lower end of the range the CASAC majority recommended and that EPA is accepting comment on:[17]

[16] EPA, Press Release, EPA to Reexamine Health Standards for Harmful Soot That Previous Administration Left Unchanged (June 10, 2021), https://www.epa.gov/newsreleases/epa-reexamine-health-standards-harmful-soot-previous-administration-left-unchanged.

[17] Canada Dep't of the Env't & Dep't of Health, Objectives for Ambient $PM_{2.5}$ and Ozone [Canadian Ambient Air Quality Standards (CAAQS) for $PM_{2.5}$ and Ozone], 147 C. Gaz. Pt.I 1243-44 & annex (May 25, 2013) (notice dated Dec. 12, 2012), https://www.canadagazette.gc.ca/rp-pr/p1/2013/2013-05-25/pdf/g1-14721.pdf#page=17; *see also* Gov't of Canada, Canadian Environmental Protection Act: guidelines and objectives, Environmental Quality (last modified Dec. 19, 2022) (confirming these remain the current Canadian ambient air quality standards for $PM_{2.5}$), https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/guidelines-objectives-codes-practice/guidelines-objectives.html#toc4; Canadian Council of Ministers of the Env't, Air Quality Report, slide 7 (last visited Mar. 12, 2023) (same), https://ccme.ca/en/air-quality-report#slide-7.

Averaging Time	Level		Form
	In 2015	In 2020	
Annual (calendar year)	10.0 μg/m³	8.8 μg/m³	3-year average of the annual average concentrations
24 hours (calendar day)	28 μg/m³	27 μg/m³	3-year average of the annual 98th percentile of the daily 24-hour average concentrations

The World Health Organization in 2021 recommended as its air quality guidelines for $PM_{2.5}$ an annual level of 5 μg/m³ and a 24-hour level of 15 μg/m³ (99th percentile), both of which are substantially stronger than any of the standards EPA is currently considering.[18] Thus, EPA's reconsideration is consistent with—or even less protective than—what other health and environmental bodies have done.

IV. THE SOURCES OF $PM_{2.5}$ POLLUTION ARE NUMEROUS AND WIDESPREAD, AND THE EFFECTS OF THIS POLLUTION ARE NOT EVENLY SPREAD

A wide array of anthropogenic sources emit $PM_{2.5}$ pollution within the United States. Mobile sources—cars and trucks—are a dominant contributor to direct $PM_{2.5}$ pollution in many urban areas, producing as much as 30% of primary $PM_{2.5}$ emissions in some highly populated counties. EPA, Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter 2-5 (EPA-452/R-22-004, May 2022) ("PA"). Light-duty vehicles and heavy-duty diesel vehicles also emit substantial quantities of elemental carbon, NO_X and volatile organic compounds ("VOCs"), contributing to secondary $PM_{2.5}$ pollution both within and outside urban areas. Margaret Zawacki et al., *Mobile Source Contributions to Ambient Ozone and*

[18] World Health Org., *WHO Global Air Quality Guidelines* at xvii tbl.0.1 & n.a (2021), https://apps.who.int/iris/rest/bitstreams/1371692/retrieve.

Particulate Matter in 2025, 168 Atmospheric Env. 129, 136 (2018)[19]; PA at 2-9 fig.2-6, 2-11 fig.2-8; *see* EPA, Control of Air Pollution from New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards: Regulatory Impact Analysis 300 (EPA-420-R-22-035, Dec. 2022) (modeling effects of reductions in heavy-duty vehicle emissions on $PM_{2.5}$ concentrations); 79 Fed. Reg. 23,414, 23,416 (Apr. 28, 2014) (describing light-duty vehicles' emissions).

Among stationary sources, electric generating stations—coal-fired power plants in particular—are responsible for most of the country's emissions of sulfur dioxide ("SO_2") and a substantial fraction of its nitrogen oxides ("NO_X") emissions, both precursors to $PM_{2.5}$. PA at 2-11 fig.2-8. Other industrial facilities—chemical plants and refineries, for example—produce substantial quantities of both direct $PM_{2.5}$, and $PM_{2.5}$ precursors. *Id.* at 2-7 fig.2-7, 2-11 fig.2-8 (industrial processes produced 20% of SO_2 emissions, 18% of VOC emissions, 12% of NO_X emissions, and 5% of direct $PM_{2.5}$ in 2017); EPA, 2017 National Emissions Inventory: January 2021 Updated Release, Technical Support Document 2-11 to -12 tbl.2-3 (EPA-454/R-21-001, Feb. 2021) (listing emissions from different sectors), https://www.epa.gov/sites/default/files/2021-02/documents/nei2017_tsd_full_jan2021.pdf.

Agricultural dust and agricultural burning produce an additional substantial fraction of the nation's direct $PM_{2.5}$ emissions. PA at 2-4 to -5 & fig.2-2; EPA, Regulatory Impact Analysis for the Proposed Reconsideration of the National Ambient Air Quality Standards for Particulate Matter 2-10 fig.2-4 (EPA-452/P-22-001, Dec. 2022) ("RIA"), https://www.epa.gov/system/files/documents/2023-01/naaqs-pm_ria_proposed_2022-12.pdf. Agricultural livestock and waste are also the dominant source of ammonia (NH_3), a precursor to $PM_{2.5}$. PA at 2-10. Notably, though EPA reports that, from all emission sources reported in the National Emissions Inventory, direct $PM_{2.5}$ emissions, as well as all other precursor emissions, have dropped by 14-84% from 2002-2017, ammonia emissions have <u>risen</u>. *Id.* 2-28 tbl.2-2. Accordingly, we go into more detail about agricultural emissions of $PM_{2.5}$ and its precursors, focusing on ammonia.

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[19] Available at https://www.sciencedirect.com/science/article/pii/S1352231018302966?ref=cra_js_challenge&fr=RR-1.

As of 2017, livestock waste was the largest source of ammonia emissions in the United States.[20] Concentrated Animal Feeding Operations ("CAFOs")—industrial livestock facilities that house many hundreds or thousands of animals in close confinement—are often the ultimate source for these emissions. When CAFO waste decomposes, it releases gases that include ammonia and hundreds of VOCs.[21] Waste pits, animal confinement buildings, and waste applied to fields emit these gases and compounds into the air. It is thus unsurprising that a recent study found that agricultural air pollution in the United States contributed to 17,900 deaths per year via its direct and secondary $PM_{2.5}$ emissions. Nina G.G. Domingo et al., *Air Quality-Related Health Damages of Food*, 118 PNAS e2013637118 (2021). Results suggest that California leads the country with the greatest number of air quality-related deaths (1,690 deaths per year) caused by its agricultural ammonia emissions—750 deaths more than the second leading state. *Id.* tbl.S2.

Moreover, the $PM_{2.5}$ compounds resulting from ammonia's reactions may have regional, if not larger impacts. $PM_{2.5}$ can persist for weeks in the atmosphere and travel tens to hundreds of miles. EPA, Integrated Science Assessment for Particulate Matter 2-5 tbl.2-1 (EPA/600/R-19/188, Dec. 2019) ("ISA"). Ammonia reacts with other compounds in the atmosphere to create "more stable PM with lower volatility," suggesting that it also contributes to $PM_{2.5}$ levels far from its origin. *Id.* at 2-13.

That said, sources that produce large fractions of $PM_{2.5}$ on a national basis are not all equally responsible for $PM_{2.5}$ pollution in the areas where such pollution is most severe. Sources responsible for $PM_{2.5}$ precursors, like power plants, contribute relatively uniformly to that pollution on a regional basis. *See id.* at 2-12, 2-65 to -66; PA 2-10. Likewise, mobile sources—cars, trucks, and buses powered by internal combustion engines—produce a consistently large fraction of direct and indirect $PM_{2.5}$ pollution in heavily polluted urban areas, though, importantly, the result of those emissions can be

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[20] *See* EPA, 2017 National Emissions Inventory (NEI) Data, https://www.epa.gov/air-emissions-inventories/2017-national-emissions-inventory-nei-data#dataq (in the "Data Queries" section, select "Ammonia – NH3" in the "Pollutant" selection box).

[21] *See* Virginia T. Guidry et al., Hydrogen Sulfide Concentrations at Three Middle Schools Near Industrial Livestock Facilities, 27 J. Exposure Sci. & Env't Epidemiology 167 (2017).

spatially variable $PM_{2.5}$ levels. ISA at 2-12, 2-66. But while what EPA refers to as fire-related emissions represent a large part of national direct $PM_{2.5}$ emissions, they are a "much smaller fraction" within urban areas where $PM_{2.5}$ pollution is highest. ISA at 2-9; *see* PA at 2-5 (noting "notable difference in contributions of sources of $PM_{2.5}$ in urban areas compared to national emissions"). A wide and varied set of sources are responsible for direct $PM_{2.5}$ pollution in urban areas suffering from high $PM_{2.5}$ concentrations; refineries produce significant quantities of pollution in some, residential wood-burning in others, while waste disposal produces a large share in others. ISA at 2-9 to -12 & fig.2-3 (summarizing sources of primary emissions in 5 different counties); *see* RIA at 2-10. That heterogeneity underscores the need for, and potential efficacy of, the localized pollution-reduction regime by which the Clean Air Act achieves compliance with an updated NAAQS. *See* RIA at ES-4 n.2 (noting "the need for control of local primary $PM_{2.5}$ sources to address the highest $PM_{2.5}$ concentrations in urban areas").

We note also that evidence about the harms of ultrafine particulate matter ("UFP") has been developing. *E.g.*, ISA at ES-10 tbl.ES-1 (upgrading and making for the first time certain causality determinations for UFP); 88 Fed. Reg. at 5590. Further, there is evidence that ultrafine particulate matter is highly variable and may last short periods of time, suggesting that the current PM standards will not cover it well. *See* ISA at ES-5, 1-11 (UFP highest near roads, highly variable, often short time periods); *see also id.* at 1-6 to -7 (describing sources and emissions of UFP). CASAC raised concerns about the potential health harms of ultrafine particles, as well. Letter from Dr. Elizabeth A. (Lianne) Sheppard, Chair, Clean Air Scientific Advisory Committee, to Michael S. Regan, Adm'r, EPA, 15 (EPA-CASAC-22-002, Mar. 18, 2022) ("CASAC Letter on PA"). We thus endorse CASAC's recommendation for more research into the health effects of ultrafine particulate matter, and add that such research must include gathering reliable data regarding ultrafine particulate matter's ambient concentrations.

Among other harms, $PM_{2.5}$ pollution inflicts serious respiratory and cardiovascular harm, including death, to the population generally. EPA, Supplement to the 2019 Integrated Science Assessment for Particulate Matter 2-3 to -23 & tbls.2-1 & 2-2, 2-34 (EPA/600/R-22/028, May 2022) ("ISA Supplement") (detailing serious human health harms caused or likely caused by $PM_{2.5}$ and noting that "a large body of evidence shows that health effects related to PM exposure, particularly $PM_{2.5}$ exposure, occur across populations with diverse characteristics"). Those harms are especially severe for children, for whom long-term $PM_{2.5}$ exposure leads to impaired lung function and increased likelihood of asthma. 88 Fed. Reg. at 5591; ISA Supplement at 2-35 to -36. The elderly also experience more serious consequences from $PM_{2.5}$ exposure. 88 Fed. Reg. at 5591 (describing "consistent evidence" associating increased short- and long-term $PM_{2.5}$ exposure by older adults with "cardiovascular or respiratory hospital admissions, emergency department visits, or mortality").

Historically marginalized communities experience a larger share of the harm caused by $PM_{2.5}$ pollution. *See* 88 Fed. Reg. at 5673 (scientific evidence "indicates that subpopulations at potentially greater risk include … lower socioeconomic status" and "minority populations (particularly Black populations)"); RIA at ES-20 to -21 ("Hispanics[22], Asians, Blacks, and those less educated … have higher national exposures" than "other populations"). This disproportionate burden is disturbingly deeply rooted: a recent study found that, as of 2010, the "redlining" that began in the 1930s and cut communities off from federal home loans on racially discriminatory bases (and was legally barred in 1968) was "associated with substantial intraurban air pollution disparities for…$PM_{2.5}$." Haley M. Lane et al., *Historical Redlining Is Associated with Present-Day Air Pollution Disparities in U.S. Cities*, Environ. Sci. & Tech. Letters 345, 345-46, 348 (2022), https://pubs.acs.org/doi/pdf/10.1021/acs.estlett.1c01012; *see generally* Richard Rothstein, *The Color of Law* 63-67, 70-75, 93-99 (2017). EPA's analyses suggest that Black and Hispanic populations especially have higher $PM_{2.5}$ exposures than non-Hispanic white populations. 88 Fed. Reg. at 5592, 5609; RIA at ES-20 to -21; *see* Christopher Tessum et al., "$PM_{2.5}$ Polluters Disproportionately and Systemically Affect People of Color in the United States," 7 Science Advances eabf4491 (April 2021).[23]

Similarly, populations consisting of people of color also face disparate burdens from $PM_{2.5}$ resulting from motor vehicles. Asian people are, on average, exposed to 34% higher levels of $PM_{2.5}$ from vehicles than the average for the total U.S. population, with Black populations' exposure being 24% higher and Latino populations' exposure 23% higher; on the other hand, exposure of white populations to $PM_{2.5}$ from vehicles is, on

[22] Because many of the underlying sources we discuss herein use the term "Hispanic," we generally use it throughout these comments for consistency. We also use the term "Latino" at times.

[23] Available at https://www.science.org/doi/10.1126/sciadv.abf4491.

average, 14% lower than the average exposure for everyone.[24] There are similar, but elevated, disparities in the Northeast and Mid-Atlantic regions, as well as California.[25]

The disproportionate effect of polluters on people of color Tessum et al. describe can also be seen in the agricultural sector. As mentioned above, CAFOs emit vast amounts of $PM_{2.5}$-forming ammonia. Decades of well-established evidence shows that CAFOs often disproportionately burden people of color and low-income communities. *E.g.*, Arbor J.L. Quist et al., *Disparities of Industrial Animal Operations in California, Iowa, and North Carolina* 7 (2022); Sacoby M. Wilson et al., *Environmental Injustice and the Mississippi Hog Industry*, 110 Env't Health Persps. 195, 199 (2002).

At a regional level there are additional differences in exposure. Under the current standard, in the northeastern United States, Black populations are exposed to significantly higher levels of $PM_{2.5}$ pollution, for example, while those living in poverty and those without a high school diploma are subject to higher relative levels of $PM_{2.5}$ pollution in California. RIA 6-12 to -14; *see also id.* at ES-21 (discussing regional differences in benefits of proposed standards). The impact of $PM_{2.5}$ pollution is further exacerbated within communities of color by "health risk disparities for both Hispanic and non-Hispanic Black populations compared to non-Hispanic White populations"; for example, asthma is especially prevalent in Black populations, as is hypertension and stroke. 88 Fed. Reg. at 5592.

As a result, EPA's "at-risk analysis indicates that Black populations may experience disproportionately higher exposures and risk under air quality conditions just meeting the current primary annual $PM_{2.5}$ standard in the study areas." 88 Fed. Reg.

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[24] David Reichmuth, Air Pollution from Cars, Trucks, and Buses in the US: Everyone Is Exposed, but the Burdens Are Not Equally Shared, https://blog.ucsusa.org/dave-reichmuth/air-pollution-from-cars-trucks-and-buses-in-the-u-s-everyone-is-exposed-but-the-burdens-are-not-equally-shared/ (Oct. 16, 2019).

[25] Union of Concerned Scientists, *Inequitable Exposure to Air Pollution from Vehicles in the Northeast and Mid-Atlantic* 2 (2019), https://www.ucsusa.org/sites/default/files/attach/2019/06/Inequitable-Exposure-to-Vehicle-Pollution-Northeast-Mid-Atlantic-Region.pdf; Union of Concerned Scientists, *Inequitable Exposure to Air Pollution from Vehicles in California* 1 (2019), https://www.ucsusa.org/sites/default/files/attach/2019/02/cv-air-pollution-CA-web.pdf.

at 5607. And EPA's RIA indicates that more stringent standards offer especially high benefits to low-income communities and communities of color. RIA at 6-42 to -43.

V. PRIMARY $PM_{2.5}$ NAAQS

Several important facts are well established:

- $PM_{2.5}$ kills people and causes other severe human health harms.
- It causes such harms over both long- and short-term exposures.
- $PM_{2.5}$ exposures and harms are not evenly distributed across the population.
- Communities of color, especially Black communities, and low-income communities generally experience higher exposures and greater harms.
- Children and older adults, too, are at elevated risk of harm.

Also well-established: the Clean Air Act requires EPA to protect such communities and population groups, with an adequate margin of safety, against adverse health effects, and basic administrative law requires EPA to act rationally in carrying out this statutory requirement. In its efforts to fulfill its health-protective legal obligation, EPA has established one standard primarily targeting annual levels of $PM_{2.5}$ and another primarily targeting 24-hour levels. These two standards both complement one another and work together to limit harmful $PM_{2.5}$ pollution in the air people breathe.

As explained below, the evidence already in the record and in these and other comments demonstrates that, to meet the Clean Air Act's requirements and to act rationally, EPA must strengthen the annual standard's level to no higher than 8 μg/m^3 and the 24-hour standard's level to no higher than 25 μg/m^3.

A. EPA must strengthen the annual standard to a level no higher than 8 μg/m^3

1. Overwhelming evidence demonstrates that the current annual standard does not protect public health with an adequate margin of safety

Overwhelming evidence demonstrates that the current annual standard does not protect public health within an adequate margin of safety. This finding is also supported by the unanimous agreement of CASAC members and the PA that the current level of the primary annual $PM_{2.5}$ standard is not sufficiently protective of public health and must be lowered. PA at 3-206, 3-213. The scientific basis for this conclusion is strong: In describing EPA staff's conclusions for the Administrator's consideration in this reconsideration of the primary $PM_{2.5}$ standards, EPA notes that recent scientific studies, including those analyzed in the May 2022 Supplement to the 2019 Integrated Science Assessment for Particulate Matter, provide stronger support for health effect associations at lower ambient $PM_{2.5}$ levels than in previous reviews. PA at 3-199 to -207.

The ISA Supplement finds that more recent studies support the conclusions of the ISA that significant health effects occur at levels well below the current annual standard. For the mortality endpoint, the ISA Supplement finds that recent epidemiologic studies conducted in the U.S. and Canada consisting of cohorts with mean annual $PM_{2.5}$ concentrations mostly below 12 μg/m^3, with the majority ranging from 5.9 to 11.65 μg/m^3 (i.e., a range that is entirely below the level of the current annual standard), add to the large evidence base indicating consistent, positive associations between long-term $PM_{2.5}$ exposure and mortality detailed in the 2019 ISA. ISA Supplement at 5-3.

For cardiovascular endpoints, the ISA Supplement also notes that "Recent studies report consistent, positive associations for cardiovascular mortality, specifically [ischemic heart disease ("IHD")] and stroke mortality, across different cohorts at varying spatial scales and across different exposure assessment and statistical methods with the majority having annual $PM_{2.5}$ concentrations ranging from 8.6 to 13.7 μg/m^3," again concentrations that go well below the level of the current standard. *Id.* at 5-2. This component of EPA's analysis includes a key study of long-term exposures among 11 million Medicare recipients in the southeastern U.S. with exposures from 2000-2012 estimated via aerosol optical depth data from satellites, land use, and chemical transport models (Yazdi et al. 2019). Importantly, that study includes a restricted analysis for $PM_{2.5}$ levels below the level of the current standard. In the restricted analysis, the authors report, long-term $PM_{2.5}$ exposure was significantly associated with an increased hazard of admissions for all studied outcomes (stroke, COPD, myocardial infarction, pneumonia, lung cancer, and heart failure), compared to the unrestricted analyses. The PA is clear that, in this case and others, epidemiologic studies that restrict annual or daily $PM_{2.5}$ concentrations provide support for positive and statistically significant associations at long-term mean $PM_{2.5}$ concentrations lower than the current standard. PA at 3-202. In the PA, EPA acknowledges other studies it reviewed that also restrict their analyses to air quality below the current annual $PM_{2.5}$ standard. Those studies, including Di et al. (2017b), Shi et al. (2016), and Dominici et al. (2019), report positive and significant associations, which are often greater in magnitude than the main (unrestricted) analyses.

Furthermore, in the PA, EPA highlights recent U.S. and Canadian epidemiologic studies that provide support for positive and statistically significant health effect associations across a broad range of ambient $PM_{2.5}$ concentrations, including for air quality distributions with overall mean concentrations lower than in previous reviews. *Id.* at 3-204.

The ISA Supplement finds that, collectively, the evidence consistently and powerfully continues to support a linear, no-threshold relationship at $PM_{2.5}$ concentrations > 8 μg/m^3. ISA Supplement at 5-3; PA at 3-205).

The risk assessment indicates that the current primary $PM_{2.5}$ standards allow a substantial number of deaths in the U.S., with the large majority of those deaths associated with long-term PM2.5 exposures. In its analysis, when air quality in the 47 study areas was adjusted to simulate just meeting the current standards, the risk assessment estimates 40,600-45,100 long-term $PM_{2.5}$ exposure-related deaths annually, with confidence intervals ranging from 30,300-59,000. While the absolute numbers of estimated deaths vary across exposure durations, populations, and concentration-response functions, EPA correctly notes in the PA that the general magnitude of risk estimates supports the potential for significant public health impacts in locations meeting the current primary $PM_{2.5}$ standards. PA at 3-203 to -04.

In commenting on the PA, CASAC noted a few potential areas for improvements in the risk assessment. These areas include "estimat[ing] the number of prevented deaths starting at current PM levels in the [core-based statistical areas ("CBSAs") analyzed in the risk assessment] and lowering them to alternative standards," considering morbidity-based risk assessments, and expanding the geographic scope of risk assessments. CASAC Letter on PA at 10.

A recent Industrial Economics ("IEc") analysis commissioned by the Environmental Defense Fund ("EDF") addresses several of CASAC's comments. IEc, *Analysis of $PM_{2.5}$-Related Health Burdens Under Current and Alternative NAAQS: Updated Final Report* (Mar. 21, 2023), https://globalcleanair.org/files/2023/03/Updated-IEc-PM-NAAQS-Analysis-March-2023.pdf. It finds that $PM_{2.5}$ levels in 2015 resulted in 42,000 $PM_{2.5}$ attributable adult deaths (at current conditions in the 47 CBSAs analyzed in the

PA). This was estimated using EPA's 12km air quality surface, which uses Bayesian downscaling to integrate monitor data with model data from a chemical transport model, county scale baseline mortality rates and concentration response functions from Turner et al. (2016). These are data and model inputs used by EPA in its PA, except that the IEc report uses the current conditions for 2015 rather than the simulated conditions of just meeting the current standard. It shows that despite being slightly lower, even without simulating just meeting the current annual average standard, populations in the 47 CBSAs are bearing significant health burdens due to $PM_{2.5}$ at current conditions.

To expand the geographic scope of the assessment across the nation beyond the CBSAs EPA analyzed in the Policy Assessment, the IEc report uses fine scale (1 km^2) ensemble model $PM_{2.5}$ data to assess the health burden—including morbidity—due to fine particle air pollution nationwide. The report finds that in 2015, $PM_{2.5}$ exposure, across the contiguous United States, resulted in:

- 120,000 premature adult deaths
- 75,000 respiratory emergency room visits
- 110,000 non-fatal heart attacks
- 27,000 cases of Alzheimer's disease
- 24,000 childhood asthma emergency room visits

The national morbidity impacts of $PM_{2.5}$ are substantial and devastating to families affected. The resulting missed school and workdays and increased health care costs are just the tip of the iceberg in terms of the ways this affects families' ability to thrive.

Also notable, up to 70% of these impacts are experienced in areas outside the 47 CBSAs analyzed in the Policy Assessment and therefore are not captured in EPA's analysis. Many of the populations bearing the burden in these areas are rural with lower access to health care. Many are Black, as well.

Though unhealthy air affects many people throughout this country, historically marginalized communities and communities of color are harmed disproportionately. EPA's most recent literature review of the science related to the health and welfare effects of particle pollution concluded that people of color, particularly Black populations, are at a greater risk for health impacts from fine particles, as are low socioeconomic status populations.[26] Black and Hispanic populations generally experience exposures to greater levels of air pollution.[27] And numerous studies have found that Hispanic, Asian and especially Black populations have a higher risk of premature death from particle pollution than white populations do.[28] 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.[29] And the risk of dying and likelihood for asthma increase in

[26] ISA Supplement at 3-160 to -61; ISA at 12-31 to -38.

[27] 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/.

[28] Kioumourtzoglou MA, Schwartz J, James P, Dominici F, Zanobetti A. $PM_{2.5}$ 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.

[29] 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 Black populations. The study, as noted above, involved air quality distributions allowed by the current NAAQS.

populations with higher unemployment, higher use of public transportation and among people eligible for Medicaid.[30]

A 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 $PM_{2.5}$). A study by Thind et al. (2019) identified high air pollution exposures among Black populations 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. The ISA notes specifically that analyses that directly compare PM-related health effects across groups—i.e., stratified analyses—indicate that communities of color have higher $PM_{2.5}$ exposures than white populations, contributing to adverse health risk in populations made up of people of color (ISA section 12.5.4). Drawing from such studies, the ISA concludes "[t]here is strong evidence demonstrating that black and Hispanic populations, in particular, have higher $PM_{2.5}$ exposures than non-Hispanic white populations" and "there is consistent evidence across multiple studies demonstrating an increase in risk for nonwhite populations." ISA at 12-38. Indeed, 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 2020 PA finds, that the groups at increased risk "represent a substantial portion of the total U.S. population." 2020 PA 3-44.

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[30] 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 $PM_{2.5}$ 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

2. **To meet the Clean Air Act's mandates, which include advancing environmental justice, EPA must set the annual standard's level no higher than 8 μg/m³**

In 2018, researchers published systematic review and meta-analysis examining the association between long-term exposure to $PM_{2.5}$ and mortality derived from 53 studies, including 8 studies that had a mean $PM_{2.5}$ level <9 μg/m³.[31] The study concludes that significant effects were observed below 10 μg/m³ and a number of studies included evidence of effects down to a mean $PM_{2.5}$ level of 4.1 μg/m³.[32] Indeed, several Canadian-based research studies evaluate the effects of air pollution on heart and lung disease and find increased risk at levels even below the WHO guidelines of 5 μg/m³. A population-based cohort study conducted in Vancouver, Canada, investigates the association between air pollution—including black carbon, a constituent of $PM_{2.5}$—and chronic obstructive pulmonary disease ("COPD") and finds an increase in COPD hospitalization and mortality (mean $PM_{2.5}$ concentration of 4.1 ug/m³).[33] In a second study, the authors used the same cohort/population-level data to assess the association between air pollution and coronary heart disease ("CHD"). In this case, the authors observed a similar phenomenon in that long-term exposure to particulate pollution was associated with adverse cardiovascular outcomes—including hospitalization and mortality.[34] Importantly, the cohort-study population includes over 450,000 residents

[31] Vodonos, A., Awad, Y. A., & Schwartz, J. The concentration-response between long-term $PM_{2.5}$ exposure and mortality; A meta-regression approach (2018). *Environmental Research*, *166*, 677-689; available at https://www.sciencedirect.com/science/article/pii/S0013935118303256.

[32] *Id.*

[33] Gan, W. Q., FitzGerald, J. M., Carlsten, C., Sadatsafavi, M., & Brauer, M. Associations of ambient air pollution with chronic obstructive pulmonary disease hospitalization and mortality (2013). *American Journal of Respiratory and Critical Care Medicine*, *187*(7), 721-727; available at https://www.atsjournals.org/doi/full/10.1164/rccm.201211-2004OC.

[34] Gan, W. Q., Koehoorn, M., Davies, H. W., Demers, P. A., Tamburic, L., & Brauer, M. (2011). Long-term exposure to traffic-related air pollution and the risk of coronary heart

(between 45-85 years), and with such a large sample size the study has the statistical power to detect the observed health outcomes (COPD and CHD).

In a separate analysis, researchers conducted a prospective cohort study of respondents linked to the Canadian Community Health Survey, which includes a population size of nearly 300,000 individuals.[35] The study examines risks of circulatory and respiratory mortality and exposure to a mean $PM_{2.5}$ level of 6.3 μg/m^3 and finds that increased risk of mortality was observed even at such a low concentration.[36]

In a recent article published in Science, researchers evaluated the World Health Organization's guidelines, which were recently issued and propose an annual average concentration of 5 ug/m^3 for $PM_{2.5}$.[37] The authors undertook a population-based cohort study of 7.1 million individuals in one of the areas with the lowest exposure levels in order to address this question. At very low (5 μg/m^3) concentrations, the data show a supralinear concentration response connection between $PM_{2.5}$ and death. In comparison to prior estimates, this modified global concentration-response function integrating this new data implies that $PM_{2.5}$ causes an additional 1.5 million fatalities globally, each year.

Taking this evidence with the other evidence discussed below, including evidence of the disproportionate harms $PM_{2.5}$ has on communities of color and low-income communities EPA must set the annual standard no higher than 8 μg/m^3.

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disease hospitalization and mortality (2011). *Environmental Health Perspectives*, *119*(4), 501-507; available at https://ehp.niehs.nih.gov/doi/full/10.1289/ehp.1002511.

[35] Pinault, L., Tjepkema, M., Crouse, D. L., Weichenthal, S., van Donkelaar, A., Martin, R. V., ... & Burnett, R. T. Risk estimates of mortality attributed to low concentrations of ambient fine particulate matter in the Canadian community health survey cohort (2016). *Environmental Health*, *15*(1), 1-15; available at https://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0111-6.

[36] *Id.*

[37] Weichenthal, S., Pinault, L., Christidis, T., Burnett, R. T., Brook, J. R., Chu, Y., & Brauer, M. How low can you go? Air pollution affects mortality at very low levels (2022). *Science Advances*, *8*(39), eabo3381; available at https://www.science.org/doi/10.1126/sciadv.abo3381.

i. Copious evidence demonstrates that an annual standard no higher than 8 μg/m³ is necessary to reduce disparities that disproportionately harm Black populations and other communities of color

Decades of historically racist policies such as redlining and siting of highways and polluting facilities have resulted in communities of color and other historically marginalized populations living in areas with a disproportionately higher number of $PM_{2.5}$ sources. This has resulted in populations of color and low-income communities experiencing higher exposure to a range of dangerous pollutants, including $PM_{2.5}$.

Studies from the last several years have quantified the magnitude of the disproportionate burden of $PM_{2.5}$ on Black and Hispanic populations. To set a standard that, consistent with the Clean Air Act, is truly protective of all populations, including the most at-risk, it is critical that EPA consider and maximally redress the pollution burden on the most sensitive populations. As we describe below, to do this, EPA must set the annual standard no higher than 8 μg/m³.

a. Disproportionate exposure and harms

A 2018 study by EPA scientists published in the American Journal of Public Health, for example, finds that communities of color overall experienced 1.28 times $PM_{2.5}$ emissions source burden of the general population, and Black populations, specifically, experienced the greatest degree of disparity in the siting of PM emitting facilities at national, state, and county levels, burdened with 1.54 times the PM emissions faced by the general population. Ihab Mikati et al., *Disparities in Distribution of Particulate Matter Emission Sources by Race and Poverty Status*, 108 Am. J. Pub. Health 480 (2018), https://doi.org/10.2105/AJPH.2017.304297)

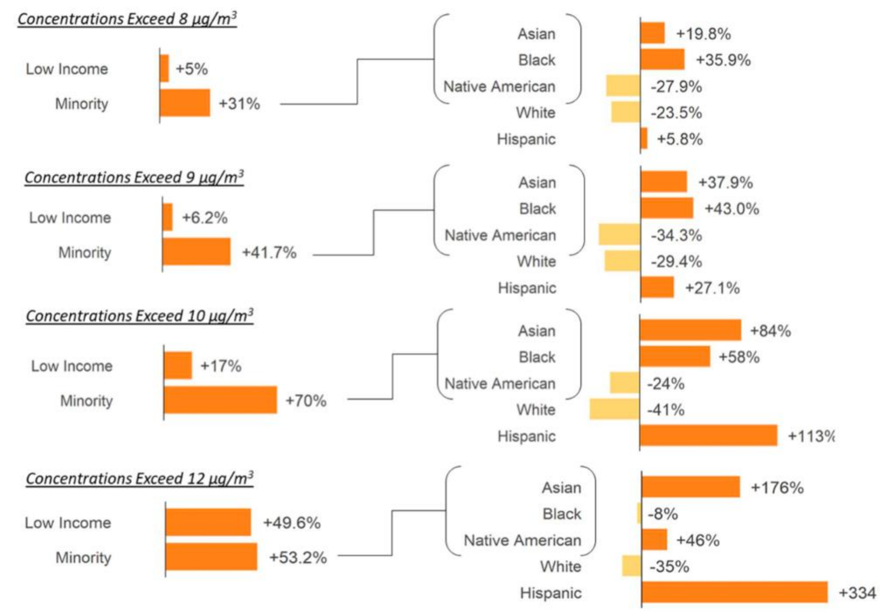
An April 2021 study in Science Advances finds that nearly all categories of $PM_{2.5}$ emission sources contribute to the "systemic $PM_{2.5}$ exposure disparity experienced by people of color," and this is true across different states, in both rural and urban areas, and when income levels and exposure levels are controlled for. Tessum et al., *$PM_{2.5}$ Polluters Disproportionately and Systemically Affect People of Color in the United States*, at 1. The study finds that in "2014 total population average $PM_{2.5}$ exposure from all domestic anthropogenic sources is 6.5 μg m^{-3} in the contiguous United States; exposures are higher than average for POC, Blacks, Hispanics, and Asians (7.4, 7.9, 7.2, and 7.7 μg m^{-3}, respectively…) and lower than average for Whites (5.9 μg m^{-3}…).” The authors estimate that:

- White populations are exposed to 8% lower $PM_{2.5}$ concentrations than the average American, from emission sources causing 60% of overall exposure.
- Black populations are exposed to 21% greater $PM_{2.5}$ concentrations than the average American, from sources contributing 78% of exposure.
- Hispanic and Asian populations are exposed to $PM_{2.5}$ from 87% and 73% of sources, respectively, and experience 11% (0.72 μg m^{-3}) and 18% (1.20 μg m^{-3}) overall exposure disparities, respectively.

The recent nationwide IEc analysis, using the Di et al. (2019) ensemble model predictions at 1 km^2, finds that $PM_{2.5}$ disparities in exposure and resulting health outcomes were substantial across the U.S.

- Older Black, Asian and Hispanic populations had greater likelihood (58%, 84%, and 113% higher, respectively) than others of living in neighborhoods where $PM_{2.5}$ pollution levels were above 10 μg/m^3.
- Older low-income populations (below 2X federal poverty limit) were 49% more likely to live in neighborhoods where levels of $PM_{2.5}$ were above 12 μg/m^3.

EXHIBIT 5-4. LIKELIHOOD OF LIVING WHERE $PM_{2.5}$ EXCEEDS SPECIFIED CONCENTRATIONS - NATION, 65-99



Note: The reference group for each race is all *other* races combined. Comparisons between individual race groups will vary.

EPA has recognized the environmental injustice posed by PM pollution. However, in the proposed rule, EPA claims that "White, Hispanic, and Asian populations were exposed to similar average $PM_{2.5}$ concentrations," 88 Fed. Reg. at 5616, contradicting the body of evidence and conclusions in the PA that Hispanic populations have higher $PM_{2.5}$ exposure. In the PA, EPA says that "there is strong evidence for racial and ethnic disparities in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk," specifically "demonstrating that Black and Hispanic populations, in particular, have higher $PM_{2.5}$ exposures than non-Hispanic White populations." PA at 3-55 (citing ISA fig.12-2; ISA Supplement fig.3-38).

Inequities in health impacts from $PM_{2.5}$ do not result solely from inequities in exposure. Many of the same racist policies, institutional practices, and low representation have caused disinvestment in communities of color, resulting in differential quality and distribution of housing, transportation, economic opportunity, education, food, access to health care, chronic stress, and beyond. All these inequities manifest in health disparities, higher underlying mortality rates, and greater vulnerability to pollution-caused disease. Rachel Morello-Frosch et al., *Understanding the Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*, 30 Health Affairs 879 (2011); Devon C. Payne-Sturges et al., *Confronting Racism in Environmental*

Health Sciences: Moving the Science Forward for Eliminating Racial Inequities, 129 Environ. Health Perspectives 055002 (2021).

EPA acknowledges the evidence on this in the PA, stating:

> Current scientific evidence indicates that some populations, such as different racial/ethnic groups, face higher health burdens from $PM_{2.5}$, including for higher levels of exposure and for increased risk of adverse health responses to a given level of exposure….

PA at 3-156. In that document, EPA reports on its own risk analysis that incorporated race- and ethnicity-specific concentration-response functions from Di et al. (2017) and found that "[a]cross all scenarios and demographic groups evaluated, Black populations are associated with the largest $PM_{2.5}$-attributable mortality risk rate per 100,000 people." *Id.* at 3-158.

These findings are consistent with a range of studies and analyses that use different methods to assess exposure, extending the analysis to areas outside those assessed in the PA and to disease outcomes that affect younger populations' ability to grow into their full potential and communities' ability to thrive.

The 2023 IEc analysis finds that nationwide, Black populations over age 65 were three times more likely to die from exposure to particulate matter than other seniors. In fact, despite Black seniors making up only 9% of the 65-year-old and above population, they bear nearly 25% of the total mortality burden from $PM_{2.5}$ (over 29,000 deaths in this group in 2015 alone). Additionally, many of these risks were borne by populations outside the PA areas, highlighting the importance of looking beyond the urban areas analyzed in the PA to fully capture the harmful impacts of $PM_{2.5}$.

EXHIBIT 2-8. CURRENT NATIONAL PM2.5-ATTRIBUTABLE MORTALITY BURDEN BY RACE, AGES 65-99

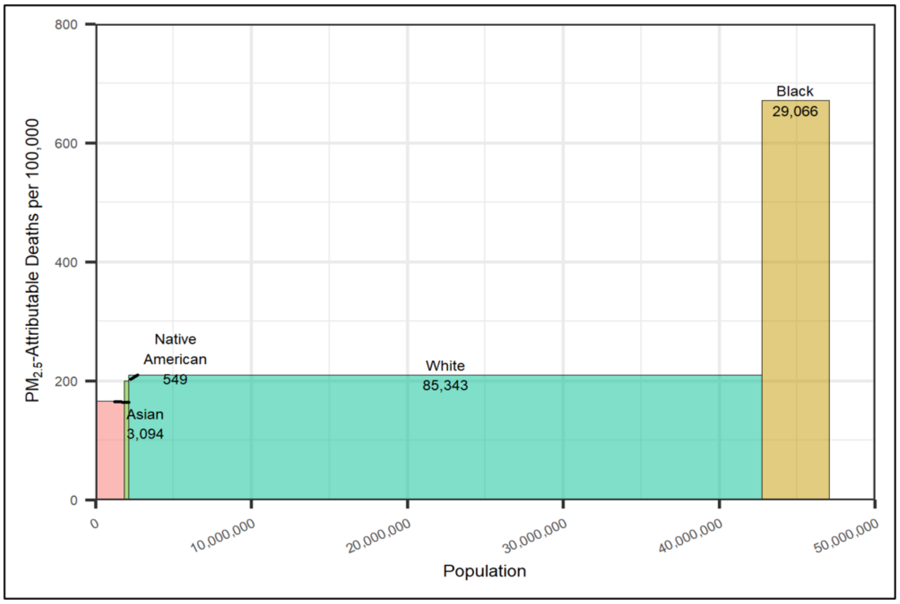
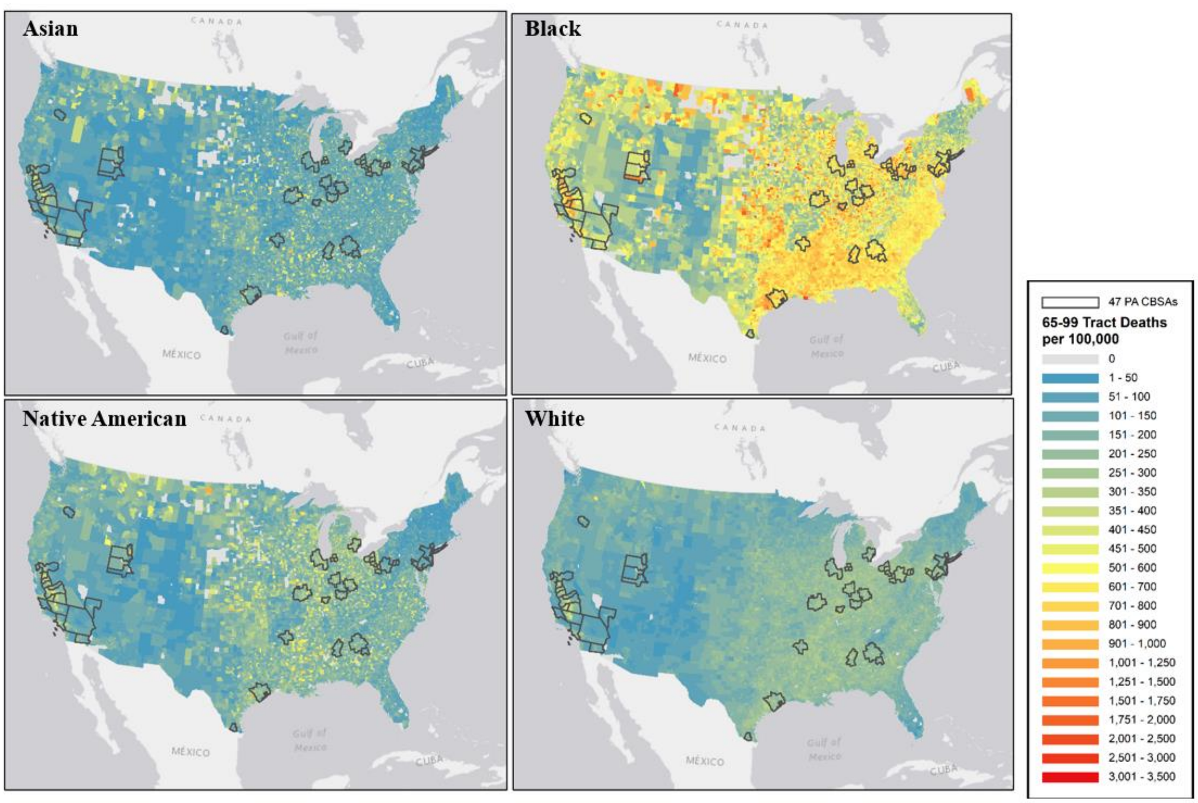


EXHIBIT 2-9. FINE SCALE PM2.5-ATTRIBUTABLE MORTALITY BURDEN PER 100,000 FOR THOSE AGED 65-99, CENSUS TRACT LEVEL



According to the CDC, asthma is the leading cause of chronic disease among children, with about 6 million children in the United States living with asthma. CDC, Asthma in Children (last visited Mar. 22, 2023), https://www.cdc.gov/vitalsigns/childhood-asthma/index.html. About 16% of Black children and 7% of white children have asthma. *Id.* There are over 790,000 emergency room visits and over 64,000 hospitalizations among children annually due to asthma. CDC, Most Recent National Asthma Data (last visited Mar. 22, 2023), https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm (click on "Heathcare Use" tab). Emergency room visits for asthma attacks were highest among young children and non-Hispanic Black children, and Black children are 5 times more likely to be hospitalized for asthma.

Developing asthma changes a child's life. It changes the trajectory of physical, emotional and academic growth. Asthma is the leading cause of missed school days each year and has been linked to diminished school performance. Bonnie B. Dean et al., *Uncontrolled Asthma: Assessing Quality of Life and Productivity of Children and Their Caregivers Using a Cross-Sectional Internet-Based Survey*, 8 Health & Quality of Life Outcomes 1 (2010). It also places an economic burden on the family. During 2008-2013, asthma was responsible for $3 billion in losses due to missed work and school days, $29 billion due to asthma-related mortality, and $50.3 billion in medical costs. Tursynbek Nurmagambetov et al., *The Economic Burden of Asthma in the United States, 2008-2013*, 15 Annals Am. Thoracic Soc'y 348 (2018).

There is a body of evidence that indicates that $PM_{2.5}$ is associated with asthma among children. The ISA concludes that the "[e]pidemiologic evidence strongly supports a relationship with decrements in lung function growth in children" and "with asthma development in children, with increased bronchitic symptoms in children with asthma, with an acceleration of lung function decline in adults, and respiratory mortality, including cause-specific respiratory mortality for COPD and respiratory infection." ISA at 1-34 tbl.1-2; PA at 3-38. Epidemiologic studies evaluated in the ISA continue to provide strong evidence for a relationship between short-term $PM_{2.5}$ exposure and several respiratory-related endpoints, including asthma exacerbation. The collective body of epidemiologic evidence for asthma exacerbation is more consistent in children than in adults. PA at 3-39 (citing ISA section 5.1.2.1).

Further, a study of over 600,000 asthma emergency department visits in Atlanta, Dallas and St. Louis (over 1993-2009), Alhanti et al. (2016), finds that $PM_{2.5}$ was associated with higher asthma emergency room visits among children, particularly among populations of color. Utilizing the results of this study, the 2023 IEc analysis finds that people of color who are children are six times more likely to visit the emergency room for air pollution-triggered childhood asthma than non-Hispanic white children. While Black children account for 14% of the population of children, they account for 30% of the PM-attributable asthma emergency room visits. More than half the PM-attributable childhood asthma emergency room visits among Black children occur outside the areas examined in the PA and considered by EPA in the current proposed rule.

EXHIBIT 2-12. CURRENT $PM_{2.5}$-ATTRIBUTABLE MORBIDITY BURDEN FOR ASTHMA ED VISITS IN CHILDREN AGED 0-18 (PER 100,000, STRATIFIED BY RACE/ETHNICITY)

STRATIFIED RISK ESTIMATE ALHANTI ET AL., 2016	RACE/ ETHNICITY	NATION	PA AREAS		NON-PA AREAS
		1KM	12KM	1KM	1KM
White	White, Non-Hispanic	10	13	12	9
Total Non-white	**White, Hispanic Plus All Other Races, Ethnicities**	58	57	69	50

EXHIBIT D-3. CURRENT $PM_{2.5}$-ATTRIBUTABLE MORBIDITY BURDEN FOR ASTHMA ED VISITS (STRATIFIED BY RACE/ETHNICITY)

AUTHOR	CONCENTRATION - RESPONSE RELATIONSHIP	AGE GROUP	RACE	ETHNICITY	NATION	PA AREAS		NON-PA AREAS
					1KM	12KM	1KM	1KM
Alhanti et al. (2016)	White	0-18	White	Non-Hispanic	4,117	1,365	1,273	2,844
	Non-white		White	Hispanic	9,820	5,295	5,056	4,764
	Non-white		Asian	All	2,254	1,271	1,182	1,072
	Non-white		Black	All	7,691	3,439	3,236	4,455
	Non-white		Native American	All	459	153	145	314

While the etiopathology of asthma is multifactorial, it is unconscionable that the air our children breathe is another source of this disparity.

b. The RIA, PA, and premature mortality

In its RIA, EPA sought to calculate the "proportionality of $PM_{2.5}$ concentration changes when moving from the current (baseline) to alternative standard levels under air quality scenarios associated with [different] emission control strategies" at both the national and regional levels. RIA at 6-20. For the national level, EPA found that alternative standard levels linked with control measures reduce the average $PM_{2.5}$ exposure concentrations experienced by the reference population by a growing proportion when the alternative standards are lowered, with a 0.7% improvement for 12/35-10/35 and a 3.8% reduction for 12/35-8/35. *Id.* at 6-22 fig.6-9. Both Hispanic and Asian populations are expected to see the greatest percentage decreases in $PM_{2.5}$ concentrations under all alternative standard levels considered, followed by those with less education. *Id.* When shifting from 12/35-10/35, Black populations experience lesser proportional $PM_{2.5}$ concentration improvements than white populations, but, with moving to stronger standards, Black populations experience better proportional $PM_{2.5}$ concentration improvements than white populations, especially when moving from 12/35-8/35. *Id.* The RIA explains that this is most likely due to the fact that gaps in $PM_{2.5}$ concentrations experienced by Black populations versus those experienced by white populations in the baseline are greater at lower ambient $PM_{2.5}$ concentrations, with Black populations experiencing higher $PM_{2.5}$ levels relative to white populations throughout the distribution but especially at lower ambient concentrations. *Id.* at 6-21. Importantly, for lower alternative $PM_{2.5}$ limits, this results in proportionately bigger benefits for Black populations and effectively narrows disparities as compared to white populations. *Id.*

The RIA further analyzes the environmental justice implications of premature mortality, citing the ISA and ISA Supplement as finding notable differences in racial and ethnic $PM_{2.5}$ exposure across the United States, with Black populations experiencing some of the greatest disparities compared to white populations. *Id.* at 6-23 to -24. Furthermore, several studies found higher $PM_{2.5}$-related mortality and other health impacts from long-term $PM_{2.5}$ exposure in Black communities. *Id.* at 6-24. Taken together, Black people are at elevated risk for $PM_{2.5}$-related health consequences due in part to inequalities in exposure. *Id.*

Figures 6-11 and Figure 6-12 in the RIA depict the nationwide averages and distributions of estimated mortality rates per 100,000 people for different demographic groups over the age of 64. The larger magnitude concentration-response relationship between exposure and mortality, which was outlined in Di et al. (2017), shows that Black populations experience higher mortality rates. *Id.* at 6-25. A heat map of this data shows the greatest decrease in mortality rates from 9/35 to 8/35 (572 per 100,000 to 559 per 100,000) when compared to a more moderate decrease in the standard of 12/35 to 10/35 (581 per 100,000 versus 579 per 100,000) for Black populations. *Id.* at 6-26 fig.6-11. It is important to note that white populations experience far fewer mortalities (over 30% fewer mortalities at the current standard of 12 ug/m^3) as well as substantially lower decreases in mortality at alternative standards—for 9/35 to 8/35, the mortality rate decreases from 184 per 100,000 to 181 per 100,000 versus 12/35 to 10/35 where the mortality rate only decreases from 186 per 100,000 to 185 per 100,000.

EPA's own analysis shows that it can achieve the greatest reductions in exposure and mortality disparities at 8 ug/m^3. Indeed, its analysis shows that it cannot possibly justify a less stringent standard given the reality that a stronger standard will achieve the greatest reductions in premature deaths, especially for Black populations and other communities of color. If not corrected, EPA's approach will leave the most affected, most overburdened populations—communities of color, especially Black populations, and low-income communities—to experience levels of $PM_{2.5}$ pollution that EPA knows cause serious adverse health effects, including death.

Further, the PA finds that, when considering both exposure and vulnerability disparities across race/ethnicity, strengthening the annual $PM_{2.5}$ standard from 12 to 8 μg/m^3 would, among the elderly in 30 metropolitan areas, prevent 4,260 $PM_{2.5}$-attributable deaths among Black populations, 1,290 $PM_{2.5}$-attributable deaths in Hispanic populations, 525 $PM_{2.5}$-attributable deaths in Asian populations, and 28 $PM_{2.5}$-attributable deaths among Native American populations; and reduce 7,490 $PM_{2.5}$-attributable deaths among white populations. PA at C-64 tbl.C-16.

The demographic risk analysis included in the PA captures average $PM_{2.5}$ concentration and mortality risk rate by demographic population under alternative $PM_{2.5}$ standards. It's critical to note that in all of the included scenarios, Black populations still experience higher average PM-attributable risk than every other demographic group; however, the gap between Black populations and other demographic groups decreases as the standard is lowered (as seen in Figure 3-20 of the PA). *Id.* at 3-159 to -160 & figs.3-20, 3-21, 3-162.

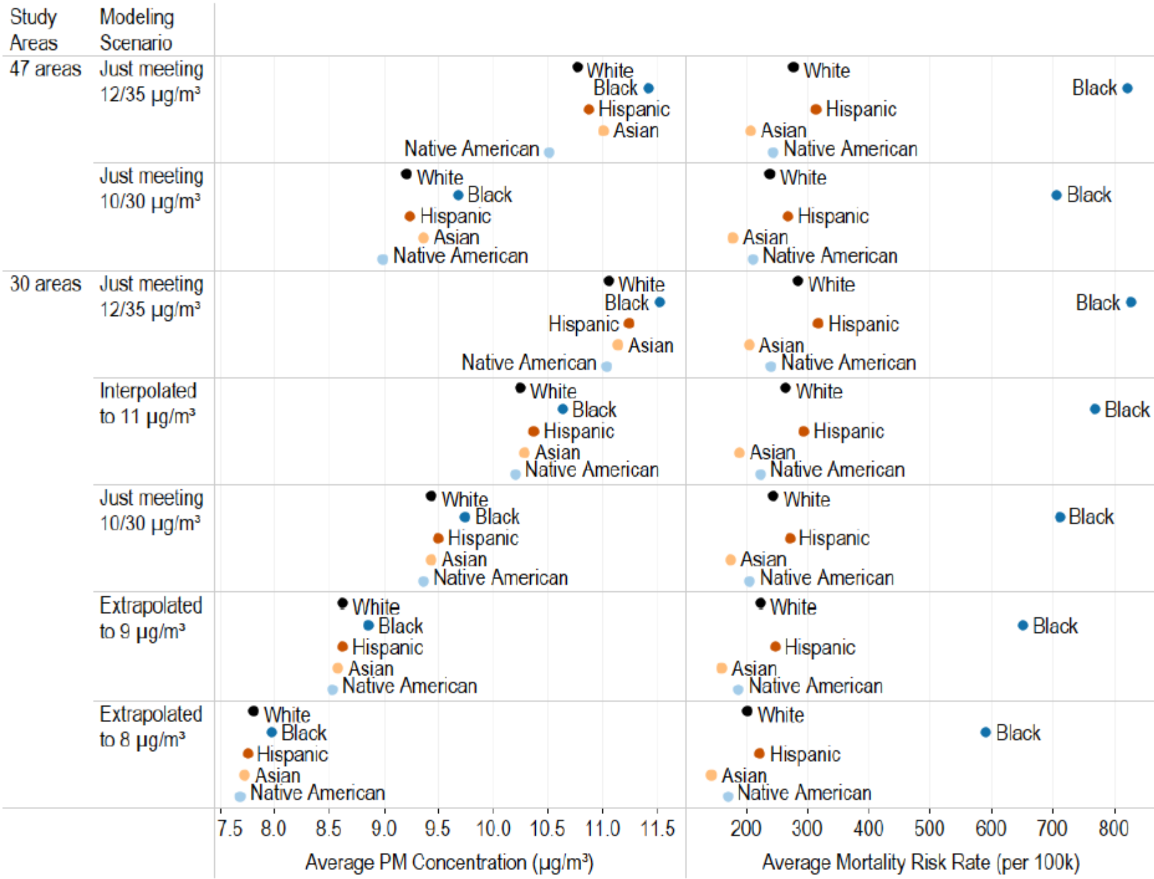


Figure 3-20. Average $PM_{2.5}$ exposure concentration and $PM_{2.5}$-attributable risk estimates by demographic population when just meeting current or alternative $PM_{2.5}$ standards.

According to the demographic risk analysis, as cited above, for Black populations, an annual $PM_{2.5}$ standard of 8 µg/m³ results in an average mortality risk rate reduction of over 250 per 100k, compared to just above 200 per 100k for 9 µg/m³ and less than 150 per 100k for 10 µg/m³. The average mortality risk rate for Black populations remains nearly three times that of white populations even under a standard of 8 µg/m³, and complementary policies to address the lingering inequity will be crucial. However, it's important to note that based on the information in EPA's own PA, a standard of 8 µg/m³ would reduce the average mortality risk rate by nearly twice as much as a standard of 10 µg/m³ and goes the furthest in reducing disparities.

The results, discussed more fully below, of Josey et al. (2023)[38] further support the findings of Di et al. (2017) (used in the PA), that the increase in mortality per unit increase in $PM_{2.5}$ is larger among older Black populations in comparison to older white populations. This recent study thus confirms that a standard of 8 μg/m^3 is necessary.

In the proposed rule EPA acknowledges the benefits of stronger standards and the recommendation from CASAC:

> The risk assessment estimates that the current primary $PM_{2.5}$ standards could allow a substantial number of $PM_{2.5}$-associated deaths in the U.S. Additionally, compared to the current annual standard, meeting a revised annual standard with a lower level is estimated to reduce $PM_{2.5}$-associated health risks in the 30 study areas controlled by the annual standard by about 7-9% for a level of 11.0 μg/m^3, 15-19% for a level of 10.0 μg/m^3, 22-28% for a level of 9.0 μg/m^3, and 30-37% for a level of 8.0 μg/m^3) (U.S. EPA, 2022a, Table 3-17). The CASAC concurred with the PA's assessment that meaningful risk reductions will result from lowering the annual $PM_{2.5}$ standard (Sheppard, 2022a, p. 16 of consensus responses).

88 Fed. Reg. at 5627-28.

On February 16, 2023, President Biden signed a new Executive Order titled Further Advancing Racial Equity and Support for Underserved Communities Throughout the Federal Government. Exec. Order 14,091, 88 Fed. Reg. 10,825 (Feb. 22, 2023). The Executive Order sets up a process to "coordinate with the White House Environmental Justice Interagency Council to ensure that equity and environmental justice efforts are consistent and mutually reinforcing." *Id.* § 2(b), 88 Fed. Reg. at 10,827-28. News reports suggest the White House Environmental Justice Advisory Committee will call for the agency to strengthen the proposed rule to ensure adequate protections of underserved communities. *See WHEJAC Establishes Workgroup for Input on NAAQS*, InsideEPA.com (Mar. 3, 2023), https://insideepa.com/daily-feed/whejac-establishes-workgroup-input-naaqs. Additionally, the Executive Order expands on earlier equity-

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[38] Josey K P, Delaney S W, Wu X, Nethery R C, DeSouza P, Braun D and Dominici F. 2023. *Air Pollution and Mortality at the Intersection of Race and Social Class*, New England Journal of Medicine, https://doi.org/10.1056/NEJMsa2300523

related Executive Orders (including the Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis), by affirming the need to advance equity in health and to "deliver environmental justice." Exec. Order 14,091 § 1, 88 Fed. Reg. at 10,826. To effectively satisfy the provisions outlined in the most recent Executive Order along with Clean Air Act mandates, EPA must strengthen the annual $PM_{2.5}$ NAAQS to at least 8 ug/m^3, where it is reasonably certain that the NAAQS will provide the greatest health benefits for underserved communities. Disparities will remain, however, and EPA and the rest of the government must take action to close them, as well.

c. Recent studies regarding disparities

Additional scientific evidence (including some studies published after EPA's ISA Supplement was finalized) indicates that long-term exposures to ambient $PM_{2.5}$ air pollution are even more harmful to historically marginalized populations than was previously understood.

Bravo et al. (2022) analyzes whether improvements in air quality ($PM_{2.5}$ and ozone) in North Carolina between 2002-2016 have been equitably distributed across subpopulations. The study estimates daily and annual $PM_{2.5}$ concentrations at the Census tract-level and calculated tract-level measures of: racial isolation of non-Hispanic Black individuals, educational isolation of non-college educated individuals, the neighborhood deprivation index, and percentage of the population in urban areas. The authors find that tracts with lower educational isolation and higher urbanicity had higher $PM_{2.5}$ and more pronounced declines in $PM_{2.5}$. Racial isolation was associated with higher $PM_{2.5}$ but not with the rate of decline in $PM_{2.5}$. This study adds to prior evidence, including in Colmer et al. (2020), that despite declines in pollutant concentrations, over time, disparities in exposure have increased for racially and educationally isolated communities.

Henneman et al. (2023) explores whether benefits from emissions reductions at U.S. coal-fired power plants over recent decades have accrued equitably across population groups. This study quantifies nationwide long-term changes in exposure to $PM_{2.5}$ associated with coal power plant SO_2 emissions by assessing how emissions changes from 1999-2020 in different locations have influenced exposure inequities, extending previous source-specific environmental justice analyses by accounting for location-specific differences in racial/ethnic population distributions. Overall, this study finds that Black populations in the South and North Central United States and Native American populations in the western United States were inequitably exposed to coal-linked $PM_{2.5}$ early in the study period. Although the authors find that inequities decreased with falling emissions, facilities in states across the North Central United States continue to inequitably expose Black populations, and Native populations are inequitably exposed to $PM_{2.5}$ resulting from emissions from coal-fired power generation in the West.

Thind et al. (2023) explores inequitable $PM_{2.5}$ exposures and health effects by analyzing impacts from inter-regional freight transportation in the contiguous United States: total mortality attributable to $PM_{2.5}$ air pollution, racial-ethnic disparities in $PM_{2.5}$-attributable mortality (and CO2 emissions). This study is the first to comprehensively compare freight modes (truck, rail, barge, and aircraft) separately and the first to explore racial/ethnic exposure disparities by route and mode, nationally. The study finds that average $PM_{2.5}$ exposures from inter-regional truck and rail are the highest for white non-Hispanic people, those from barge are the highest for Black people, and those from aircraft are the highest for people who are mixed/other race.

Additional peer-reviewed science suggests that the exposure-response risk functions used by EPA in its risk assessment and PAs may also be significantly underestimating race-specific mortality due to long-term $PM_{2.5}$ exposure. Spiller et al. (2021) explores the policy implications of using race/ethnicity-specific concentration-response functions and mortality data in comparison to standard federal approaches when estimating the impact of air pollution on non-white racial/ethnic subgroups. Using new estimates from the epidemiological literature on race/ethnicity-specific concentration-response functions paired with race/ethnicity-specific mortality rates, the authors estimate the mortality impacts of air pollution from all sources from a uniform increase in concentrations and from the regulations imposed by the Mercury and Air Toxics Standards. Importantly, the study finds that application of race/ethnicity-specific information increased $PM_{2.5}$-related premature mortality estimates in older populations by 9% and among older Black populations by 150% for all-source pollution exposure. Under a uniform degradation of air quality and race/ethnicity-specific information, older Black people were found to have approximately 3 times higher mortality relative to white people, a finding that is obscured under a non-race/ ethnicity-specific modeling approach. Standard approaches of using non-racial/ethnic specific information underestimate the benefits of the Mercury and Air Toxics Standards to older Black populations by almost 60% and overestimate the benefits to older white populations by 14%, relative to using a race/ethnicity-specific modeling approach.

Because of the public availability of the race-specific concentration-response functions, EPA should use this information to quantify disparity in $PM_{2.5}$ impacts on older Black populations. Based on these results, we recommend that the best available race/ethnicity-specific inputs be used in regulatory assessments to understand and reduce environmental injustices. Given that EPA deployed this type of "standard approach" in its assessment for the current proposal, there is strong reason to believe that the inequitable burdens of long-term $PM_{2.5}$ exposure are underestimated by EPA and that the current standard must be strengthened in accordance with the Clean Air Act to advance environmental health equity and address longstanding environmental injustice as it relates to the heavy burden of $PM_{2.5}$ air pollution on vulnerable populations.

Wang et al. (2022) details a population-based cohort study, comprising all Medicare enrollees aged 65 or older in the southeastern United States from 2000-2016, to explore the associations between long-term exposure to $PM_{2.5}$ major components and all-cause mortality among the elderly. The authors estimate ZIP code-level annual mean concentrations for five major $PM_{2.5}$ components, including black carbon, nitrate, organic matter, sulfate, and soil particles. Data are analyzed using Cox proportional hazards models, adjusting for potential confounders. In single component models, all five major $PM_{2.5}$ components are significantly associated with elevated all-cause mortality at the average exposure level of 9.56 $\mu g/m^3$ using satellite-derived, unweighted exposure estimates (25th percentile: 8.14 $\mu g/m^3$).

Shi et al. (2023) also finds evidence of $PM_{2.5}$ harms at annual average levels below 10 $\mu g/m^3$. The authors conducted a nationwide population-based cohort study (2000 to 2017) by integrating the Medicare Chronic Conditions Warehouse database and two independently sourced datasets of high-resolution $PM_{2.5}$ major chemical composition. Those air pollution estimates were retrieved from two independent sources, including black carbon, organic matter, nitrate, sulfate, ammonium, and soil dust. Using one exposure source, the dementia cohort had an average $PM_{2.5}$ mass concentration of 9.58 $\mu g/m^3$, with an interquartile range (IQR) of 3.68 $\mu g/m^3$. The secondary exposure data showed similar means and IQRs for all $PM_{2.5}$ constituents of interest except for black carbon, which showed lower levels than exposure I, albeit with overlapping distributions. Results using two exposure datasets consistently indicated higher rates of incident dementia and Alzheimer's disease for an increased exposure to $PM_{2.5}$ and its major constituents. An interquartile range increase in $PM_{2.5}$ mass was associated with a 6 to 7% increase in dementia incidence and a 9% increase in Alzheimer's disease incidence.

An additional recent study (Josey et al. 2023)[39] further demonstrates that an annual standard no higher than 8 μg/m³ is necessary to reduce disparities that disproportionately harm marginalized subpopulations. This study analyzes Medicare data from 73 million people 65 years or older from 2000-2016 to estimate associations between annual $PM_{2.5}$ exposure and mortality in subpopulations defined simultaneously by racial identity (Black vs. white) and income level (Medicaid eligible vs. ineligible). Annual $PM_{2.5}$ exposure was estimated using a validated exposure prediction model that provides estimated daily $PM_{2.5}$ levels at a 1-km² grid scale across the contiguous United States.[40] The authors aggregated the gridded $PM_{2.5}$ exposure data to the ZIP code level to match the spatial resolution of Medicare data and averaged daily ZIP code level $PM_{2.5}$ estimates across each year of the study to estimate annual average $PM_{2.5}$ exposures. While the study reported that lower $PM_{2.5}$ exposure was associated with lower mortality in the full population, historically marginalized subpopulations benefited more as $PM_{2.5}$ levels decreased from 12 to 8 μg/m³. In this study analyzing health risks within the range of the proposed annual standard being considered by EPA, higher-income Black populations, low-income white populations, and low-income Black populations benefited more from lower $PM_{2.5}$ levels than higher-income white populations.

[39] Josey K P, Delaney S W, Wu X, Nethery R C, DeSouza P, Braun D and Dominici F. 2023. *Air Pollution and Mortality at the Intersection of Race and Social Class*, New England Journal of Medicine, https://doi.org/10.1056/NEJMsa2300523

[40] Di Q, Amini H, Shi L, et al. An Ensemble-Based Model of $PM_{2.5}$ Concentration Across the Contiguous United States with High Spatiotemporal Resolution. Environ Int 2019;130:104909. https://doi.org/10.1016/j.envint.2019.104909

ii. An annual standard no higher than 8 μg/m^3 will save many thousands of lives and prevent significant numbers of other serious human health harms, including for children and for people experiencing poverty

EPA's own analysis, as well as more recent analysis, demonstrates that an annual standard no higher than 8 μg/m^3 is requisite to protect public health with an adequate margin of safety. For the 30 CBSAs (25% of the full U.S. population) where the annual standard is controlling the air quality, 38,900 deaths (26,600-51,000) are attributed to $PM_{2.5}$ when just meeting the current standard of 12 μg/m^3. PA at 3-152 tbl.3-16. This drops by 3,610 (9.3%), 7,200 (18.5%), 10,800 (28%) and 14,300 (37%) when moving from the current standard to alternative standards of 11 μg/m^3, 10 μg/m^3, 9 μg/m^3 and 8 μg/m^3, respectively, when controlling sources of pollutants that give rise to secondary $PM_{2.5}$ as the main process for achieving the alternate standards. *Id.* at 3-153 tbl.3-17.

The March 2023 IEc report builds on EPA's analysis of racial and ethnic disparities in pollution exposure and health impacts under the current and alternative standards, and supplements EPA's PA. This report considers current $PM_{2.5}$ levels in estimating the benefit of alternative standards, expands the geographic scope of the analysis, and assesses morbidity benefits and benefits to children. The study utilizes the Di et al. (2019) hybrid exposure model predictions at 1 km^2, Di et al. (2017) race- and ethnicity-specific effect estimates (for $PM_{2.5}$ and mortality), Alhanti et al. (2016) race- and ethnicity-specific effect estimates (for $PM_{2.5}$ and childhood asthma emergency room visits), and fine-scale race- and ethnicity-specific baseline disease rates and ACS data.

The findings of the report support the conclusion that the current standard is not adequate to protect health and finds significantly larger benefits to at-risk groups at an 8 μg/m^3 annual standard over 10 μg/m^3.

Nationally, a standard of 8 μg/m^3 would have over 3 times greater health benefits than a standard of 10 μg/m^3. Strengthening the annual standard to 8 ug/m^3 could prevent 16,000 premature deaths and 10,000 respiratory emergency room visits each year, compared to an avoided 4,600 premature deaths and 3,000 respiratory emergency room visits avoided at an annual standard of 10 μg/m^3. An annual standard of 9 ug/m^3 would deliver nearly double the health benefits of a 10 ug/m^3 standard, but 40% fewer health benefits than a 8 μg/m^3 standard.

The benefits of finalizing a more protective standard than EPA proposed are particularly important for areas outside of the PA study areas ("non-PA areas") which bear up to 70% (up to 83,000 premature deaths) of the national burden of air pollution under current conditions. If annual average levels dropped to 10 μg/m^3 in these non-PA areas (a flat rollback of $PM_{2.5}$ concentrations to 10 μg/m^3) the reduction in PM attributable mortality would be only 420 deaths avoided from a burden of 83,000 premature deaths attributable to $PM_{2.5}$ under estimated current conditions in 2015. This is less than 1% reduction in air pollution mortality burden across a large part of the country. This is because most of these areas already have annual average $PM_{2.5}$ levels below 10 μg/m^3. Nationally 11-19% of the population (differs by race and ethnicity) have annual average exposure above 10 ug/m^3, but only 6% of the population is exposed to levels above this threshold in the non-PA areas. *See* Exhibit 1 (Population Exposure Percentages by Race and Geographic Area Relating to IEc Report (2023)). Thus, setting a standard of 10 μg/m^3 will do very little to reduce air quality health burdens in these areas.

In the non-PA areas, reducing annual average exposures from 10 μg/m^3 to 9 μg/m^3 results in an additional 1,400 avoided deaths, and reducing exposures to 8 μg/m^3 would result in 5,000 deaths avoided. Irrespective of race, ethnicity or poverty level, a standard of 8 μg/m^3 would have 3 times higher and 15 times higher per capita $PM_{2.5}$ mortality rate reduction than 9 μg/m^3 and 10 μg/m^3 respectively in areas outside the study areas considered by EPA (70% of the U.S. population). In considering the benefit of federal policies, EPA must not ignore the burdens faced by communities across small towns and rural America.

As discussed above, there are dramatic racial and ethnic disparities in both exposure and health impacts from $PM_{2.5}$, and this holds in non-PA areas. Nearly 60% of the deaths among the older Black population occur outside the areas assessed by EPA. In these areas, alternate standards of 10 and 9 μg/m^3 have little benefit in PM mortality burden among the older Black population (2% or less reduction). The benefit of an alternate standard of 8 μg/m^3 in these areas is about 3.5 times higher than an annual standard of 9 ug/m^3.

Black American PM attributable mortality (per 100,000 population) benefits of reducing PM concentrations to 10, 9, 8 µg/m3

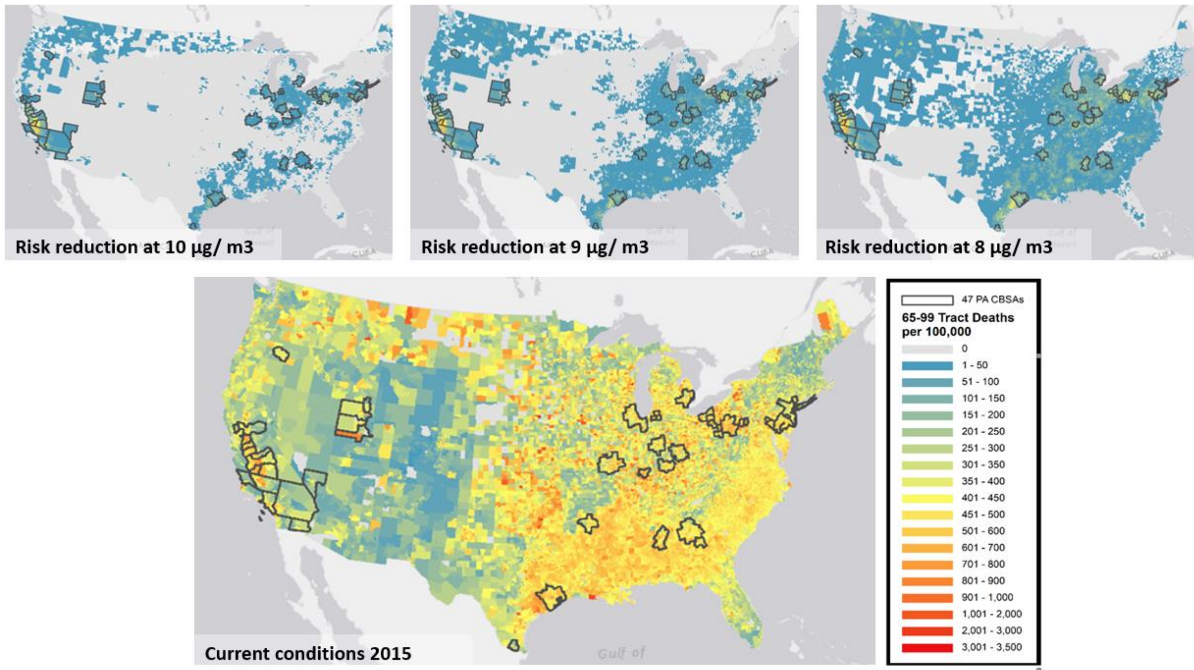
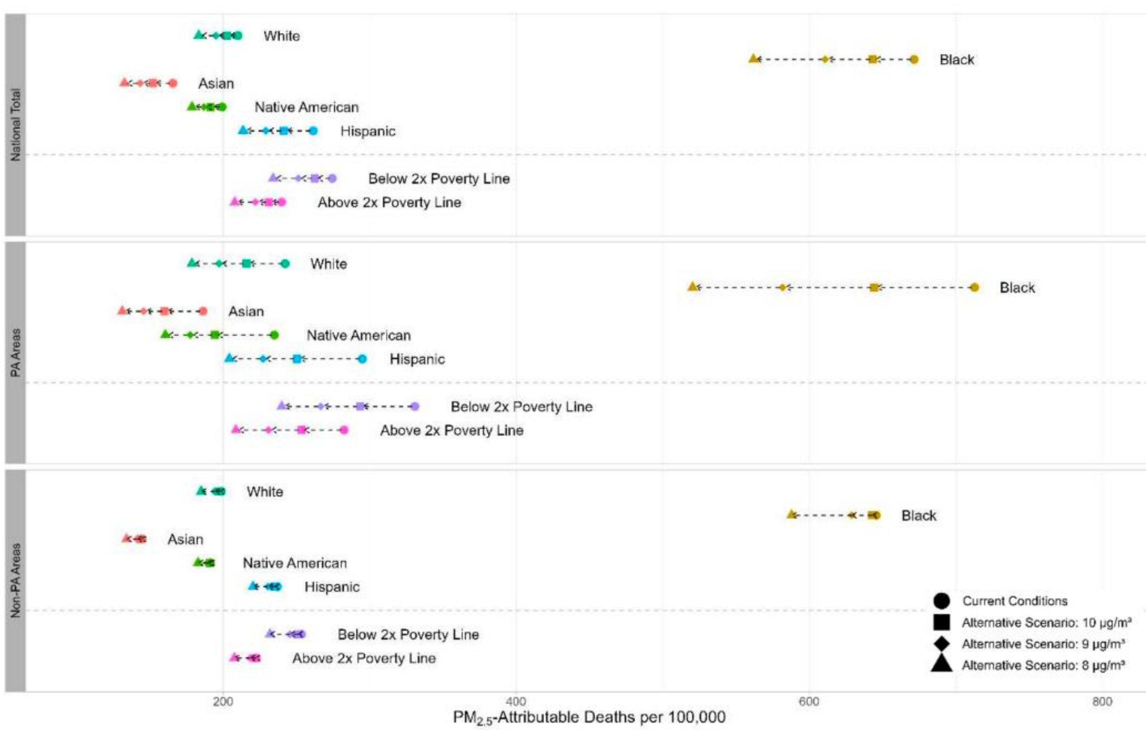


EXHIBIT 5-12. MORTALITY RATES UNDER CURRENT AND ALTERNATIVE PM NAAQS, AGES 65-99

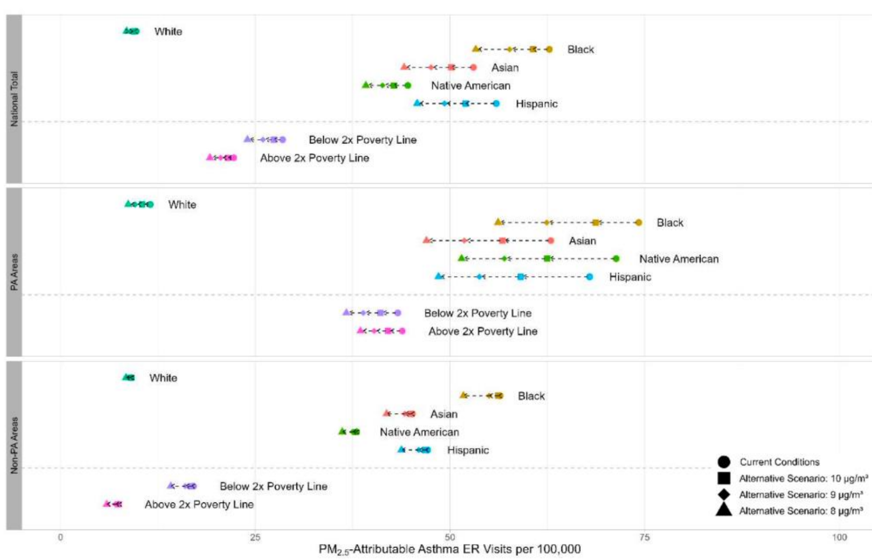


Because the recent IEc report examines non-PA areas, it also provides important information about disparities in $PM_{2.5}$ mortality impacts across poverty status that the

PA does not. The recent IEc report reveals that older adults experiencing poverty would see 35% higher benefits from a more protective standard in terms of per capita $PM_{2.5}$-attributable mortality avoided compared to higher income communities. Of the 16,000 air pollution-attributed deaths in 2015 avoided at 8 μg/m³, nearly 6,000 deaths are among populations below 2X poverty line. Of that nearly 2 out of 5 are among populations living in poverty in non-policy assessment areas. In the non-PA areas, including rural and small-town populations across the country, significant benefits are seen for populations below 2X poverty line. In those areas, under a 8 μg/m³ standard, the avoided PM mortality among populations below 2X poverty line would be 2.7X higher than that under a 9 μg/m³ and 8X higher than at 10 μg/m³.

As for populations under the age of 65, a standard of 8 μg/m³ would result in 16% lower childhood asthma emergency room visit burden. This is 3 times higher than the benefits under a 10 μg/m³ standard and 60% higher than the benefits at 9 μg/m³. Reducing $PM_{2.5}$ levels to 8 μg/m³ would go furthest in reducing disparities in $PM_{2.5}$ asthma emergency room visits between people of color who are children and white non-Hispanic children and those living above and below 2 times the poverty level.

EXHIBIT 5-15B. AVOIDED ASTHMA-RELATED EMERGENCY ROOM VISITS IN CHILDREN BY ALTERNATIVE NAAQS (PER 100,000, STRATIFIED BY RACE/ETHNICITY AND POVERTY)



The recent Josey et al. (2023) study, discussed also above, adds new information that buttresses the IEc report's findings. The Josey et al. (2023) analysis confirms that mortality impacts of $PM_{2.5}$ are higher for older Black populations than for older white populations and adds the nuance that low income older white populations also bear higher mortality risks in comparison to higher income white populations.

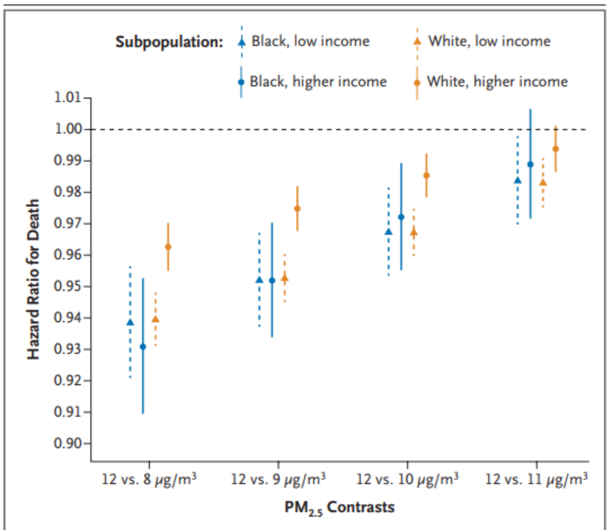


Figure 4. Differences in Mortality with Decreasing $PM_{2.5}$ Exposure among Marginalized Subpopulations.

Shown are point estimates and 95% confidence intervals of the hazard ratio for death comparing different levels of annual average $PM_{2.5}$ exposure (12 μg per cubic meter vs. 11, 10, 9, or 8 μg per cubic meter) on average for subpopulations defined in selected ways. Low income was defined as dual eligibility for both Medicare and Medicaid. Confidence intervals were not adjusted for multiplicity; therefore, they should not be used in place of hypothesis testing.

As seen in Figure 4 of the paper shown above, lowering exposure from 12 μg/m³ to 8 μg/m³ was associated with a hazard ratio of 0.931 (95% CI, 0.909 to 0.953) for the higher-income Black population and 0.963 (95% CI, 0.955 to 0.970) for the higher-income white population; for the low-income white population, it was 0.940 (95% CI, 0.931 to 0.948), and for the low-income Black population, 0.939 (95% CI, 0.921 to 0.957). Put another way, the study finds that if that standard is lowered to 8 μg/m³, the result would be an estimated 4% reduction of mortality rate for higher-income white older adults, while for marginalized communities it would be considerably higher: approximately 7% for Black higher-income and 6% for both white low-income and Black low-income older adults. This means that the at-risk vulnerable population group is broader, and stronger standards are likely to produce greater benefits in terms of premature deaths avoided among a wider array of disproportionately affected people than estimated in the PA.

Further, separately in the RIA, EPA sought to analyze factors that might contribute to differing impacts on specific populations, with the populations at issue including children and communities of color. RIA at 6-24. Importantly, EPA cites its

ISA, which found “adequate evidence” that children and various races are at elevated risk of $PM_{2.5}$-related health impacts—due in part to inequities in exposure. *Id.* Yet, EPA claims it lacks the epidemiologic data needed to undertake a health impacts study for children. *Id.* EPA’s failure to fully account for and address children’s health in its proposal—and focus most of its health benefits analysis on mortality—results in individual level vulnerability during sensitive windows of development for which there is a robust literature base showing the adverse effects of $PM_{2.5}$ on child development.

In 2019, Project TENDR (Targeting Environmental Neurodevelopmental Risks) published a commentary describing the evidence-base linking neurodevelopmental disorders and exposure to air pollution in the American Journal of Public Health.[41] The commentary synthesizes the growing evidence base that associates air pollution exposure with adverse health outcomes in children, including preterm birth, low birth weight, developmental effects, and autism spectrum disorder (ASD).[42] Indeed, these effects have been observed in a number of peer-reviewed research articles, including the foundational Nurses’ Health Study, which is an ongoing prospective cohort study that includes over 116,000 American nurses and their children.[43] Researchers conducted a

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[41] Payne-Sturges DC, Marty MA, Perera F, Miller MD, Swanson M, Ellickson K, Cory-Slechta DA, Ritz B, Balmes J, Anderko L, Talbott EO, Gould R, Hertz-Picciotto I. Healthy Air, Healthy Brains: Advancing Air Pollution Policy to Protect Children’s Health (2019). *Am J Public Health*. Apr; 109(4):550-554; available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6417586/. “Project TENDR (Targeting Environmental Neurodevelopmental Risks), a unique collaboration of leading scientists, health professionals, and children’s and environmental health advocates, points to growing scientific evidence linking exposure to toxic chemicals during early brain development with brain disorders and calls on individuals, industries, and policymakers to reduce these exposures.”

[42] *Id.*

[43] Raz R, Roberts AL, Lyall K, Hart JE, Just AC, Laden F, Weisskopf MG. Autism spectrum disorder and particulate matter air pollution before, during, and after pregnancy: a nested case-control analysis within the Nurses’ Health Study II Cohort (2015). *Environ Health Perspect.* 2015 Mar; 123(3):264-70; available at https://pubmed.ncbi.nlm.nih.gov/25522338/.

nested-case control study of children born with ASD and those born without ASD and find that exposure to $PM_{2.5}$ during pregnancy was significantly associated with an increased risk of ASD and the association was strongest during the third trimester.[44]

In a recently published commentary, the lead authors of the aforementioned study describe the burgeoning epidemiological evidence that links air pollution and ASD and argues that while it may not be possible to conduct a randomized controlled trial (a gold-standard epidemiological research methodology), it is "imperative to act, in this case to protect children, [and we] cannot await a complete understanding of the exact details of how an environmental agent causes harm."[45] The Project TENDR commentary makes a similar plea and urges the EPA to "give greater consideration to the evidence on the effects of air pollutants on neurodevelopment when setting standards for combustion-related air pollution."[46]

Importantly, the current ISA updates the causality determination for nervous system effects, whereas the 2009 PM ISA was not able to make a causality determination based on a lack of available data.[47] The 2019 PM ISA determined that the toxicological and epidemiological evidence supports a "likely to be causal relationship between long-term $PM_{2.5}$ exposure and nervous system effects including…effects on neurodevelopment."[48] This causality determination means that the "evidence is sufficient to conclude that a causal relationship is likely to exist…[and] results are not explained by chance, confounding, and other biases, but uncertainties remain in the evidence overall."[49] The reality is that in just the span of a decade, the weight of evidence has grown immensely, and yet, the distinctive vulnerabilities surrounding

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[44] *Id.*

[45] Raz, R., & Oulhote, Y. Invited Perspective: Air Pollution and Autism Spectrum Disorder: Are We There Yet? (2022). *Environmental Health Perspectives*, *130*(1), 011303; available at https://ehp.niehs.nih.gov/doi/full/10.1289/EHP10617.

[46] *Id* at 38.

[47] ISA at ES-15.

[48] *Id.*

[49] ISA at P-12 tbl.P-2.

child development have not been meaningfully accounted for in the standard-setting process.

In 2012, EPA's own Children's Health Protection Advisory Committee submitted a letter to the record during the last PM NAAQS review cycle in support of tightening the standard to the lowest end of the range recommended by CASAC.[50] The letter states that

> Children are a vulnerable population, due to unique sensitivities during early lifestages to $PM_{2.5}$ exposures. While far more studies assess adult morbidity and mortality due to $PM_{2.5}$ exposures, many epidemiologic studies report that exposures in childhood can significantly affect morbidity and subsequent respiratory health in adulthood. Therefore, when creating regulatory standards, children's health impacts due to $PM_{2.5}$ exposure deserve individualized and focused attention.[51]

There is no doubt that $PM_{2.5}$ has serious adverse effects on children's health and development. EPA must address those harms, as well, to ensure that the standards are truly protective of our nation's most vulnerable population.

Overall, looking at factors besides race and ethnicity, a standard of 8 $\mu g/m^3$ would go further than the other standards being considered to reduce the health burden of air pollution, and the inequities in that burden, with benefits for the most at risk in communities and families.

Even with strengthened standards, substantial disparities in the health impact of particulate pollution would persist. It is essential that EPA also takes complementary actions that directly tackle environmental injustice.

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[50] Children's Health Protection Advisory Committee. National Ambient Air Quality Proposed Standards (September 10, 2012). Available at https://www.epa.gov/sites/default/files/2014-09/documents/9-10-2012-chpac-letter-on-pm-naaqs-and-naaqs.pdf.

[51] *Id.* at 3.

iii. The CASAC majority found an annual standard of 8 μg/m^3 scientifically supported

The majority of CASAC found the scientific evidence they reviewed supported an annual standard as low as 8 μg/m^3. *E.g.*, CASAC Letter on PA at 16 (majority endorses 8 μg/m^3 as part of "the recommended alternative annual standard"). Indeed, CASAC said that the evidence for an 8 μg/m^3 standard was both "strong and compelling." *Id.* at 6. Though CASAC noted generically that there is more uncertainty in the evidence at lower concentrations, it plainly found that uncertainty insufficient to override confidence that concentrations at least as low as 8 μg/m^3 harm public health. Moreover, CASAC also pointed out that EPA's assessment had inconsistencies surrounding this claim of increasing uncertainty at lower concentrations. *Id.* at 14 (noting inconsistencies between draft PA's characterization of uncertainties and draft ISA Supplement's characterization of uncertainties being less even down to 4 μg/m^3).

Beyond express statements, the overall letter reinforces the support the majority of CASAC provided for an 8 μg/m^3 standard. For example, the majority repeatedly criticized the PA's emphasis on study-reported means (and comparing them with design values) as overly "conservative." *Id.* at 8-9, 16. CASAC repeatedly cited strong evidence that there is no threshold for effects of $PM_{2.5}$ exposure, criticizing the draft PA's weaker description. *E.g.*, *id.* at 9, 16. The majority also found substantial gains for Black residents would occur at levels of 9 μg/m^3 or lower. *Id.* at 16.

3. EPA's attempts to set a standard weaker than 8 μg/m^3 are unlawful and arbitrary

Seeking to justify a less protective standard than what the science and law demand, the approach in EPA's proposal takes numerous analytical steps that contravene the Clean Air Act, the record, and rational decision-making. If not corrected, EPA's approach will leave the most affected, most overburdened populations—communities of color, especially Black populations, and low-income communities—to experience levels of $PM_{2.5}$ pollution that EPA knows cause serious adverse health effects.

Going against the Act's protective direction, the agency seeks to cast doubt on the overwhelming record evidence that $PM_{2.5}$ causes adverse health effects at concentrations at least as low as 8 μg/m^3.

EPA also fails to rationally and lawfully justify its proposed approach to considering data from epidemiologic studies in setting the standard's level. Despite the enormous scope of key studies—and the great statistical power they have, especially in conjunction with the wealth of other evidence establishing that $PM_{2.5}$ causes precisely the types of health harms they examine—EPA proposed to take the conservative approach of keying decision-making to the study-reported mean concentrations, rather than lower concentrations where evidence of $PM_{2.5}$-induced harm remains robust. The Act requires the agency to take a precautionary approach, not the conservative approach applied here.

Even if this mean-centric approach were rational, EPA's proposal is still illegal and arbitrary because it inflates the study-reported means via an irrational comparison with design values before proposing to establish the standard's level based off that inflated level. Among other unlawful and irrational flaws, this approach would leave the populations living in the most $PM_{2.5}$-polluted portions of areas to breathe air contaminated with $PM_{2.5}$ above the levels demonstrated to cause serious health harms. The Act does not permit an approach with that outcome, and EPA does nothing to rationally explain the contrary. Notably, record evidence demonstrates that these populations are sizable and tend to be made up of greater percentages of people of color and low-income communities than found in the relevant county as a whole.

EPA also arbitrarily treats evidence that demonstrates a standard at the levels it proposes would fail to protect public health with an adequate margin of safety. It does not rationally consider the results of Canadian epidemiologic studies, restricted analysis studies, or accountability studies in setting the standard's level. Nor is its consideration of its own risk assessment rational.

Accordingly, it would be arbitrary and unlawful for EPA to establish a standard with a level above 8 μg/m³, especially standards of 10-11 μg/m³.

i. There is no meaningful doubt that $PM_{2.5}$ causes serious harms down to an annual average of 8 μg/m³

In declining to propose a standard of 8 μg/m³, EPA points generically to the purported "uncertainties" of such a standard being "too great at this time" *See* 88 Fed. Reg. at 5629; *see also id.* at 5604-05 (discussing general uncertainties PA perceives in evidence regarding health effects). These attempts lack support in the record and contravene the Clean Air Act.

EPA's attempts to cast doubt on the strength of the conclusion that 8 μg/m^3 average annual concentrations of $PM_{2.5}$ cause serious harms are irrational on this record. As explained herein, in EPA documents, and other comments, the evidence that $PM_{2.5}$ causes serious health harms at concentrations down to 8 μg/m^3 is extremely consistent and strong. The scientific basis for that conclusion rests on a variety of types of studies. Many of these studies have been and continue to be performed, and they collectively and individually tell a cohesive and compelling story. Indeed, when EPA tries to cast doubt on these studies as a whole, its efforts cannot be rationally reconciled with the actual facts before it, as we explain below in addressing EPA's groundless attempt to dismiss the results of its own risk assessment.

Even just considering EPA's own statements, EPA's efforts to identify uncertainties sizable enough to forego a standard of 8 μg/m^3 are arbitrary. Despite those efforts, EPA repeatedly acknowledges that the concentration-response function for $PM_{2.5}$ is well-characterized down to 8 μg/m^3. *Id.* at 5582-83, 5605, 5610, 5614, 5619, 5625. The evidence about concentration-response is "consistent" and has recently been strengthened by new studies. *E.g.*, *id.* at 5583. The only uncertainties regarding the concentration-response function that EPA identifies relate to its shape below 8 μg/m^3. *Id.* at 5582-83, 5605, 5610, 5614, 5619, 5625. EPA thus <u>strengthens</u> the case for there being no meaningful uncertainties at or above 8 μg/m^3.

EPA further notes that epidemiologic studies it had not previously considered "reduce key uncertainties identified in previous reviews, including those related to potential copollutant confounding." *Id.* at 5583; *see id.* at 5582, 5585, 5625 (discussing how new studies address potential confounding). Thus, EPA provides substantial evidence to support the conclusion that the harmful effects of $PM_{2.5}$ above 8 μg/m^3 are well established, with stronger and stronger evidence still accumulating. Nowhere does EPA give a rational basis to doubt that compelling evidence or provide substantial evidence contradicting the existing evidence. For EPA to conclude that there are somehow meaningful uncertainties about the harms $PM_{2.5}$ causes above 8 μg/m^3 thus lacks a rational connection to the substantial evidence in the record.

Finally, to the extent EPA seeks to seize on any relevant minor uncertainties to reject the 8 μg/m^3 annual standard that is requisite to protect public health with an adequate margin of safety, such efforts are contrary to the Clean Air Act's protective purpose. Far from requiring the agency to act only with 100% certainty, the Act requires the agency to take a precautionary, health-protective approach. *See supra* § II.B.2; *see also, e.g.*, *Am. Petroleum*, 684 F.3d at 1353 (EPA has a "duty to err on the side of caution"); 88 Fed. Reg. at 5564 (requirement to include adequate margin of safety "address[es] uncertainties"). Indeed, "'[q]uestions 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.'" *Wisconsin v. EPA*, 938 F.3d 303, 319 (D.C. Cir. 2019).

ii. The weight EPA places on study-reported means, as opposed to other measures of $PM_{2.5}$ concentrations, is irrational and unlawful

In considering the level for a revised annual standard, EPA chiefly relies on several U.S.-based epidemiologic studies examining the relationship between $PM_{2.5}$ concentrations and premature death, specifically on the mean $PM_{2.5}$ concentrations reported in these studies. *See* 88 Fed. Reg. at 5628; *see also id.* at 5625-29. Depending on how the studies characterize $PM_{2.5}$ exposure (via ground-based monitoring or hybrid modeling approaches that apply population weighting), EPA finds the range of study-reported means to vary from 9.3-12.2 $\mu g/m^3$ for studies using a hybrid modeling approach[52] and from 9.9-16.5 $\mu g/m^3$ for studies using ground-based monitoring. *Id.* at 5625-26; *see also id.* at 5602, 5611.

Though EPA has historically relied on study-reported means in establishing the level of the annual $PM_{2.5}$ standard, that approach is irrationally conservative for this reconsideration in light of the available evidence and advice from CASAC. Indeed, the majority of CASAC warned that "use of the mean to define where the data provide the most evidence is conservative since robust data clearly indicate effects below the mean in concentration-response functions." CASAC Letter on PA at 16. Such conservatism is unlawful and irrational in light of the Clean Air Act's precautionary, health-protective

[52] In this section of these comments, unless specifically stated otherwise, any reference to studies using a hybrid modeling approach includes only such studies that apply population weighting.

approach to the NAAQS. *See supra* § II.B.2. It is further irrational on the record before the agency.

Recent large-scale studies of $PM_{2.5}$'s health effects, including Di et al. (2017), Di et al. (2019), Vodonos and Schwartz (2021), Yazdi et al. (2019), and Yitshak-Sade et al. (2019), are based on gigantic datasets unlike those upon which earlier revisions of the standards relied. As Dr. Joel Schwartz explained, they thus provide "considerable confidence" that $PM_{2.5}$ exposure in various studies results in health effects at levels <u>below</u> the study-reported mean or median. EPA-HQ-OAR-2015-0072-1522 at 17-18 (discussing Wei 2021 study that has "over 60 million person-years in each decile of exposure" and accordingly "provides considerable confidence that effects continue below 8 [μg/m^3]"). Dr. Joel Schwartz highlighted the irrationality of EPA's contrary position. Dr. Schwartz is a noted expert epidemiologist, especially on the "health effects of air pollutants," including $PM_{2.5}$, and has published very extensively in this area. *See* https://connects.catalyst.harvard.edu/Profiles/display/Person/70291. In comments on the draft PA, he explained that, fundamentally, the strength of a study's support for observing effects below the mean "depends on the number of observations in that range, not the percentage": "The Medicare cohort, for example, had 637 million person-years of observation. Hence there were over 63 million observations at the tenth percentile or lower. This is a very large number for an epidemiology study and clearly would have enough health effects to generate confidence if it were a separate study on its own." EPA-HQ-OAR-2015-0072-1522 at 13-14. He characterized the PA's reliance on study-reported means as misunderstanding "both epidemiology and statistics" and having "no merit." *Id.* Specifically, he warned against using "averaged values in a study to estimate levels at which effects are seen" as "the way to determine levels at which effects are seen," explaining that instead "the appropriate way" looks at "the concentration-response curves reported, the sequential truncation models reported, and the decile comparisons reported in Wei." *Id.* at 16.

Consistent with Dr. Schwartz's comments, CASAC advised EPA that "[e]pidemiologic studies require consideration of distribution around the mean of exposure to identify effects and thus <u>lower levels than the mean must be considered as part of the range where the data provide higher confidence</u>." CASAC Letter on PA at 13 (emphasis added). CASAC further warned that EPA's "focus on the mean concentration in this approach has some limitations for informing the adequacy of the annual and 24-hour standards." *Id.* at 8.

Yet EPA's proposal repeatedly invokes that it has greatest confidence or the strongest support for adverse effects occurring at or near the study-reported mean, and relies chiefly on such means as a result. *E.g.*, 88 Fed. Reg. at 5595 (discussing PA), 5625-26, 5628, 5629; *see, e.g., id.* 5629 (proposing not to set annual standard at 8 μg/m³ because of purported "uncertainties"). This is arbitrary for at least two reasons. First, it does not address the discussion above and is thus both unsupported by the record and unexplained. Second, as explained repeatedly in these comments, the Act does not require EPA to act only when it has most confidence, but rather when it has sufficient confidence. EPA's explanation thus is irrational and unlawful under the Act. *See Tripoli Rocketry Ass'n v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 437 F.3d 75, 81-83 (D.C. Cir. 2006) (basing regulatory judgment on mere categorization of one thing as "much" more of something than another thing, without any "points of comparison" is irrational).

Elsewhere, EPA describes the PA as deprecating reliance on 10th or 25th percentile concentrations on the purported basis that comparing design values with such concentrations "is more uncertain than such comparisons with the mean." 88 Fed. Reg. at 5612. The proposal's summary is also irrational for at least two reasons: as already explained, mere greater uncertainty isn't a rational basis for decisionmaking here and, as explained in the next section, fundamentally, comparison of study-reported concentrations with design values as EPA does is utterly irrelevant, unlawful, and irrational.

The proposal very briefly addresses $PM_{2.5}$ concentrations below study-reported means, but its treatment of them is irrational and illegal for similar reasons. It notes the PA's conclusion that such information is relevant to assessing where "the data become appreciably more sparse and, thus,…confidence in the associations observed in epidemiologic studies would become appreciably less," and notes that "most studies do not report such data." 88 Fed. Reg. at 5626. Relying on these notes, the proposal highlights purported "uncertainties" about the 25th percentile data, and frames consideration of such data as a matter for assessing the adequacy of the required margin of safety, before concluding that any level within the range of 8-11 μg/m³ would do something to limit exposures at the 25th percentile, "with the lower end of this range further limiting those exposures." *Id.* at 5627.

Again, this explanation fails to rationally address the fundamental flaws with EPA's overreliance on study-reported means: (1) given the wealth of data, findings at lower levels of $PM_{2.5}$ concentrations have great statistical power; (2) it is not at all impossible to make the necessary determinations while remaining consistent with the Act's protective and precautionary approach to standard-setting; and (3) it focuses on relative confidence, rather than whether EPA has adequate confidence.

iii. EPA's inflation of study-reported means in epidemiological studies is arbitrary and unlawful

Even if EPA's mean-centric approach were not illegal and irrational, the revised approach EPA takes here would still be illegal and irrational. Rather than simply propose to set the standard's level "somewhat below" the lowest study-reported mean, as EPA has successfully done repeatedly in the past, *Nat'l Ass'n of Mfrs. v. EPA*, 750 F.3d 921, 924 (D.C. Cir. 2014) (upholding 2012 PM NAAQS, which followed such an approach); *accord Am. Trucking Ass'ns*, 283 F.3d at 372 (upholding 1997 PM NAAQS, which followed similar approach), EPA first inflates the study-reported means by 10-20% or 15-18%, depending on how the study calculates exposure, saying it does so to relate the study-reported means to the design value that determines NAAQS compliance. 88 Fed. Reg. at 5625-26, 5628, 5629; *see also id.* at 5596-97. Only then does EPA address the question of what the standard's level ultimately should be—but now, rather than keying off study-reported means ranging from 9.3-12.2 μg/m³ or 9.9-16.5 μg/m³, depending on how the study calculates exposure, EPA keys its consideration off values ranging from 10.7-11 μg/m³ or 10.9-11.9 μg/m³. *Id.* at 5626. EPA's analysis is unlawful and arbitrary for several reasons.

First, EPA's analysis violates the Clean Air Act and is irrational because it leaves people who live in places with the most pollution to experience adverse health effects—including death—simply because other people happen to live farther from the most polluted places. Notably, as EPA has long recognized, the people most exposed to and most vulnerable to $PM_{2.5}$ are disproportionately people of color. *E.g.*, *id.* at 5561, 5576, 5592, 5609-10; 78 Fed. Reg. at 3125 (in 2006, EPA "found that the highest concentrations in an area tend to be measured at monitors located in areas where the surrounding population is more likely to have lower education and income levels and higher percentages of minority [*sic*] populations"). More specifically, comments on the draft PA addressed, for 10 areas including in EPA's risk assessment, the relationship between the demographics within three miles of a controlling monitor compared with a county as a whole, finding that "populations living in the most polluted neighborhoods, as determined by the monitor network, tend to have higher percentages of [people of color] and greater poverty." EPA-HQ-OAR-2015-0072-1538 at 7-8. In warning EPA against following the line of analysis it ultimately proposes here, CASAC similarly noted that "people exposed to these higher concentrations are often disproportionately persons of color and lower-income populations." CASAC Letter on PA at 8-9.

New analysis reveals that, based on 2021 design values and the most recent population data available, the critiques of EPA's draft PA continue to hold, as substantial numbers of people live within 5 km of the monitor recording the highest design value ("controlling monitor" or "design value monitor") in a county, and the population living in this radius tends to have a greater percentage of Black residents, Hispanic residents, people of color, and people living in poverty than the county as a whole:

# Counties with valid design value:	517
Population of counties with valid design value:	201,085,798
Population living within 5 km of controlling monitor:	32,230,434
% population living within 5 km of controlling monitor:	16.03%
# Counties where % of population within 5 km of controlling monitor that is Black is > % of county population that is Black:	323
Average disparity (% within radius-% in county:	4.07%
# Counties where % of population within 5 km of controlling monitor that is Hispanic is > % of county population that is Hispanic:	336
Average disparity (% within radius-% in county:	1.05%
# Counties where % of population within 5 km of controlling monitor that is people of color is > % of county population that is people of color:	347
Average disparity (% within radius-% in county:	5.16%
# Counties where % of population within 5 km of controlling monitor that is in poverty is > % of county population that is in poverty:	355

Average disparity (% within radius-% in county:	5.37%

Table 1: Summary of Near Controlling Monitor Demographic Analysis

Data Source for Table 1: Exhibit 2 (sheets titled "Summary" and "design_monitors_community_chara") (analysis of demographics of counties with valid monitoring data and near-monitor demographics).

EPA's proposal cannot and does not dispute any of this: significant numbers of people, disproportionately people of color and people with lower income and socioeconomic status, live in the portions of areas with the highest levels of $PM_{2.5}$ pollution, which control the design value for a broader area.

EPA's basis for inflating the study-reported means is that study-reported means for areas are not the same thing as design values for areas, and it is the design value that is compared to the standard's level; EPA thus proposes that in setting the level, EPA focuses on what design value will result in levels at or below overall area means reported in the relevant studies. 88 Fed. Reg. at 5625-26, 5628. EPA's approach amounts to inflating study-reported means, then setting the level somewhere below the inflated result. But the evidence that adverse health effects occur is by EPA's admission "strongest" at "the study-reported mean $PM_{2.5}$ concentrations." *Id.* at 5626. These study-reported means extend as low as 9.3 μg/m^3. And, as EPA itself acknowledges, areas are "expected" to have a "gradient of concentrations across the area," with the highest $PM_{2.5}$ levels "near the design value monitor." *Id.* at 5626 n.102. Thus, though EPA's inflationary approach might keep <u>overall</u> mean levels throughout an area below the study-reported means, it plainly allows $PM_{2.5}$ concentrations in portions of the area, including the area near the controlling design value monitor, to remain <u>above</u> the study-reported mean—concentrations where the evidence of adverse health effects is strongest. Many people live in those areas, and those people are, on average, more likely to be Black, Hispanic, people of color, and/or living in poverty. The outcome of EPA's inflationary approach contravenes the Clean Air Act's mandate (as definitively interpreted by the D.C. Circuit) that <u>all</u> populations in the country must be protected against adverse health effects, with an adequate margin of safety. *See supra* § II.B.1.

Notably, too, EPA itself "strongly" rejected a very similar argument when polluters made it in comments on the proposal for the 2012 NAAQS. 78 Fed. Reg. at 3146. There, polluters urged EPA to set the level by identifying a "mean composite monitor $PM_{2.5}$ level that should be achieved and then identify the maximum monitor level that would result in that composite value." *Id.* EPA explained one reason for its strenuous disagreement with the polluters was that "for areas in which the maximum monitor concentration is appreciably higher than other monitor concentrations within the same area, public health would not be protected with an adequate margin of safety if the disproportionately higher exposures of at-risk, susceptible populations around the monitor measuring the highest concentration were in essence averaged away with measurements from monitors in other locations within large urban areas." *Id.* (emphasis added). The argument polluters made in 2012 is conceptually identical to the approach EPA proposes to take now. EPA shift of position is more than just profoundly disappointing—as explained above, "EPA had it right the first time" when it rejected the argument. *NRDC v. EPA*, 777 F.3d 456, 468 (D.C. Cir. 2014).

Second, EPA's reasoning to support this outcome is further irrational. EPA attempts to address how it is not providing requisite protection to the populations in the most exposed locations by seemingly contending that, under its approach,[53] "even those people living near an area design value monitor (where $PM_{2.5}$ concentrations are generally highest) will be exposed to $PM_{2.5}$ concentrations below the air quality conditions reported in the epidemiologic studies where there is the highest confidence of an association." 88 Fed. Reg. at 5626. Yet EPA's contention both lacks any supporting citation and is contradicted by other pieces of EPA's own analysis and regulations. In particular, EPA itself notes that an area's design value—*i.e.*, the highest known $PM_{2.5}$ concentration in an area—is 10-20% or 15-18% higher than the study-reported mean (depending on how exposure is characterized), and that such monitors are supposed to characterize $PM_{2.5}$ concentrations in at least a portion of an area (i.e., not characterize unique concentrations that appear nowhere else). *Id.*; 40 C.F.R. pt.58 app.D, § 4.7.1(b) ("The required monitoring stations or sites must be sited to represent area-wide air quality."), (b)(1) ("At least one monitoring station is to be sited at neighborhood or larger scale in an area of expected maximum concentration."), (c) (repeatedly emphasizing importance of having $PM_{2.5}$ monitors be "representative of," "represent," or "characterize" "human exposure," "similar situations," "conditions in areas where people commonly live and work for periods comparable to those specified in the

[53] To the extent the quoted statement addresses an alternative approach to establishing the standard's level, EPA would then entirely fail to consider the harmful ramifications of its proposed approach for the people living near design value monitors.

NAAQS," "an entire metropolitan or rural area," or "regional scale," with "most important spatial scale" being "neighborhood"). EPA gives no rational explanation for its refusal to provide requisite protection, with an adequate margin of safety, for populations living in the portions of areas with the highest $PM_{2.5}$ concentrations, and there is none.

Indeed, expert commenters, like Dr. Joel Schwartz, and CASAC (see below) highlighted the irrationality of EPA's analysis. In commenting on the draft PA, Dr. Schwartz described EPA's analysis on this point as "a bizarre analysis to justify the argument that the $PM_{2.5}$ exposure in the epidemiology studies using multiple exposure models, including the Di et al[.] exposure, produce lower effect estimates than the monitor level design value, and hence cannot be used to accurately judge the concentrations at which health effects are happening, or to set standards enforced at monitors." EPA-HQ-OAR-2015-0072-1522 at 3-4. He similarly explained that EPA's approach at issue in this section "turns logic on its head" and would result in standard-setting decisions that are "ridiculous":

> That studies using hybrid exposure models can capture whether there are health effects at low concentrations by providing evidence in suburban and rural areas is a key advantage of those studies. <u>To argue that their mean exposure (irrelevant to the C-R curves) is therefore lower than the exposure at the highest monitor and therefore allowing higher exposure at the highest monitor is protective, turns logic on its head.</u> The ability of hybrid exposure models to capture effects in suburban areas where exposure is lower is directly relevant to determining whether people in densely populated urban areas with currently higher exposures (e.g. the maximum monitor value) will benefit from a reduction in those exposures. Consider that in the Wei study, we found there is an elevated risk of death at 6.6 $\mu g/m^3$ in a study whose mean was 9.85 $\mu g/m^3$. Clearly this illustrates the poverty of interpreting the study as showing effects at it [*sic*] mean concentration. It also means that reducing exposure at the highest monitor from 10 $\mu g/m^3$ to 6.6 $\mu g/m^3$ would improve the health of people in that urban area who were exposed to 10, or 9, or 8, or 7 $\mu g/m^3$ by forcing all those exposures downward. <u>To describe that study as estimating effect at 9.85 $\mu g/m^3$, and argue that a maximum monitor value</u>

> <u>of e.g. 11 or 12 μg/m^3 would suffice to protect people against the exposures seen in that study is ridiculous.</u>

Id. at 14 (emphasis added).

Dr. Schwartz explained further that EPA's analysis does not present relevant information regarding what $PM_{2.5}$ concentrations people are actually exposed to within an area (*i.e.*, does not actually test the accuracy of the hybrid modeling some of the key studies rely on). *See id.* at 4 ("If you want to compare to [*sic*] the hybrid predictions to the design values, you should compare the hybrid predictions at the design value monitor to that monitor's readings. But comparing predictions at lower exposure locations to the design monitor values misrepresents the ability of those models to <u>capture true ambient concentrations</u>." (emphasis added)). Dr. Schwartz related these irrationalities in EPA's analysis directly to its key irrational step of inflating study-reported means, as well as echoing the core concern—that EPA's approach ignores the people who live in the areas with highest pollution levels—expressed in these comments:

> While it is true that the maximum monitor value is higher than the population average, it is also true that some people live near the maximum monitor. Hence, if a study reports increased death rates in a neighborhood where the concentrations are e.g. 8 μg/m^3, then failure to set a standard at 8 μg/m^3 will result to increased risk to people living near the maximum monitor, and at every other location where the exposure is above 8 μg/m^3, even if a maximum monitor value of e.g. 10 μg/m^3 meant that most people in that urban area were exposed to concentrations below 8 μg/m^3. <u>Hence relying on most people being exposed below the maximum monitor value does not protect the heath [*sic*] of many people who are not.</u>…<u>The ability of hybrid exposure models to capture effects in suburban areas where exposure is lower is directly relevant to determining whether people in densely populated areas with currently higher exposures (e.g. the maximum monitor value) will benefit from a reduction in those exposures.</u>

Id. at 14 (emphasis added). Without rational explanation, EPA's proposal replicates the flaws Dr. Schwartz warned of.

Moreover, for studies using hybrid modeling approaches to characterize $PM_{2.5}$ exposure, EPA's approach of comparing study-reported area-wide averages with design values likely introduces significant uncertainties in interpretation. At least in certain areas, different models, like EPA's downscaler and the model that resulted in the Di et al. data, depart by different degrees from the monitored values, including having their modeled high levels fail to match the monitored high levels, both in terms of level and location of high level within the area. Such uncertainties and challenges likely do not arise when simply interpreting the highly consistent results of epidemiologic studies that find associations between various health effects and $PM_{2.5}$ concentrations down to levels well below 10 μg/m^3 and which have been analyzed together to generate a concentration-response function in which researchers—and EPA—have very high levels of confidence down to at least 8 μg/m^3. *See* discussion throughout these comments on these points.

EPA's approach of allowing above-mean exposures also assumes the design value monitor is in fact located at the point of highest $PM_{2.5}$ concentration, but this may not be a reasonable assumption to make. As the U.S. Government Accountability Office found, the existing regulatory air quality monitoring system "is unable to meet needs for information on…air pollution hotspots, or local areas of high pollution."[54] Further, monitoring in these attainment areas is even less likely to occur if the area is "low-income (or nonwhite)."[55]

Though it still lacks the requisite three years of data, a new monitor in the Houston area illustrates many of these issues well. In 2021, after years of community

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[54] GAO, *Opportunities to Better Sustain and Modernize the National Air Quality Monitoring System* 38, app.III 66 (GAO-21-38, Nov. 2020), https://www.gao.gov/assets/gao-21-38.pdf; *accord* GAO, *Need Remains for Plan to Modernize Air Monitoring* 7 (GAO-22-106136, July 2022), https://www.gao.gov/assets/gao-22-106136.pdf; *see also* Revesz, *Air Pollution and Environmental Justice*, at 240-44 (summarizing such flaws with monitoring system); Corbett Grainger & Andrew Schreiber, *Discrimination in Ambient Air Pollution Monitoring?*, 109 AEA Papers & Proceedings 277, 277 (2019) ("Relative to non-attainment counties, monitors in attainment counties tend to be less likely to be sited near pollution hotspots (as measured with remote sensing data).").

[55] Grainger & Schreiber, *Discrimination in Ambient Air Pollution Monitoring?*, at 281.

advocacy, the Texas Commission on Environmental Quality installed and began operating an air quality monitor at 7330 1/2 N. Wayside Drive, squarely within a residential neighborhood of Houston, Texas. More than 60,000 people live within three miles of the new North Wayside monitor; 97% are people of color, compared with 59% of the people in Texas and 40% of the people in the United States; 58% are low income, compared with 33% of the people in Texas and 30% of the people in the United States.[56] In 2021, the annual average of that monitor was the highest in the Houston area.[57] The second highest 2021 average was 11.39 µg/m^3, at the monitor at 822 North Loop, Houston, TX, which is about 50 yards from a major roadway, I-610.[58] Though official values for 2022 have not yet been reported, initial analysis shows that the new monitor continues to record higher $PM_{2.5}$ levels than any other monitor, including the currently controlling design value monitor for Harris County (822 North Loop):

[56] EJScreen Report at 3, https://ejscreen.epa.gov/mapper/ (search for "29.828086, -95.284096"; click on appropriate place on map; change "buffer" to 3 miles; click on "Get Printable Standard Report…").

[57] *See* EPA, $PM_{2.5}$ Design Values, 2021, tbl.5a (Site-Level Design Values for the 2012 Annual $PM_{2.5}$ NAAQS) (reporting 2021 "annual mean value" for this monitor of 12.51 µg/m^3) (filter for just monitors in CBSA "Houston-The Woodlands-Sugar Land, TX"), https://www.epa.gov/system/files/documents/2022-05/PM25_DesignValues_2019_2021_FINAL_05_24_22.xlsx. A similar result obtains for 24-hour 98th percentile values in 2021: this monitor's 24-hour 98th percentile value was 26.5 µg/m^3, the highest in the area. *See id.* tbl.5b (Site-Level Design Values for the 2006 24-hour $PM_{2.5}$ NAAQS).

[58] *Id.*

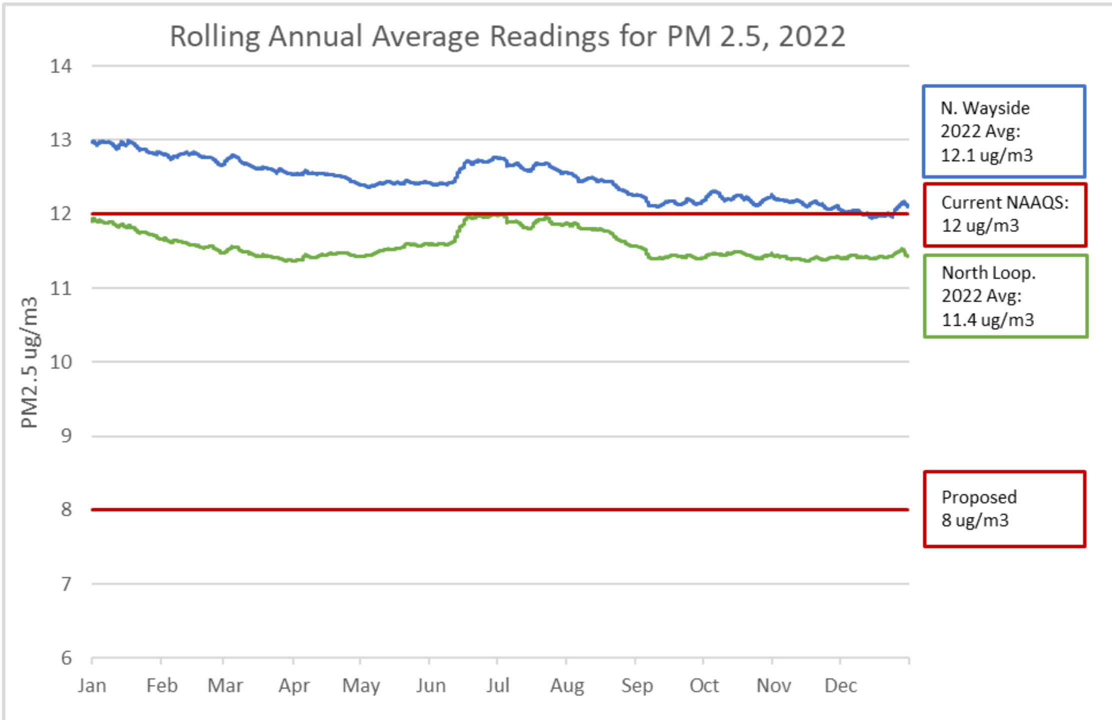

Figure 1: 2022 $PM_{2.5}$ Monitoring Data at N. Wayside Monitor and Current Area Design Value Monitor

Data Sources for Figure 1: Texas Comm'n on Envtl. Quality, Texas Air Monitoring System Database, https://www17.tceq.texas.gov/tamis/index.cfm?fuseaction=home.welcome (click "Start Report," then select "Raw Data Report (AQS)," enter dates to cover all of 2022, select appropriate individual sites and appropriate pollutant, then select "Valid Measurements Only" and 1-hour sample duration); and Texas Comm'n on Envtl. Quality, CAMS 1052 Monthly Summary Report, https://www.tceq.texas.gov/cgi-bin/compliance/monops/monthly_summary.pl?cams=1052 (generate monthly report for December 2022).

Scientific research confirms there is significant variability in PM levels within an urban area, as well.[59] Thus, when EPA proposes to set the level of the standard based

[59] *E.g.*, R.U. Shah et al., *Socio-Economic Disparities in Exposure to Urban Restaurant Emissions Are Larger Than for Traffic*, 15 Environ. Res. Lett. 114039, at 1-2 (2020), https://iopscience.iop.org/article/10.1088/1748-9326/abbc92/pdf; S. Jain et al., *Spatial Modeling of Daily $PM_{2.5}$, NO_2, and CO Concentrations Measured by a Low-Cost Sensor*

not on the study-reported mean, but a higher level, it is not just relegating the people near the design-value monitor to experience higher $PM_{2.5}$ concentrations than those EPA agrees cause serious health harms, it may be allowing even more people to experience such concentrations at even higher levels than EPA knows occur. *See* Revesz, *Air Pollution and Environmental Justice*, at 240-41.

Moreover, EPA's analysis of the relationship between study-reported means and design values depends on backward-looking data. But when EPA changes the standards, the range and pattern of concentrations itself may change, rendering it irrational to rely on its backward-looking analysis. EPA itself warned of this in 2012, when it rejected polluters' suggestion that it adopt an approach analogous to the one it now proposes to adopt:

> [T]he commenter's suggested approach would be based on annual average $PM_{2.5}$ concentrations that have been measured over some past time period. Such an approach would reflect the air quality that existed in the past, but it would not necessarily provide appropriate constraints on the range of concentrations that would be allowed by such a standard in the future, when relationships between maximum and composite monitor concentrations in areas across the country may be different."

78 Fed. Reg. at 3146.

EPA's 2012 rationale has support in reality, too. The trend of design values from 2012 through 2021 in four metropolitan areas (CBSAs for Pittsburgh, PA; Los Angeles, CA; Phoenix, AZ; and Detroit, MI) with multiple monitors shows differences in improvements over time, looking only at monitors with design values in both 2012 and 2021. *See* EPA, $PM_{2.5}$ Design Values, 2021, tbl.6a (Site-Level Design Value History for the 2012 Annual $PM_{2.5}$ NAAQS). In two airsheds (Los Angeles and Detroit), the location of

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Network: Comparison of Linear, Machine Learning, and Hybrid Land Use Models, 55 Environ. Sci. Technol. 8631, 8631 (2021), https://pubs.acs.org/doi/pdf/10.1021/acs.est.1c02653 ("Numerous studies have shown that pollutant concentrations have small-scale spatial variations that are not captured by regulatory networks. These spatial variations create variations in human pollutant exposures and resultant health impacts." (citations omitted)).

the highest monitor changed over the decade. *See id.* (note also that in Detroit, the now-controlling monitor did not operate in 2012, but has the same level as the controlling monitor in 2012, and is about 2 miles away). Two areas (Los Angeles and Phoenix) had some monitoring locations increase with others decreasing. *See id.* For the two areas (Pittsburgh and Detroit) where all monitors operating in 2012 and 2021 saw improved air quality, the reductions were variable, modifying the spatial distribution of the more to less polluted neighborhoods. *See id.*

- Pittsburgh: 9 monitors. Design value decreases by 3.6 μg/m^3; changes throughout area range from 1.4 μg/m^3 increase to 4.7 μg/m^3 decrease; monitor average decreases by 3.0 μg/m^3. Design value monitor remains the same; rankings of other monitors shift, with, for example, the third-worst monitor in 2012 becoming the second-best in 2021.
- Los Angeles: 8 monitors. Highest monitor reporting design value in 2012 and 2021 increases by 0.5 μg/m^3; changes throughout area range from 0.8 μg/m^3 increase to 0.2 μg/m^3 decrease; monitor average increases by 0.4 μg/m^3. Highest monitor shifts location.
- Detroit: 7 monitors. Highest monitor reporting design value in 2012 and 2021 decreases by 0.8 μg/m^3; decreases throughout area ranging from 0.2 to 1.9 μg/m^3; monitor average decreases by 1.3 μg/m^3. Highest monitor shifts location. Monitor that did not operate in 2012 now records highest 2021 design value in the area, which is the same as the 2012 design value for the area, albeit in a different location.
- Phoenix: 6 monitors. Highest monitor reporting design value in 2012 and 2021 decreases by 0.5 μg/m^3; changes throughout area range from 1.2 μg/m^3 increase to 2.1 μg/m^3 decrease; monitor average decrease by 0.4 μg/m^3. Highest monitor remains the same; rankings of all other monitors change.

Third, EPA's proposed inflation of study-reported means based on its assessment of the relationship between study-reported means and design values departs irrationally and unlawfully from CASAC's unanimous warning that such inflation fails to provide requisite protection. CASAC Letter on PA at 8-9, 14. In specifically addressing the draft PA's treatment of potential annual standard levels, CASAC, without any disagreement, expressed its concern over EPA's inflation because "even if a design value is somewhat higher than the area average, it reflects actual exposure levels and thus any portion of the population living near the design value monitor does experience exposures at that level and consequent health effects of exposure to that higher concentration." *Id.* at 13-14. CASAC accordingly recommended EPA "take into account th[is] perspective[]." *Id.* at 14. As explained above, EPA's proposal fails to do so rationally.

CASAC also went into great detail about how EPA's proposed approach falls short of the Act's requirements:

> The use of area mean values, and how they relate to the design value, is likely not providing adequate protection to people who live in areas with higher concentrations, such as those living near the monitoring location where the design value was recorded, and people who live in areas that do not have ground monitors but have concentrations higher than the design or mean value. Even though the design value is higher than the area mean value, people exposed to concentrations near the design value monitoring location may more often experience health effects as a function of the higher exposure at the design value monitor, not the area mean value. Thus, while the area mean value may be a useful metric for determining average health effects of the area population as a whole, health effects of that population may be unequally distributed and more pronounced among people living near the design value monitor and those exposed to higher ambient PM concentrations than the area mean value. Importantly, people exposed to these higher concentrations are often disproportionately persons of color and lower-income populations. Therefore, tying standards to the area mean value is not providing adequate protection to the entire population.

Id. at 8-9. CASAC may not have urged EPA to redo its analysis, but it suggested that EPA recognize "the limitations of the current approach" and discuss how relying on data other than study-reported means might make a difference. *Id.* at 9. EPA's proposal fails to provide any rational basis for departing from CASAC's advice and thus contravenes the Clean Air Act and is arbitrary.

Fourth, EPA's current approach cannot be reconciled with its past approach, nor does EPA even attempt to rationally explain how it is or why EPA is departing from its past, correct approach. We have already noted in this section several instances where

EPA in 2012 correctly interpreted the evidence, Act, and binding caselaw to bar the approach it takes here.

Another example is EPA's rejection in 2012 of polluters' opposition to EPA's proposal to eliminate spatial averaging as an option for complying with the annual standard. Polluters took a similar tack as EPA does in this proposal, arguing "that because spatial averaging is consistent with how air quality data are considered in the underlying epidemiological studies, such averaging should not be eliminated. Specifically, commenters…pointed out that $PM_{2.5}$ epidemiological studies use spatially averaged multi-monitor concentrations, rather than the single highest monitor, when evaluating health effects. Therefore, these commenters contended that allowing spatial averaging would make the $PM_{2.5}$ standard more consistent with the approaches used in the epidemiological studies upon which the standard is based." 78 Fed. Reg. at 3126. Similarly, in this proposal, EPA notes that epidemiologic studies report area-wide mean $PM_{2.5}$ concentrations that are associated with adverse health effects, rather than focusing on the highest monitor in the area, and putatively seeks to make the results of the study more consistent with the design value metric relevant to assessing compliance with the standard. But in 2012, EPA correctly rejected the polluters' comments:

> the Administrator concludes that public health would not be protected with an adequate margin of safety in all locations, as required by law, if disproportionately higher exposure concentrations in at-risk populations such as low income communities as well as minority communities were averaged together with lower concentrations measured at other sites in a large urban area. *See ALA v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) ("this court has held that 'NAAQS must protect not only average healthy individuals, but also sensitive citizens such as children,' and 'if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard'") and *Coalition of Battery Recyclers Association v. EPA*, 604 F.3d 613, 617 (D.C. Cir. 2010) ("Petitioners' assertion that the revised lead NAAQS is overprotective because it is more stringent than necessary to protect the entire population of young U.S. children ignores that the Clean Air Act allows protection of sensitive subpopulations.")[.] In reaching this conclusion, the Administrator further notes that her concern over possible disproportionate $PM_{2.5}$-related health impacts in at-risk populations extends to populations living near

important sources of $PM_{2.5}$, including the large populations that live near major roadways

78 Fed. Reg. 3127. EPA must again adopt its correct 2012 position and reject its illegal proposed approach or rationally explain why its new approach is consistent with the Act, an impossible task given the Act's health-protective focus and the record evidence that EPA's approach consigns significant portions of the population, disproportionately people of color and low-income communities, to air pollution levels EPA is quite confident cause death.

iv. EPA's discussion of Canadian epidemiological studies, restricted analyses, and accountability studies is unlawful and arbitrary

a. Canadian epidemiological studies

In the proposed rule, EPA cites several Canadian studies that support a clear causal relationship between elevated $PM_{2.5}$ concentrations and detrimental health effects. *See, e.g.*, 88 Fed. Reg. at 5585. In fact, EPA states that U.S. and Canadian epidemiological studies were critical to the Administrator's conclusion that the current primary $PM_{2.5}$ standard is inadequate to protect public health. *See id.* at 5580.

And yet, EPA then implausibly concludes that Canadian studies should not inform the level of the revised primary standard, because those studies "can be more difficult to directly compare to the [U.S.] annual design value." *Id.* at 5619. To justify this position, EPA vaguely invokes "differences between the exposure environments in the U.S. and Canada." *Id.* at 5627. The agency's reasoning is arbitrary and capricious for three reasons.

First, as discussed elsewhere in this comment, EPA's view that area averages in epidemiological studies must directly relate to U.S. design values is irrational. Thus, Canadian studies provide powerful evidence for adopting a primary standard level at the bottom of the EPA's considered range (8-11 $\mu g/m^3$), because they generally reported lower mean $PM_{2.5}$ concentrations than U.S. studies. *Id.* at 5602. This includes monitor-based studies (means ranged from 7-9 $\mu g/m^3$) and hybrid-modeled studies (means ranged from 6-8 $\mu g/m^3$, for studies examining nationwide exposure). *Id.* Thus, as CASAC noted, the Canadian studies are "paramount to assessing the 'low end' of the [concentration-response] curves." CASAC Letter on PA at A-56 to -57. By demonstrating positive associations at average $PM_{2.5}$ concentrations below 8 μg/m³, the Canadian studies are "consistent with no threshold and a possible supra-linear concentration-response function" at levels approaching (or dipping below) 8 μg/m³. *Id.* at 16. Even if there are methodological differences between U.S. and Canadian studies, *see* CASAC Letter on PA at A-57, the agency irrationally fails to explain why the Canadian studies do not <u>directionally</u> support a level at the bottom of the proposed range.

Second, even if it were rational for EPA to relate area averages to design values, the agency entirely fails to consider (or even acknowledge) CASAC's conclusion that EPA can derive U.S. design values from the Canadian area averages. In CASAC's consensus responses to the PA, the committee emphasized that "while there may be no design value in Canada, there are data that indicate what a U.S. design value would be if an area average like that found in the Canadian studies were to occur in the U.S." CASAC Letter on PA at 13-14. For the same reason, one member of CASAC stated that "Canadian studies **<u>should</u>** contribute to consideration" of the level of the revised primary standard. *Id.* at A-93 (emphasis in original). Put simply, EPA's stated rationale for excluding Canadian studies (*i.e.*, the difficulty of correlating area averages with U.S. design values) fails by its own terms.

Nothing in the proposed rule acknowledges, much less disputes, CASAC's opinion that the agency could extrapolate U.S. design values from Canadian area averages. Instead, the agency simply offers the conclusory assertion that using Canadian studies to inform the U.S. design value will or may provoke "uncertainty" or "present challenges." 88 Fed. Reg. at 5598, 5627. An agency may not simply "recite the terms 'substantial uncertainty' as a justification for its actions." *See State Farm*, 463 U.S. at 52. It must arrive at a rational conclusion after considering all the available evidence. Here, EPA fails to explain how—if at all—it considered the Canadian epidemiological studies.

To be sure, the Administrator states that he is "not excluding Canadian studies from his consideration…but he is considering them in light of the limitations and challenges presented." *Id.* at 5627. Yet, the Administrator's subsequent discussion of a proposed range for the primary standard fails to mention a single Canadian study (while broadly referencing several U.S.-based studies). *Id.* at 5628-29. In essence, the Administrator claims he is not <u>formally</u> excluding Canadian studies from consideration, while <u>effectively</u> excluding those studies from consideration. The agency cannot have it both ways. EPA thus failed to rationally explain why it effectively excluded Canadian studies from its analysis, and, as a result, the agency "entirely failed to consider an important aspect of the problem." *See State Farm*, 463 U.S. at 43.

Third, EPA's minimization of the Canadian studies relies on vague references to "differences in the exposure environments" between the U.S. and Canada. *See* 88 Fed. Reg. at 5610. This argument is conclusory and unexplained, especially in light of EPA's consistent reliance on Canadian research elsewhere in the rulemaking. *See, e.g.*, *id*. at 5598, 5619. Moreover, EPA's position conflicts with the agency's approach in previous particulate matter rulemakings. Nowhere in its 2012 or 2006 rulemakings did EPA suggest that the Canadian "exposure environment" was too unique to inform the level of a U.S. particulate matter standard. *See* 78 Fed. Reg. 3086; 71 Fed. Reg. 61,144. On the contrary, the 2006 rulemaking directly referenced several Canadian studies when evaluating the level for the PM10 standard. *See* 71 Fed. Reg. at 61,199. EPA has not, and cannot, provide a rational explanation for changing its position on the relevance of Canadian epidemiological studies when setting the level of a particulate matter standard, rendering its about-face arbitrary and capricious. *See FCC v. Fox Television Stations*, 556 U.S. 502, 515-16 (2009). Its generalized invocation of "differen[t] exposure environments" is hardly the required "detailed justification." *Id.*

b. Restricted studies

The proposed rule acknowledges several studies (i.e., "restricted studies") that analyze the health effects of $PM_{2.5}$ concentrations "below the level of the current annual standard." 88 Fed. Reg. at 5627. EPA cites two restricted studies—Di 2017b and Dominici 2019—in the proposed rule's preamble, noting that both studies' restricted analyses found positive associations with all-cause mortality at mean $PM_{2.5}$ concentrations of 9.6 $\mu g/m^3$. *Id.* The agency then notes that a standard of 9-10 $\mu g/m^3$ would be close to those reported mean values. *Id.*

EPA's discussion of restricted studies is arbitrary for two related reasons.

First, the proposed rule fails to mention several other studies that conducted restricted analyses at mean concentrations below 9.6 $\mu g/m^3$. For example, the PA cites two other restricted studies (in the U.S. and Canada) that EPA should have considered: Zhang 2021 and Shi 2016. *See* PA Supplement at 3-123 to -24. EPA presumably excludes these studies from the proposed rule because they did not expressly report a mean $PM_{2.5}$ concentration for the restricted analysis. *Id.*

But this blinkered approach misses the point. Shi 2016's main analysis reported a mean concentration of 8.1 μg/m³, implying that the restricted analysis's mean was "somewhat below" 8.1 μg/m³. *Id.* The same logic applies to Zhang 2021, which found a mean concentration of 7.8 μg/m³ in the main analysis. *Id.* CASAC agrees. In its consensus response to the PA, CASAC noted that "several newer studies . . . report health effects when . . . overall means are below 12 μg/m³ and even below 8 μg/m³, [meaning the studies would] have had even lower means when the data are restricted." CASAC Letter on PA at 13. Thus, EPA arbitrarily ignores studies that examined health impacts at mean concentrations well below the agency's proposed standard of 9-10 μg/m³.

Second, and just as importantly, the studies that EPA ignores "report positive and significant associations, often with effect estimates that are greater in magnitude than those reported in the main analysis." PA at 3-219. Thus, EPA did not just ignore studies that examined mean concentrations below 9-10 μg/m³, it ignored studies that suggested significant (and larger) public health improvements at mean concentrations below 9-10 μg/m³. The agency does not adequately explain this decision, which clashes with the PA and CASAC's expert guidance. Therefore, the agency's treatment of restricted studies is arbitrary and capricious.

c. Accountability studies

The proposed rule acknowledges several recent accountability studies (Corrigan et al. (2018), Henneman et al. (2019b), and Sanders et al. (2020a)), which assess the health impacts of policy interventions that reduce ambient $PM_{2.5}$ concentrations. 88 Fed. Reg. at 5627. And EPA correctly acknowledges those studies find clear public health benefits to lowering the primary $PM_{2.5}$ standard below 12 μg/m³. *Id.*

In the next sentence, however, EPA notes only that a revised standard of 9-10 μg/m³ would "be at or below the lowest starting concentration of these accountability studies (*i.e.*, 10.0 μg/m³)." *Id.* This misses the point. Even if the revised standard is below the accountability studies' <u>starting</u> mean concentrations, that does not demonstrate that the revised standard is low enough to protect public health. The better question is whether the accountability studies show robust health improvements at their <u>ending</u>

concentrations, which are often below the proposed standard of 9-10 μg/m³. Even granting (for the sake of argument) that EPA correctly relies on average annual means to determine the level of the revised annual standard, the more relevant question is whether the accountability studies show robust health improvements at mean concentrations below the proposed standard of 9-10 μg/m³.

At least one of the accountability studies does just that. Henneman (2019b) analyzes 30 million U.S. Medicare patients, noting that the patients' average $PM_{2.5}$ exposure fell from 10 μg/m³ to 7.2 μg/m³ between 2005 and 2012. *See* PA at 3-131; Henneman (2019b) at 4, 18. The study finds robust evidence of reduced cardiovascular morbidity during that period. *See* PA at 3-131 to -132. Thus, at the very least, Henneman (2019b) strongly suggests that a level of 10 μg/m³ is insufficient to protect public health with an adequate margin of safety. EPA's focus on starting concentrations (rather than ending concentrations) irrationally ignores this fact. The agency does not rationally explain why a standard of 10 μg/m³ will protect the public health, especially in the face of accountability studies (like Henneman 2019b) that suggest a lower primary standard will further reduce adverse health effects. As a result, EPA's minimization of the accountability studies is arbitrary and capricious.

v. EPA's attempts to dismiss the results of its own risk assessment are arbitrary and unlawful

EPA has irrationally discounted the risk assessment results when proposing to set the standard's level. *See* 88 Fed. Reg. 5627-28. Instead of taking into account the large benefits under a standard of 8 μg/m³, EPA states that several factors create uncertainty in the benefits estimated at 8 μg/m³. The purportedly meaningful uncertainties in sections II.C.2 and II.D.2.b of the proposal fall into three main categories:

1. Uncertainties related to the modeling and adjustment methods for simulating air quality scenarios;
2. The potential influence of confounders on the relationship between $PM_{2.5}$ exposure and mortality; and
3. The interpretation of the shapes of concentration-response functions, particularly at lower concentrations, which includes:
    a. Claims of relatively low data density in the lower concentration range, and

b. The possible influence of exposure measurement error.

The at-risk analysis highlights an additional purportedly meaningful uncertainty:

4. The claimed limited availability of studies to inform the at-risk analysis.

Below, we discuss these uncertainties in greater detail. The level of uncertainty does not rationally warrant dismissing a standard of 8 μg/m³.

1. <u>Uncertainties related to the modeling and adjustment methods for simulating air quality scenarios</u>:

The modeling scenarios in the Policy Assessment Supplement are based on "across-the-board" changes in primary $PM_{2.5}$ (Pri. PM) or NO_X and SO_2 emissions from all anthropogenic sources (Sec. PM) throughout the U.S. by fixed percentages. This approach, while not tailored to specific periods or sources and not a real-world implementation plan, represents a subset of the possible emissions cases that could be used to adjust $PM_{2.5}$ concentrations. EPA carried out a sensitivity analysis that finds that the difference between the estimates developed under the two approaches do not change the conclusions of the risk assessment. As seen in Figure 3-19 of the Policy Assessment Supplement (shown below) the choice of modeling approach does not change the overall ranking of estimated benefits under different alternative standards.

		Annual PM Concentration of Lower Standard (1 μg/m³ bins)											
Annual Standard Change	Simulation Method	2	3	4	5	6	7	8	9	10	11	12	Sum
12-11 (interpolated) μg/m³	Pri PM		0	3	11	17	39	110	381	1,534	763	62	2,920
	Sec PM		0	4	9	26	40	122	628	1,836	858	89	3,611
12-10 μg/m³	Pri PM		1	18	12	81	116	569	3,205	1,720	103		5,826
	Sec PM		1	23	23	89	287	1,632	3,377	1,681	87		7,201
12-9 (extrapolated) μg/m³	Pri PM		3	27	82	106	596	4,467	3,252	185			8,718
	Sec PM	0	5	48	98	529	2,754	4,953	2,334	47			10,768
12-8 (extrapolated) μg/m³	Pri PM	0	11	85	161	368	5,324	5,408	238				11,595
	Sec PM	0	50	129	1,116	3,527	6,390	3,101					14,314

Figure 3-19. Distribution of the difference in risk estimates between the current annual standard (level of 12.0 μg/m³) and alternative annual standards with levels of 11.0, 10.0, 9.0, and 8.0 μg/m³ for the subset of 30 urban study areas where the annual standard is controlling.[70]

An alternative standard of 8 μg/m³ has the highest benefit to public health irrespective of air quality modeling strategy.

2. The potential influence of confounders on the relationship between $PM_{2.5}$ exposure and mortality:

This issue has been discussed in detail above, as well as in Dr. Schwartz's comments to EPA on the draft ISA Supplement/PA.

In summary, a multitude of studies, across different cohorts, time periods, populations, exposure ranges, and study and analytical designs, have found that the association between $PM_{2.5}$ exposure and mortality is not due to confounding, and confounding does not affect the conclusions of the risk assessment in terms of the magnitude and ranking of the benefits at different alternative standards.

EPA reaches the same conclusion in the Policy Assessment Supplement:

> Cohort studies used to characterize the $PM_{2.5}$-mortality relationship used a variety of approaches to account for these and other potential confounders (e.g., see Appendix B). Across studies, a variety of study designs and statistical approaches have been used to account for potential confounding in the $PM_{2.5}$-mortality relationship. The fact that across this diverse body of evidence epidemiologic studies continue to report consistently positive associations that are often similar in magnitude, adds support the conclusion that the $PM_{2.5}$-mortality association is robust. Specifically regarding copollutants, the final PM ISA notes that, overall, associations remained relatively unchanged in copollutant models for total (nonaccidental) mortality, cardiovascular, and respiratory adjusted for ozone. Studies focusing on copollutant models with NO2, $PM_{10\text{-}2.5}$, SO_2 and benzene were examined in individual studies, and across these studies the $PM_{2.5}$-mortality association was relatively unchanged."

PA at C-76 to -77.

At the proposal stage, EPA provides no evidence to support any rational meaningful doubt about these conclusions.

3. The shape of C-R functions, particularly at lower concentrations:

The shape of such functions as in the Di et al. (2017) study is not uncertain and does not create uncertainty in the estimates of health benefits at 8 μg/m^3 contained in the risk assessment. The Di et al. (2017) study evaluates the relationship between long-term $PM_{2.5}$ exposure and all-cause mortality in nearly 61 million U.S. Medicare enrollees (over the age of 64) through 460 million person-years of follow-up and roughly 22 million observed deaths. This cohort comprises approximately 15% of the total U.S. population, includes people living in rural areas, and is one of the largest cohort studies published to date. The authors modeled $PM_{2.5}$ exposure across the contiguous U.S. using a hybrid methodology that included land use regression, satellite data, and monitor data, and resolved estimations to 1 x 1-kilometer areas. Di et al. (2017) uses Cox proportional-hazards models with a generalized estimating equation. Adjustment for potential confounding by the co-pollutant ozone was performed, which only slightly attenuated the relationship between $PM_{2.5}$ and mortality.

The C-R function in this study is plotted in Figure 3 of the paper and excerpted below. From this figure it is important to note that the confidence intervals of the association between $PM_{2.5}$ and mortality plotted on the graph here do not include 1 at 8 $\mu g/m^3$. In fact, the study authors note, “There was a significant association between $PM_{2.5}$ exposure and mortality when the analysis was restricted to concentrations below 12 μg per cubic meter, with a steeper slope below that level. … Moreover, we found no evidence of a threshold value—the concentration at which $PM_{2.5}$ exposure does not affect mortality—at concentrations as low as approximately 5 μg per cubic meter.”

This means that the avoided mortality benefits of lowering $PM_{2.5}$ levels to 8 $\mu g/m^3$ are likely larger than what has been estimated by EPA.

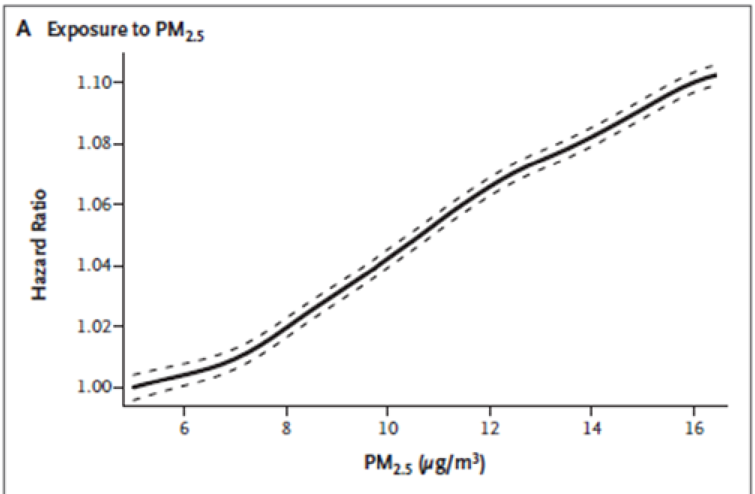
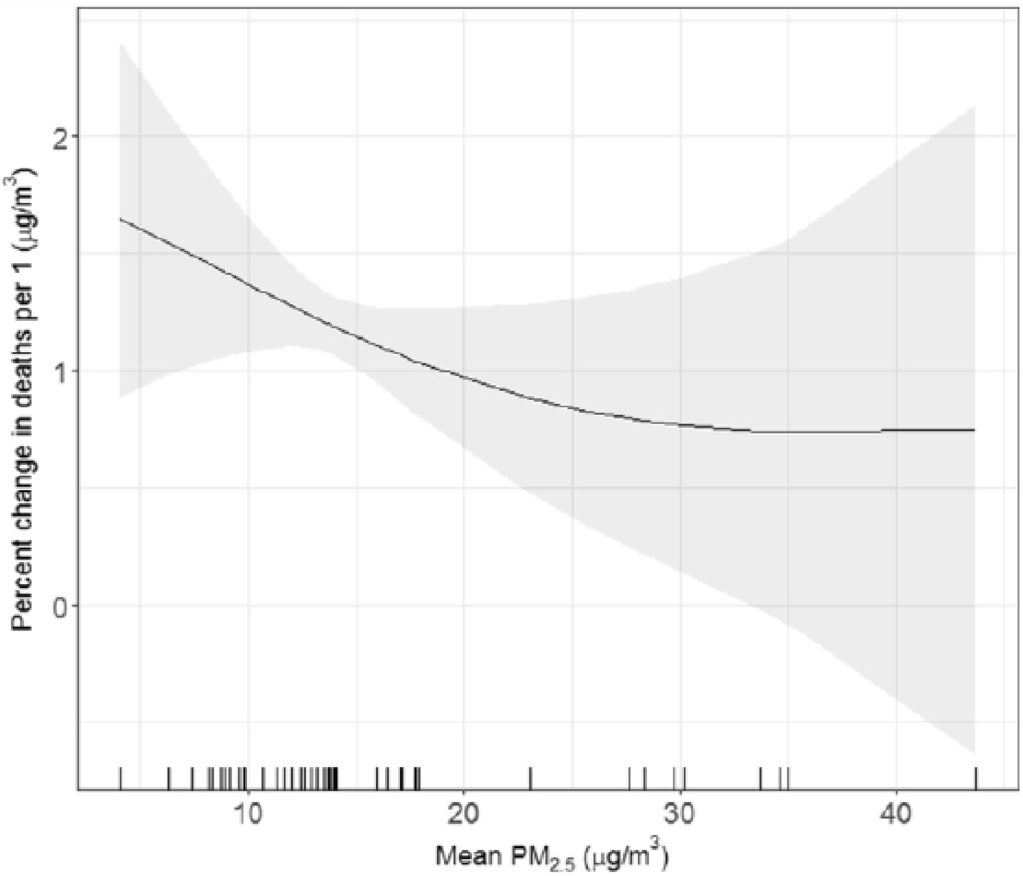


Figure 3. Concentration–Response Function of the Joint Effects of Exposure to $PM_{2.5}$ and Ozone on All-Cause Mortality.
A log-linear model with a thin-plate spline was fit for both $PM_{2.5}$ and ozone, and the shape of the concentration-response surface was estimated (Fig. S8 in the Supplementary Appendix). The concentration–response curve in Panel A was plotted for an ozone concentration equal to 45 ppb. The concentration–response curve in Panel B was plotted for a $PM_{2.5}$ concentration equal to 10 µg per cubic meter. These estimated curves were plotted at the 5th and 95th percentiles of the concentrations of $PM_{2.5}$ and ozone, respectively. The complete concentration–response three-dimensional surface is plotted in Fig. S8 in the Supplementary Appendix.

This is now supported by multiple other studies. In particular, Vodonos et al. conducted a meta-analysis in 2018 that examined over 100 effect estimates from 52 cohorts, 14 of which had mean exposures below 10 µg/m^3. They considered studies showing cardiovascular mortality impacts and all-cause mortality impacts. Integrating the literature, they found that the effect size for all-cause deaths varied with the mean $PM_{2.5}$ concentration, with the slope increasing at lower concentrations (supralinear effect). This is shown in the following plot from the paper, showing the slope of the C-R curve vs. mean $PM_{2.5}$ concentration. It shows the confidence interval does not include 0 down to 5 µg/m^3 or less. CASAC highlighted this study in its recommendations to EPA, CASAC Letter on PA at 16, yet EPA does not even mention the study in the PA or the proposal.



a. Claims of relatively low data density:

Such claims in the lower concentration range are not true and do not contribute to uncertainty in the concentration response function at 8 μg/m^3 and therefore do not affect the certainty of the benefits at an alternative standard of 8 μg/m^3. The Di et al. (2017) study is enormous, comprising over 61 million U.S. Medicare enrollees (over the age of 64) through 460 million person-years of follow-up and roughly 22 million observed deaths. During the course of the study, annual $PM_{2.5}$ concentrations ranged from 6.2 to 15.6 μg/m3 (5th and 95th percentiles, respectively). Qian Di et al., *Air Pollution and Mortality in the Medicare Population*, 376 New England J. Medicine 2513 (2017). This means that the data in the 5th percentile includes over 3 million Medicare beneficiaries or at the very least 23 million person years of observations below an annual average level of 6.2 μg/m^3. This is much larger than the total population involved in the American Cancer Society Cancer Prevention Study-II.

b. The possible influence of exposure measurement error:

This is unlikely to be a large source of uncertainty in the risk assessment results. The Di et al. (2017) study utilizes hybrid models to predict $PM_{2.5}$ levels across the country developed earlier in Di et al. (2016). The model uses:

1) Air monitoring data from the U.S. EPA Air Quality System (for both model building and cross-validation),
2) Aerosol optical depth (AOD) data, obtained from the moderate resolution imaging spectroradiometer (MODIS),
3) Surface reflectance data obtained from MODIS (MOD09A1),
4) Chemical transport model outputs derived from the widely used GEOS-Chem model. In addition to producing ground-level PM2.5 estimates, the GEOS-Chem model is also useful for calibrating AOD,
5) Meteorological data from the North American Regional Reanalysis project (air temperature, accumulated total precipitation, downward shortwave radiation flux, accumulated total evaporation, planetary boundary layer height, low cloud area fraction, precipitable water for the entire atmosphere, pressure, specific humidity at 2 meters, visibility, wind speed, medium cloud area fraction, high cloud area fraction, and surface reflectance),
6) Aerosol index data taken from the absorbing aerosol index measured by the ozone monitoring instrument (OMI), onboard the Aura satellite,
7) Land-use terms representing emissions and helpful for informing small spatial scale variations; land-use data incorporate a variety of variables (such as population and road densities, emissions inventory, elevation, percentage urban, etc.),
8) Regional and dummy variables in the regression models to account for regional and temporal variability due to differences in meteorology and aerosol composition.

The $PM_{2.5}$ model performed relatively well, with R^2 of 0.84 (range 0.74 to 0.88). Further, the authors of the Di et al. (2017) study carried out a sensitivity analysis, matching a subgroup of the population in the study to the nearest monitoring site measurement within a distance of 50 km. While the health effect estimates using air pollution data from proximal monitoring sites are lower than estimated exposure data, they are still statistically significant.

EPA notes in the PA that exposure measurement error is likely to be a low source of uncertainty in the risk assessment. EPA reasons that

> While none of these approaches eliminates the potential for exposure error in epidemiologic studies, such error does not call into question the findings of key $PM_{2.5}$ epidemiologic studies. The ISA notes that, while bias in either direction can occur, exposure error tends to result in underestimation of health effects in epidemiologic studies of PM exposure (U.S. EPA, 2019, section 3.5). Consistent with this, a recent study Hart et al. (2015) reports that correction for $PM_{2.5}$ exposure error using personal exposure information results in a moderately larger effect estimate for long-term $PM_{2.5}$ exposure and mortality (though with wider confidence intervals). 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). Thus, to the extent key $PM_{2.5}$ epidemiologic studies are subject to exposure error, correction for that error would likely result in larger effect estimates, and thus larger estimates of $PM_{2.5}$-associated mortality incidence in the risk assessment.

PA at C-79 to -80.

4. <u>The claimed limited availability of studies to inform the at-risk assessment</u>.

The Administrator points to purported uncertainties attributed to the limited availability of studies to inform the at-risk analysis as reason to avoid relying on the results of the at-risk analysis. However, EPA's PA assesses several studies that indicate higher risk of mortality due to $PM_{2.5}$ exposures among Black populations. PA at 3-144.

The Policy Assessment further states that Di et al., 2017b best characterizes potentially at-risk communities of color across the U.S. using study and risk estimate criteria described in the Estimating $PM_{2.5}$ and Ozone-Attributable Health Benefits TSD (U.S. EPA, 2022). *Id.* at 3-144 n.54.

Demographic Population	Citation	Cohort	Location
White	Awad et al., 2019	Medicare	National US
	Di et al., 2017	Medicare	National US
	Lipfert et al., 2020	Veterans	31 VA clinics in 27 states
	Parker et al., 2018	NHIS	National US
	Son et al., 2020	North Carolina	North Carolina
	Wang et al., 2017	Medicare	7 southeastern states
	Wang et al., 2020	Medicare	National US
White (75th percentile cities)	Kioumourtzoglou et al., 2016	Medicare	National US (207 cities)
Black	Awad et al., 2019	Medicare	National US
	Di et al., 2017	Medicare	National US
	Lipfert et al., 2020	Veterans	31 VA clinics in 27 states
	Parker et al., 2018	NHIS	National US
	Son et al., 2020	North Carolina	North Carolina
	Wang et al., 2017	Medicare	7 southeastern states
	Wang et al., 2020	Medicare	National US
Black (75th percentile cities)	Kioumourtzoglou et al., 2016	Medicare	National US (207 cities)
Asian	Di et al., 2017	Medicare	National US
	Son et al., 2020	North Carolina	North Carolina
	Wang et al., 2020	Medicare	National US
Asian (75th percentile cities)	Kioumourtzoglou et al., 2016	Medicare	National US (207 cities)
Hispanic	Di et al., 2017	Medicare	National US
	Parker et al., 2018	NHIS	National US
	Son et al., 2020	North Carolina	North Carolina
	Wang et al., 2020	Medicare	National US

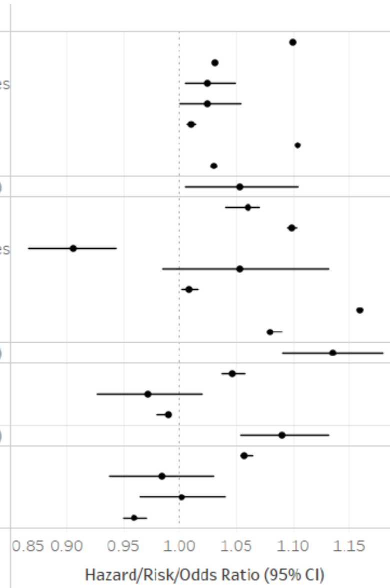
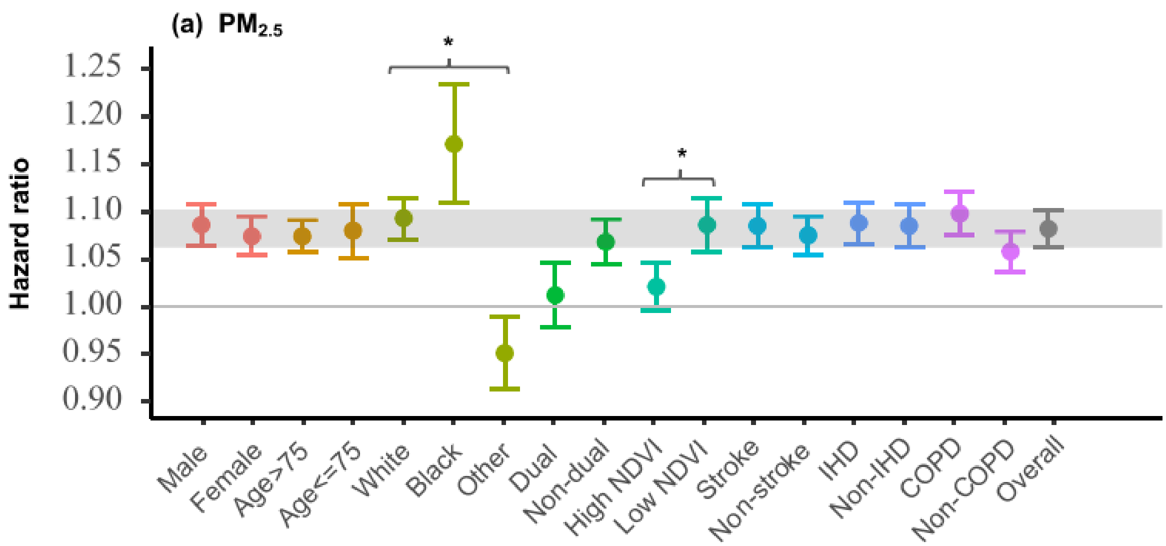


Figure 3-17. Available epidemiologic associations between long-term $PM_{2.5}$ exposure and mortality outcomes in demographic populations.[55]

A recent study by scientists at Emory University, American Cancer Society and Harvard University, Liuhua Shi et al., *Low-Concentration Air Pollution and Mortality in American Older Adults: A National Cohort Analysis (2001-2017)*, 56 Environ. Sci. & Tech. 7194 (2021), further reinforces these conclusions. This analysis includes all Medicare beneficiaries, ages 65 years and older, in the contiguous U.S. from 2001 through 2017. The full cohort includes 68.7 million Medicare enrollees, 27.2 million deaths (39.7%) and the long-term mean $PM_{2.5}$ concentration was 9.7 ± 3.3 μg/m^3. In subgroup analyses, a higher estimated risk of mortality was observed among Black populations.

In contrast with the previous Di et al. (2017) analysis, this analysis uses updated and improved ensemble model $PM_{2.5}$ predictions with higher validity of predictions at lower $PM_{2.5}$ concentrations, sensitivity tests of robustness of findings to model specification (including application of advanced causal modeling approach) and additional 5 years of follow up in the Medicare population.



vi. Standards with levels in and above EPA's proposed range would not comply with the Clean Air Act's health-protective mandate and would be arbitrary

As an initial matter, annual standards above 8 μg/m^3 would allow persistence of significant disparities in exposures to $PM_{2.5}$ concentrations and mortality risks from such exposures. This disparity is most striking between the more-exposed Black population, which has a much higher mortality risk rate, and the less-exposed, and substantially less-likely to die, white population in the locations EPA modeled. *See* PA at 3-162; *accord id.* at 3-159 to -163 & figs.3-20, 3-22. But with a standard of 8 μg/m^3, "disparities in exposure are virtually eliminated." *Id.* at 3-162. The mortality risk gap persists at 8 μg/m^3, but is the narrowest. *See id.* at 3-159 fig.3-20. Because national ambient air quality standards must protect vulnerable populations—not just the average or overall population—EPA must minimize the disparity in mortality risk that the Black population faces. Only a standard of 8 μg/m^3 does that.

Looking at the broader population, too, standards above 8 μg/m^3 would allow many more deaths and other health harms than a standard of 8 μg/m^3. Specifically, a standard of 8 μg/m^3 would have over 3 times the health benefits—prevented deaths and prevented emergency room visits for respiratory issues overall and for children with asthma—of a standard of 10 μg/m^3. *See supra* § V.A.2.ii. Compared with a standard of 9 μg/m^3, a standard of 8 μg/m^3 would provide about 67% greater benefits. *See id.* EPA has identified no rational basis for meaningfully doubting the harmful effects of $PM_{2.5}$, including at concentrations down to 8 μg/m^3. Accordingly, it is inconsistent with the Act not to set the standard's level at 8 μg/m^3 when such a level would save significantly more lives and avert many more other harms than higher standards, and EPA has offered no rational reason to conclude otherwise.

Moreover, standards above 8 μg/m^3 would provide little or no margin of safety for vulnerable populations like communities of color and low-income communities, and, in any event, EPA has not rationally explained how such standards would provide the legally required adequate margin of safety. EPA's explanation for the 9-10 μg/m^3 standard it proposes depends fundamentally on (1) narrowing the universe of epidemiologic studies it will principally rely on for establishing the level, (2) homing in on the study-reported means in that narrowed universe, and (3) inflating those study-reported means based on design values.[60] *See* 88 Fed. Reg. at 5628 (concluding with what EPA "provisionally concludes" regarding standard level); *see also id.* at 5628-29 (discussing "other lines of evidence" EPA "also considers" in arriving at proposed level). The PA's detailed summary of how key epidemiologic studies calculated their study-reported means makes clear that, with potentially two exceptions—both Canadian studies, upon which EPA did not rely (Erickson et al. 2020 and Pappin et al. 2019)—the study-reported means represented some broad average, not one that speaks to the disparate exposures EPA knows different populations experience. *See* PA at B-7 to -91 & tbl.B-4. EPA's explanation thus relies on <u>average</u> exposures in an <u>overall</u> population. Populations that are more vulnerable to lower $PM_{2.5}$ concentrations may thus have their experience drowned out by other populations that can endure higher concentrations. Accordingly, setting the standard's level by relying on concentrations below study-reported means is necessary to ensure vulnerable populations are protected with an adequate margin of safety against $PM_{2.5}$'s harmful effects. EPA fails to do that rationally here because its approach allows the many people who live in the portions of communities with the highest $PM_{2.5}$ concentrations to experience pollution levels <u>above</u> the study-reported means. The populations who will thus be affected are often disproportionately at-risk communities—communities of color and low-income communities. *See supra* § V.A.3.iii.

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[60] As explained above, each of those three steps is irrational.

EPA's explanation of how it proposes to protect the health of vulnerable populations with an adequate margin of safety is further irrational. In its key substantive discussion of proposed levels, 88 Fed. Reg. at 5624-29, EPA provides details of how it is working the margin of safety into its decision-making in three places only. *See id.* at 5627, 5628, 5629; *see also id.* at 5624, 5627, 5628, 5629 (using phrase "margin of safety" precisely nine times). In the first place, EPA "preliminarily" takes the position "that a revised standard should limit exposures to ambient concentrations near the 25th percentile of reported studies" and finds that a standard in the 8-10 $\mu g/m^3$ "is generally within the range" of the 25th percentile values, and that the even broader range of 8-11 $\mu g/m^3$ "would limit exposures to ambient concentrations near the 25th percentile reported in the available studies," noting that lower standard levels would limit such exposures more. *Id.* at 5627. This position thus does no work because any standard level under consideration meets it, as does the current standard. *See id.* at 5623 ("the current level of the annual standard is above most of the 25th percentile values reported in the key epidemiologic studies" (emphasis added)). EPA's explanation is thus irrational because it justifies literally any decision EPA might make. *See, e.g.*, *Shays v. FEC*, 414 F.3d 76, 114-15 (D.C. Cir. 2005) (agency action establishing threshold is invalid because rationale for the action applies with equal force to levels above and below the threshold); *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962) (agency must articulate a "rational connection between the facts found and the choice made").

In the second place, wherein EPA walks through what it "provisionally concludes," EPA says the U.S.-based epidemiologic studies it relies on "include and assess impacts on the most at-risk populations" and that a standard in the 9-10 $\mu g/m^3$ range would purportedly "limit air quality exposures to concentrations well below those associated with the study reported mean" and thus provide an adequate margin of safety for such populations. 88 Fed. Reg. at 5628. But, as explained above, under EPA's approach to setting the standard's level, with a standard of 10 $\mu g/m^3$, at-risk populations would likely experience exposures to $PM_{2.5}$ concentrations above study-reported means EPA relies principally on, to say nothing of study-reported means in studies EPA refused to rely principally on or other relevant metrics in either set of studies. In 2012, EPA itself said this outcome did not provide an adequate margin of safety, for it rejected polluters' arguments that would've allowed $PM_{2.5}$ concentrations above the long-term mean reported in studies where there's a causal relationship between $PM_{2.5}$ exposure and adverse health effects. There, EPA reasoned that the polluters' preferred outcome "would allow that level of air quality, where the evidence of health effects is strongest, and its associated risk of $PM_{2.5}$-related mortality and/or morbidity effects to continue. Selecting such a standard level could not be considered sufficient to protect the public health with an adequate margin of safety." 78 Fed. Reg. at 3147. Certainly, here EPA provides no rational explanation of how such an outcome now protects the health of—much less provides an adequate margin of safety for—the at-risk populations in areas with high levels of $PM_{2.5}$.

Similarly, with a standard of 9 μg/m^3, EPA has not rationally explained how the standard would provide at-risk populations requisite health protection with an adequate margin of safety when they would likely experience exposure to $PM_{2.5}$ concentrations within 0.3 μg/m^3 of a study-reported mean EPA relied principally on.

In the last place EPA provides some detail regarding how it is incorporating margin of safety considerations into its decision-making, EPA rationally explains how an approach to justify a standard above 10 μg/m^3 "may fail to provide an adequate margin of safety." 88 Fed. Reg. at 5629. Indeed, a standard above 10 μg/m^3, such as 11 μg/m^3, <u>would</u> fail to provide any margin of safety for all the reasons given above. We note also that the majority of CASAC declined to recommend a standard of 11 μg/m^3, further illustrating such a standard would be illegal and arbitrary. *See* CASAC Letter on PA at 16.

We further highlight that, even based solely on the studies EPA discusses and purports to give some weight in its proposal, a standard of 10 μg/m^3 would fail to protect public health with an adequate margin of safety and that EPA has failed to explain how it would. As discussed above, EPA addresses "two key studies" that include analyses restricted to $PM_{2.5}$ concentrations below 12 μg/m^3, explaining that both have mean concentrations of 9.6 μg/m^3. 88 Fed. Reg. at 5627. EPA notes that "these studies are useful in supporting the confidence and strength of associations at lower concentrations." *Id.* at 5603; *accord id.* at 5620. Though EPA points generally to purported uncertainties surrounding those analyses, the agency has not squared its endorsement of those studies, in addition to the great weight EPA places on study-reported means, with setting the standard at a level above those means. Similarly, the Henneman accountability study, also discussed above, has a starting concentration of 10 μg/m^3 and reported public health improvements resulted from lowering the concentration from that level. Were EPA to set the standard at 10 μg/m^3, the starting concentration in the Henneman study would be lawful throughout the country and all the public health gains that would result from going below it would be forsaken. Whatever uncertainty remains in Henneman about whether a particular $PM_{2.5}$ concentration below 10 μg/m^3 somehow represents a cut-point below which public health benefits might not be requisite, EPA gives no rational explanation—and none exists—of how a standard <u>at</u> 10 μg/m^3 protects public health with any margin of safety, much less an adequate one.

Since early 2022, new studies have also come out that CASAC members may not have seen when they considered and drafted their letter on EPA's draft PA. *See supra* § V.A.2.i. These studies have further strengthened the existing record by providing, among other things, more studies with reported means below 10 μg/m^3. The CASAC majority's recommendation might have shifted had they seen those studies. In any event, though the CASAC members are experts in their scientific fields, they are not legal experts, and the Clean Air Act's mandate is a legal one: "NAAQS must protect not only average healthy individuals, but also sensitive citizens such as children, and if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *Coal. of Battery Recyclers Ass'n*, 604 F.3d at 618 (quoting *Am. Lung Ass'n*, 134 F.3d at 389). A standard of 10 μg/m^3 does not meet those legal requirements.

vii. If EPA insists on setting an annual standard with level above 8 μg/m^3, it must select a level of 9 μg/m^3

As explained above, the only rational option EPA has is to set the annual standard with a level of 8 μg/m^3. If, nevertheless, it persists in refusing to do so, it must set the standard at 9 μg/m^3 (or whatever lower level above 8 μg/m^3 is the least departure justifiable). Indeed, EPA cannot and does not rationally explain how a standard of 10 μg/m^3 protects public health with an adequate margin of safety. We note also that a standard of 9 μg/m^3 would have huge benefits compared with the higher alternative levels EPA is considering. For example, it would prevent about twice as many deaths as a standard of 10 μg/m³. RIA at ES-17 tbl.ES-6.[61]

B. EPA must strengthen the 24-hour standard to no higher than 25 μg/m³

The latest scientific knowledge and CASAC majority recommendation show that the current 24-hour standard provides inadequate protection and would allow an unacceptably high level of risk to public health from short-term exposures to $PM_{2.5}$. EPA must revise the primary $PM_{2.5}$ 24-hour standard to no higher than 25 μg/m³ to protect public health with the adequate margin of safety required by the Clean Air Act.

1. The latest scientific knowledge shows that the current 24-hour standard does not protect public health with an adequate margin of safety even in conjunction with a strengthened annual standard

The available scientific evidence indicates that the 24-hour standard must be lowered to protect public health with the adequate margin of safety required by the Clean Air Act. As the majority of CASAC found, "[t]here is substantial epidemiologic evidence from both morbidity and mortality studies that the current standard is not adequately protective" and the CASAC majority felt there was "less confidence that the annual standard could adequately protect against health effects of short-term exposures." CASAC Letter on PA at Cover Letter 3-4. A majority of the CASAC recommended "that the EPA revise the level as part of the current review, and that a range of 25-30 μg/m³ for the 24-hour $PM_{2.5}$ standard would be adequately protective." *Id.* at 17. The scientific evidence and CASAC majority recommendation clearly support a strengthened 24-hour standard.

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[61] The PA does not analyze as many areas and reports a standard of 9 μg/m³ would save about 30% more lives than a standard of 10 μg/m³, accounting for just 30 areas. PA at 3-153 tbl.3-17.

i. EPA must revise the 24-hour standard because the combination of primary standards must provide adequate protection from health risks linked to both long-term and short-term exposures

To protect public health with an adequate margin of safety from health risks linked to both short-term and long-term exposures to $PM_{2.5}$, EPA must strengthen the 24-hour standard. It must do so even if the annual standard is set as low as 8 μg/m^3. The decision whether or not to strengthen the primary standards for fine particulate matter must be made based on whether the latest scientific knowledge indicates that the annual and 24-hour primary standards protect public health with the adequate margin of safety required by the Clean Air Act. For the 24-hour standard specifically, the question must be whether the current 24-hour standard of 35 μg/m^3 or a revised, more protective, standard, in combination with the levels of annual standards under consideration, will provide the required protection from the health effects associated with both long-term and short-term exposures to $PM_{2.5}$. Or as EPA describes it, "the current annual standard and 24-hour standard, together, are intended to provide public health protection against the full distribution of short- and long-term $PM_{2.5}$ exposures" and "changes in $PM_{2.5}$ air quality designed to meet either the annual or the 24-hour standard would likely result in changes to both long-term average and short-term peak $PM_{2.5}$ concentrations." 88 Fed. Reg at 5561.

The annual and 24-hour standards are not equally effective at addressing both types of exposures, because as EPA recognizes, "the annual standard is most effective at controlling exposures to 'typical' daily $PM_{2.5}$ concentrations that are experienced over the year, while the 24-hour standard, with its 98th percentile form, is most effective at limiting peak daily or 24-hour $PM_{2.5}$ concentrations" and "changes designed to meet a lower 24-hour standard, with a 98th percentile form, would most effectively result in fewer and lower peak 24-hour $PM_{2.5}$ concentrations, but also have an effect on lowering the annual average $PM_{2.5}$ concentrations." *Id.* at 5617. As we explain below, none of the levels for the annual standard under consideration in this proposal (proposed or which EPA has asked for comment on) would provide adequate protection without a strengthened 24-hour standard.

ii. The available scientific evidence provides a strong basis for strengthening the 24-hour standard

In addition to the health risks linked to long-term exposures to $PM_{2.5}$ discussed in § V.A, EPA has determined that there is a causal relationship between short-term exposures to $PM_{2.5}$ and mortality and cardiovascular effects, and that a causal relationship is likely to exist between short-term $PM_{2.5}$ exposure and respiratory effects. 88 Fed. Reg. at 5589. EPA has also determined that there is evidence suggestive of, but not sufficient to infer a causal relationship between short-term $PM_{2.5}$ exposure and nervous system effects, metabolic effects, reproduction and fertility, and pregnancy and birth outcomes. *Id.* at 5590. Since it is most effective at limiting short-term exposures, EPA must set the 24-hour standard at a level that provides adequate protection (in combination with the annual standard) from these health risks.

As the CASAC found, "both primary standards, 24-hour and annual, are critical to protect public health given the evidence on detrimental health outcomes at both short-term and longer-term exposures including peak events (e.g., wildfires)." CASAC Letter on PA at 13. Furthermore, a majority of the CASAC recommended both tightening the annual standard as low as 8 $\mu g/m^3$ and tightening the 24-hour standard to as low as 25 $\mu g/m^3$ which is indicative of the majority's lack of confidence that a tightened annual standard would be sufficient to address the risk of health effects from short-term exposures. *Id.* at 16-17.

The CASAC majority was "convinced that there is substantial epidemiologic evidence from both morbidity and mortality studies that the current standard is not adequately protective" including "three U.S. air pollution studies with analyses restricted to 24-hour concentrations below 25 $\mu g/m^3$." *Id.* at 17. EPA acknowledges that "the substantial epidemiologic evidence available in this reconsideration, including the studies that restrict short-term (24-hour average $PM_{2.5}$ concentrations) $PM_{2.5}$ exposures below 25 $\mu g/m^3$, provides support for positive and statistically significant associations between exposure to short-term $PM_{2.5}$ concentrations and all-cause mortality (Di et al., 2017a) and CVD hospital admissions (deSouza et al., 2021, and Di et al., 2017a)." 88 Fed. Reg. at 5621. The epidemiologic evidence is particularly relevant to this reconsideration because, as EPA acknowledges, "the epidemiologic studies available in this reconsideration include diverse populations that are broadly representative of the U.S. population as a whole, and include those populations identified as at-risk (i.e., children and older adults), as well as individuals in the general population with pre-existing disease, such as cardiovascular disease and respiratory disease." *Id.* at 5625. This compares favorably to the other available information from controlled human exposure studies and the risk assessment, which are not as broadly representative of the entire nation's population.

EPA also admits that "for the available epidemiologic studies that employ restricted analyses of short-term exposure studies, multicity studies indicate that positive and statistically significant associations with mortality persist in analyses restricted to short-term (24-hour average $PM_{2.5}$ concentrations) $PM_{2.5}$ exposures below 35 $\mu g/m^3$ (Lee et al., 2015), below 30 $\mu g/m^3$ (Shi et al., 2016), and below 25 $\mu g/m^3$ (Di et al., 2017a)." *Id.* at 5621. Furthermore, "the Administrator agrees that these studies help to provide additional support for reaching conclusions on causality in the 2019 ISA." *Id.* at 5621. Despite acknowledging these associations and the relevance to causality, EPA treats the epidemiological studies that use restricted analyses as being more relevant to the annual standard, and not providing adequate evidence to strengthen the 24-hour standard. Indeed, EPA states that "[w]hile this is useful information, it does not help to inform questions on the adequacy of the current 24-hour standard given that the 24-hour standard focuses on reducing 'peak' exposures (with its 98th percentile form)." *Id.* EPA claims that these studies do not help address the 24-hour standard for three reasons, specifically that (1) there are uncertainties regarding the methodologies used to exclude concentrations, that (2) the studies evaluate concentrations that correspond to the levels of the standards, but not the forms and averaging times, and that (3) the study-reported means from these studies are not useful for identifying impacts from peak 24-hour exposures, but are more useful for identifying impacts from typical 24-hour exposures. *Id.*

On the first issue of uncertainty regarding the studies, it is worth noting that a majority of EPA's expert panel, which is composed of highly qualified experts in their fields, reviewed the available scientific research and felt that these studies could be relied upon. While some uncertainty is inevitable with scientific research, that cannot rationally preclude EPA from relying on relevant scientific studies. On the second purported problem, it is important to recognize that the forms and averaging in the 24-hour and annual standards actually result in less protection than the levels might otherwise suggest. Thus, if anything, EPA should be more concerned that the standard provides inadequate protection because of the averaging over multiple years and, in the case of the 24-hour standard, the 98th percentile form that allows exceedances. Finally, while the study-reported means from these studies may be more useful for identifying impacts from typical 24-hour exposures, they also indicate health risks at relatively high exposures below the current 24-hour standard that must be addressed.

While these studies provide evidence to support strengthening the annual standard, as the average across the 24-hour periods in a year, they also provide evidence of potential health impacts from daily exposures at or below 25 $\mu g/m^3$. This is indicative of health impacts caused by peak exposures at levels below the current 24-hour standard. While these studies provide useful information and evidence in support of strengthening the annual standard, they also show harm when peak exposures are limited to levels that would comply with the existing 24-hour standard and therefore provide a strong basis for strengthening the 24-hour standard. EPA's assertion that these studies indicate the risks from short-term $PM_{2.5}$ exposure are not disproportionately driven by peak exposures does not suggest those peak exposures should not be addressed, and because no threshold has been identified below which exposure is not associated with health risks, those exposures still pose significant risks, which if addressed can also lower average exposures.

Far from undermining the epidemiologic evidence, controlled human exposure studies support the conclusion that the 24-hour standard must be strengthened. As the CASAC noted, controlled human exposure studies are not compelling evidence for retaining the 24-hour standard. As EPA acknowledges, the primary NAAQS must protect public health with an adequate margin of safety, including vulnerable populations. Controlled human exposure studies "preferentially recruit less susceptible individuals and have a typical exposure duration much shorter than 24 hours" and often do not expose people to the mix of pollutants that appears in the real world. CASAC Letter on PA at 6-7, 17. CASAC therefore warned against interpreting the absence of effects that may be found at a certain level in a particular controlled human exposure study to mean $PM_{2.5}$ causes no harmful effects at that level. *Id.* EPA appears to agree at least to some degree with the CASAC majority's concern, as "the Administrator agrees with the majority of the CASAC's comment that the controlled human exposure studies have significant limitations which must be considered when reaching conclusions on the adequacy of the current 24-hour standard." 88 Fed. Reg. at 5621.

The CASAC majority further explained that, even taking into consideration their limitations, the controlled human exposure studies provide some support for strengthening the 24-hour standard: "evidence of effects from controlled human exposure studies with exposures close to the current standard support epidemiological evidence for lowering the standard." CASAC Letter on PA 17. EPA claims "that $PM_{2.5}$ exposure concentrations evaluated in most of these controlled human exposure studies are well-above the 2-hour ambient $PM_{2.5}$ concentrations typically measured in locations meeting the current primary standards." 88 Fed. Reg. at 5594. However, as the CASAC noted, "if the prior 20 hours of ambient exposure and the 2-4 hours of the controlled human exposure were taken as a time-averaged 24-hour concentration, the exposure would likely be in the realm of normal ambient 24-hour exposures." CASAC Letter on PA at 7. Therefore, EPA must focus less on peak concentrations "typically measured" at locations meeting the current standards because even if those do not typically exceed the levels of the controlled human exposure studies, the 24-hour standard must protect against atypical peak concentrations that cause public health harm or reduce the margin of safety in the standard, and the current standard allows for exposures comparable to those in controlled human exposure studies.

Furthermore, it is important to view the controlled human exposure studies, which "are important in establishing biological plausibility," 88 Fed. Reg. at 5593, in light of the other scientific evidence, particularly the epidemiological studies, as the CASAC majority does. The combination of epidemiological studies that provide evidence of effects below the current 24-hour standard and controlled human exposure studies that provide biological plausibility and show effects at levels that, if averaged over 24 hours, would likely be in the realm of normal ambient 24-hour exposures, provides strong support for strengthening the 24-hour standard.

Also, EPA's risk assessment does little to inform a decision regarding the 24-hour standard. The risk assessment is limited in scope and does not provide a comprehensive view of the potential impact of a lower 24-hour standard. At best, the risk assessment provides a partial assessment of mortality risk that can be compared between the existing standard and a 30 $\mu g/m^3$ 24-hour standard because, as EPA admits, the risk assessment "did not provide quantitative information on risk impacts associated with an alternative 24-hour standard level of 25 $\mu g/m^3$." *Id.* at 5622. Any assertion of which standard is "controlling" based on the risk assessment does not apply to a 24-hour standard of 25 $\mu g/m^3$.

The CASAC majority was particularly "concerned that the risk assessment may not adequately capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective." CASAC Letter on PA at 17. This contradicts EPA's claim that "current air quality shows that the 24-hour standard is controlling in very few areas and thus, it is understandable that there are very few areas that would be included in the study areas in the risk assessment." 88 Fed. Reg. at 5622. In one example, Fairbanks, Alaska has been in nonattainment under the 24-hour standard since 2009, yet in that time has never been designated a nonattainment area under the annual standard, and was not included in the risk assessment. One member of the CASAC panel also expressed concern about areas in the Northwest with wintertime stagnation and heating by woodstoves being excluded because they are affected by periodic wildfires. CASAC Letter on PA at A-89.

Finally, the number of areas failing to attain the 24-hour standard without failing to attain the annual standard is not a rational relevant metric in determining whether the 24-hour standard is currently providing adequate protection from short-term exposures to $PM_{2.5}$. Consistent with its statements that the two standards work together, EPA must treat the 24-hour standard as a complement to the annual standard that provides better protection against peak exposures rather than as a kind of "backstop" value. Tightening the annual standard without tightening the 24-hour standard would leave an unacceptably high level of health risk from peak exposures because areas could attain the tightened annual standard without attaining a tighter 24-hour standard.

iii. Even an annual standard of 8 μg/m^3 would not provide adequate protection from short-term peak exposures without a stronger 24-hour standard

An annual standard as low as 8 μg/m^3, while providing much better protection against typical/average exposures than the current annual standard, would not protect public health with the adequate margin of safety required by the Clean Air Act because it would not adequately address peak exposures.

Furthermore, the future areas that are not projected to attain either the annual or 24-hour standard could attain the annual standard but not necessarily attain the 24-hour standard because control measures that address typical exposures fail to adequately limit peak exposures to $PM_{2.5}$. With climate change affecting wildfires and weather patterns, there is significant risk of unprecedented or unusual events, and therefore it is not rational for EPA to expect future events to reflect historical patterns. As the CASAC noted, "there is an underlying assumption that the 24-hour standard adequately controls for short-term effects of peak exposures embedded in the 24-hour period but there is no adjustment made regarding the increased incidences of short-term peak exposures in recent years." CASAC Letter on PA at 7. The Agency must therefore set the 24-hour standard at a protective level regardless of typical historical data regarding exposures under the existing standards. It would be arbitrary and capricious to retain the 24-hour standard based on historical data when EPA knows and has been warned about changes that suggest historical patterns may not be indicative of future exposures.

2. Monitor data shows that strengthening the 24-hour standard in combination with a strengthened annual standard provides significantly better protection against 2-hour and 4-hour peak exposures

Though controlled human exposure studies have limited value in deciding whether or not to strengthen the 24-hour standard, EPA acknowledges that "[s]tatistically significant effects on one or more indicators of cardiovascular function are often, though not always, reported following 2-hour exposures to average $PM_{2.5}$ concentrations at and above about 120 μg/m^3." 88 Fed. Reg. at 5593. EPA also notes that "Wyatt et al. (2020) found significant effects for some cardiovascular (*e.g.*, systematic inflammation markers, cardiac repolarization, and decreased pulmonary function) effects following 4-hour exposures to 37.8 μg/m^3 in healthy young participants (18-35 years, n=21) who were subject to intermittent moderate exercise." *Id.* Therefore, the 24-hour standard must at least provide protection from risk of the health effects shown in these studies. Analysis of recent monitor data shows that strengthened 24-hour and annual standards would provide significantly better protection from these types of exposures.

Looking at the range of combinations of standards recommended by CASAC, and based on 2017-2020 data, for monitors that achieved or were close to achieving an annual standard of 10 μg/m^3 and a 24-hour standard of 30 μg/m^3 (9.8-10.2 and 28-32), there are, on average, 1.5 days per monitor per year with 2-hour max over 120 μg/m^3, while for monitors that just achieved or were close to achieving a combination of 8 μg/m^3 and 25 μg/m^3 (7.8-8.2 and 23-27), there were on average only 0.2 days per monitor per year that have 2-hour max over 120 μg/m³, which is virtually eliminating those exposures. Considering the Wyatt et al. study, which showed health effects from peak exposures above 37.8 μg/m³, for monitors that just achieved or were close to achieving standards of 10 μg/m³ and 30 μg/m³ (9.8-10.2 and 28-32), there are on average 24 days per monitor per year with 4-hour max over 37.7 μg/m³. For monitors that achieved or were close to achieving standards of 8 μg/m³ and 25 μg/m³ (7.8-8.2 and 23-27), there were only 8 days per monitor per year. Based on data from 2017-2021, at any annual standard, monitors that just achieve or are close to achieving a standard of 35 μg/m³ (33-37) averaged 1.81 days per monitor per year of peak 2-hour exposures over 120 μg/m³ and 24.28 days per monitor per year of 4-hour peak exposures over 37.7 μg/m³. For monitors just achieving or close to achieving 25 μg/m³ (23-27), there were on average only .54 days per monitor per year of peak 2-hour exposures over 120 μg/m³, and 10.27 days per monitor per year of 4-hour peak exposures over 37.7 μg/m³.

Finally, the current 24-hour standard of 35 μg/m³ was set back in 2006 when the annual standard was 15 μg/m³. The scientific evidence connecting health risks to lower $PM_{2.5}$ concentrations has grown, yet as the annual standard has been tightened, the 24-hour standard has remained unchanged. The Independent Particulate Matter Review Panel noted that "[i]n past reviews and in this review, there is an underlying notion that there is a typical mean ratio between annual and 24-hour levels" and therefore "if the annual level is revised downward, the 24-hour level should be revised downward proportionally." EPA-HQ-OAR-2015-0072-0037 ("IPMRP Letter") B-31. If the annual standard is reduced from 12 μg/m³ to 8-10, a linearly proportional reduction of the 24-hour standard would be 23-29 μg/m³. *Id.*

3. To meet the Clean Air Act's mandates and advance environmental justice, EPA must set the 24-hour standard's level no higher than 25 μg/m³

EPA must revise the 24-hour standard to 25 μg/m³ for the primary standards to provide adequate protection against health effects linked to both long-term and short-term exposures for overburdened and historically marginalized groups. The CASAC majority felt that it was "important to note that risk disparities across racial and ethnic groups remain substantial with the focus on an annual standard." CASAC Letter on PA at Cover Letter 2. Concerns regarding some groups are further supported by a nationwide study of population-weighted mean exposures from 2012-2016, which found that compared to non-Hispanic white people, people of color experienced 23 more days with $PM_{2.5}$ concentrations greater than or equal to 15 $\mu g/m^3$, 6.4 more days with $PM_{2.5}$ concentrations greater than or equal to 25 $\mu g/m^3$, and 1.7 more days with $PM_{2.5}$ concentrations greater than or equal to 35 $\mu g/m^3$. Timothy Collins & Sara Grineski, *Racial/Ethnic Disparities in Short-Term $PM_{2.5}$ Air Pollution Exposures in the United States*, 130 Env't Health Persp., Aug. 2022, at 087701-1, 087701-1 to -3. The study found that "[d]isparities appear larger for short-term vs long-term $PM_{2.5}$ exposures nationwide." *Id.* at 087701-3. The study also found that "POC groups within regions were much more likely than NH White people to have greater than regional average exposure, whereas NH White people were more likely than POC groups to have less than regional average exposure." *Id*. at 087701-1.

An analysis of the projected populations in monitored counties that EPA projects would be in attainment and nonattainment areas in 2032 at various annual and 24-hour standard levels shows that there would be significantly larger populations of people of color living in nonattainment areas if the 24-hour standard is tightened. Measures in plans to implement the NAAQS to address this pollution and improve air quality would have large health benefits for such demographics because "[a]s part of these plans, states have the opportunity to use tools to advance environmental justice, in this case for overburdened communities in areas with high PM concentrations above the NAAQS, as provided in current PM NAAQS implementation guidance to meet requirements." 88 Fed. Reg. at 5563.

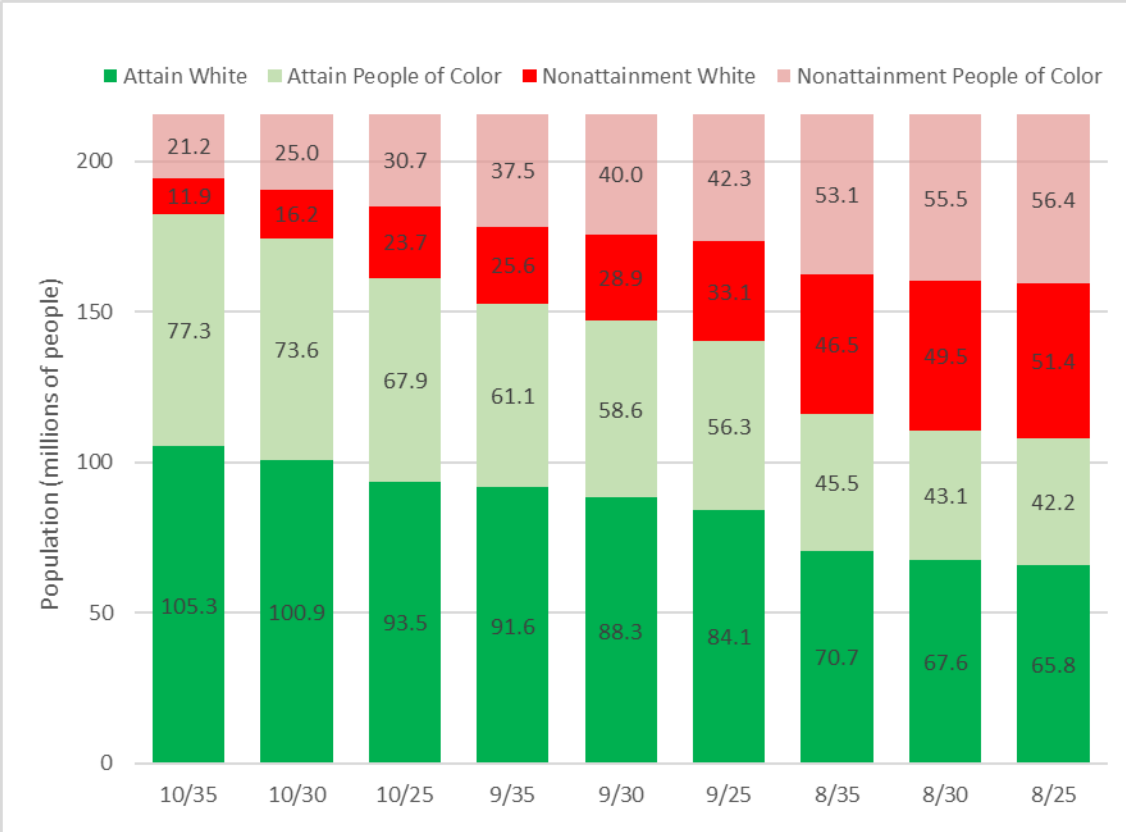

Figure 2: Projected 2032 attainment/nonattainment county-level populations at various annual/daily standard combinations.

Data Sources for Figure 2: Design Value data from EPA's 2032 Projections, County Max annual and daily values; Population values are taken from EPA's EJScreen dataset for 2021, Total and People of Color Populations

The chart shows the least to most stringent standard combinations from left to right, with changes in annual standard generally resulting in a greater shift in population from attainment to nonattainment counties than a shift in daily standard. Note that there are 569 counties that have a projected design value out of the over 3,100 counties in the continental U.S. Total U.S. population was nearly 325 million people, of whom nearly 128 million are people of color. The monitored counties include nearly 216 million people, with about 99 million people of color, representing ~2/3 of the total population and 77% of the population of people of color. Note monitoring is generally conducted in more populated and polluted areas.

For an annual standard of 10 μg/m^3, among the monitored populations, lowering the 24-hour standard from 35 μg/m^3 to 25 μg/m^3 results in the population of people of color covered by nonattainment areas increasing by 9.5 million people, or a 9.6% increase. At an annual standard of 9 μg/m³ the 24-hour standard of 25 μg/m³ results in the nonattainment population of people of color increasing by an additional 4.8 million people, or nearly 5%. And at 8 μg/m³ the nonattainment population of people of color increases by 3.3 million people, or 3.3%. These numbers show significant increases in the number of people of color who would be in nonattainment areas under a tightened 24-hour standard, and therefore benefit from air quality improvements from implementation. As a percentage of total U.S. population, at levels of 10 μg/m³ for the annual and 35 for the 24-hour standard, the populations in nonattainment areas in this dataset would be 10.2% of the total white population and 21.6% of the population of people of color. For levels of 8 μg/m³ for the annual and 25 μg/m³ for the 24-hour standard, the percentages are 43.8% of the total white population and 57.2% of the population of people of color. In going from a combination of 10 μg/m³ and 35 μg/m³ to 8 μg/m³ and 25 μg/m³, the percentages increase by 33.6% for the white population and 35.6% for the population of people of color. Therefore, the increase in percentage of population in nonattainment areas increases by a larger amount for people of color than for the white population.

We also carried out an analysis based on current (2019-21) design values[62] and demographic data from EJScreen 2021. It shows similar trends to the results for EPA's projected 2032 design values. The counties with design values are mostly the same, but not entirely. The current design value set has about 15 million fewer people in counties with monitors. Both analyses are illustrative, since the designation process could include some counties without monitors, and the classification of counties with monitors in that process is likely to reflect the worst design values in the metro area, vs. a county-specific worst design values used here.

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[62] As of the comment deadline, the 2021 design values are the most recent available. EPA, Air Quality Design Values, https://www.epa.gov/air-trends/air-quality-design-values#report; *see* EPA, $PM_{2.5}$ Design Values, 2021, https://www.epa.gov/system/files/documents/2022-05/PM25_DesignValues_2019_2021_FINAL_05_24_22.xlsx (design value report).

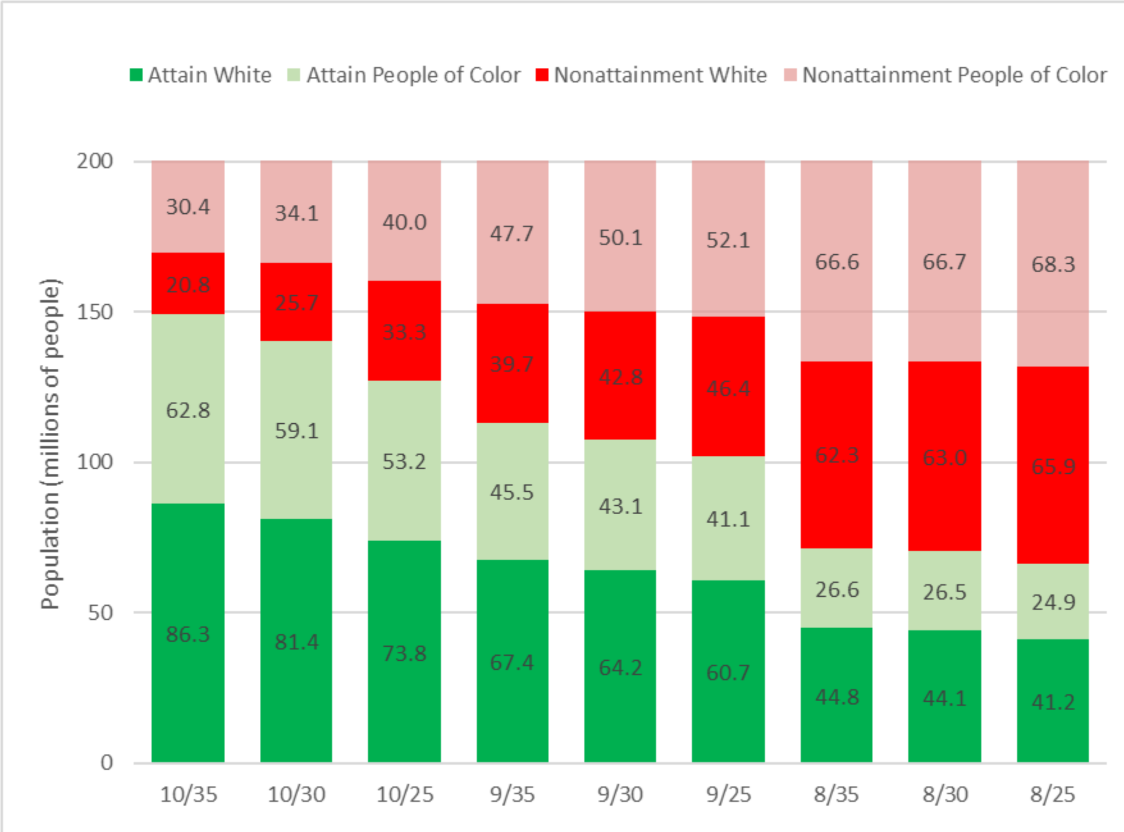

Figure 3: County-level populations at various annual/daily standard combinations under most current (2021) design values.

Data Sources for Figure 3: Design Value data from EPA's 2021 Design Value Report, County Max annual and daily values; Population values are taken from EPA's EJScreen dataset for 2021, Total and People of Color Populations.

4. EPA's reasoning for retaining the 24-hour standard is arbitrary and inconsistent with the Clean Air Act

EPA's proposed decision to retain the 24-hour standard is inconsistent with the scientific evidence and the advice of the majority of the CASAC. As discussed in § II.B.4, CASAC is a highly qualified panel established under the Clean Air Act. EPA has failed to provide an adequate reasoned explanation for proposing to retain the standard, and instead relies on arbitrary and capricious reasoning for contradicting the scientific evidence and CASAC in its proposed decision.

i. Deciding whether or not to revise the 24-hour standard based on a comparison to the information and evidence available on the annual standard is arbitrary and unlawful

EPA's discussion of whether "there is less information available to support decisions on the 24-hour standard" than the annual standard is arbitrary and capricious, and not a relevant consideration when deciding whether to revise the 24-hour standard. The relevant question is not whether "the Administrator finds it is less clear whether the available scientific evidence and quantitative information calls into question the adequacy of the public health protection afforded by the current 24-hour standard." 88 Fed. Reg. at 5624. Having less information available regarding one standard compared to the other does not rationally prevent EPA from revising either standard.

The decision regarding revising the 24-hour standard must be based on the combined protection offered by the standards from short-term and long-term exposures, not the relative strength of the evidence supporting revisions to either of the standards. While there is compelling evidence to support a revision to the 24-hour standard, even if the evidence and quantitative information in support of revising the 24-hour standard is not as compelling as the evidence supporting revision of the annual standard, revising the 24-hour standard is still supported and required.

ii. EPA's treatment of the scientific evidence and the risk assessment in deciding to retain the current 24-hour standard is arbitrary and unlawful

The available scientific evidence as previously discussed, *see supra* § V.B.1.ii, strongly supports revising the 24-hour standard. EPA's proposal to not revise the 24-hour standard and its treatment of the scientific evidence, the risk assessment, and the CASAC majority's recommendations regarding them are arbitrary and unlawful.

EPA claims that the epidemiologic evidence "provides limited support for judging adequacy of the level of the 24-hour standard" and that the studies relied on by the CASAC majority in recommending a revision to the 24-hour standard "are an inadequate basis for revising the level of the 24-hour $PM_{2.5}$ standard." 88 Fed. Reg. at 5623. As discussed in § V.B.1.ii, EPA claims that because of uncertainty regarding methodology, the studies not incorporating the form and averaging time of the 24-hour standard, and the study-reported means being more useful for identifying impacts from typical exposures but not peak exposures, the epidemiologic studies with restricted analyses do not help address the 24-hour standard. These assertions run counter to the CASAC majority's recommendation, and for the reasons discussed in § V.B.1.ii, EPA's treatment of this evidence is arbitrary and unlawful.

EPA's treatment of the controlled human exposure studies is also arbitrary and unlawful, largely for reasons discussed in § V.B.1.ii. While the limitations of controlled human exposure studies have been well established, as discussed in § V.B.1.ii, those studies still provide support for tightening the 24-hour standard based on effects at levels of exposures that may occur in areas that attain the current 24-hour standard. EPA appears to dismiss the support from controlled human exposure studies by suggesting "it is unclear how the results from these studies alone and the importance of the effects observed in these studies, should be interpreted with respect to adversity to public health" and that "just observing the occurrence of impaired vascular function alone does not clearly suggest an adverse health outcome." 88 Fed. Reg. at 5593. However, as the agency acknowledges, "impaired vascular function can signal an intermediate effect along the potential biological pathways for cardiovascular effects following short-term exposure to $PM_{2.5}$ and show a role for exposure to $PM_{2.5}$ leading to potential worsening of IHD and heart failure followed potentially by ED visits, hospital admissions, or mortality." *Id.* And as previously discussed, the controlled human exposure studies are limited because they include only healthy individuals, and therefore are not representative of the U.S. population, which includes at-risk populations that must be protected. Even if the effects observed may not be clearly adverse in the controlled human exposure study participants, that does not mean they would not be clearly adverse for vulnerable or at-risk groups. The relevant question is not whether these effects are adverse to the limited participants in controlled human exposure studies, but whether they would be adverse to the more vulnerable or at-risk groups who must be protected by the standard.

EPA's treatment of the risk assessment, and the agency's reliance on the risk assessment as support for proposing not to revise the 24-hour standard are arbitrary and unlawful for the reasons more fully discussed in § V.B.1.ii. In brief, the CASAC majority was concerned about the scope of the risk assessment, and "the majority of CASAC members [were] concerned that the current risk assessment may not adequately characterize mortality risks associated with short-term $PM_{2.5}$ exposures."

CASAC Letter on PA at 11. The fact that the risk assessment, as designed, is not particularly helpful in determining whether the 24-hour standard is adequate does not weigh against revising the 24-hour standard. EPA's reliance on the risk assessment for the assertion that the annual standard is "the controlling standard" for most of the U.S. despite its serious limitations (including considering only the weakest standard recommended by the CASAC majority) is arbitrary and capricious, as is any decision to retain the 24-hour standard that is based on this notion of which standard is "controlling." 88 Fed. Reg. at 5561. As the agency acknowledges, "the risk assessment did not provide quantitative information on risk impacts associated with an alternative 24-hour standard level of 25 $\mu g/m^3$." *Id.* at 5622.

Furthermore, it would be arbitrary and capricious for EPA to retain the standard based on the expectation that, because the current standards have, for the most part, resulted in attainment areas having peak concentrations below levels in controlled human exposure studies in the past, they will continue to do so into the future. The standards should be set at levels that will provide adequate protection in the future, including where circumstances in the future may be different due to climate change.

iii. EPA arbitrarily relies on strengthening the annual standard to provide all the necessary protection against short-term peak exposures

While the annual standard and 24-hour standard may provide some protection against short-term and long-term exposures to $PM_{2.5}$, as EPA acknowledges, the 24-hour standard is better at and more targeted toward addressing the short-term peak exposures than the annual standard. EPA "notes that, for most of the U.S., the annual standard is the controlling standard and that the risk assessment estimates reductions in $PM_{2.5}$-associated risks across more of the population and in more areas with alternative annual standard levels compared to estimates for alternative 24-hour standard levels." 88 Fed. Reg. at 5624. However, this is based on the risk assessment (with its inherent limitations) and would be an arbitrary basis for not strengthening the 24-hour standard.

Furthermore, it is possible that areas failing to attain both the annual standard and 24-hour standard (for which EPA considers the annual standard "controlling") could achieve a tighter annual standard without achieving a tighter 24-hour standard because high peak concentrations may still be allowed by the annual standard. EPA must provide adequate protection from the health effects associated with high short-term exposures, and therefore it would be arbitrary and capricious to leave the 24-hour standard unchanged while relying entirely on the annual standard to provide additional protection from short-term exposures.

5. EPA should revise the form of the 24-hour standard to a 99th percentile of daily averages over 3 years

EPA should revise the form of the 24-hour standard to a 99th percentile form to provide better protection from peak exposures. The current form of the standard ostensibly allows exceedances on 7 days per year, but is further weakened by being averaged over 3 years. In fact, for the four monitor locations that just met the current daily standard for 2019-21 (design value 35 $\mu g/m^3$), one site had 23 exceedances in one year; the average number over three years for the sites were 6.33, 9, 9, and 10.33. Fundamentally, there is a mismatch between EPA's stated concern about 24-hour peak exposures, which the 24-hour standard is supposed to most effectively control, 88 Fed. Reg. at 5617, 5618-19, and the form effectively writes off many high pollution days each year. The form is thus irrational.

Moreover, CASAC recommended that "EPA provide a more comprehensive assessment of the 24-hour standard that includes the form as well as the level" in future reviews and that "[i]n particular, the midnight-to-midnight averaging time splits high wood smoke episodes into two days, thus potentially underestimating the effect of high 24-hour exposures, especially in areas with wood-burning stoves and wintertime stagnation." CASAC Letter on PA at 18. In its letter, CASAC suggested "considering a rolling 24-hour average and examining alternatives to the 98th percentile of the 3-year average (e.g., average of concentrations ≥ 98th percentile or alternative percentiles)." *Id.* A 99th percentile form for the 24-hour standard would provide stronger protection for public health regardless of the level of the standard and EPA should consider it.

VI. SECONDARY PM NAAQS

A. EPA's legal obligations in reviewing and setting the secondary standards

The Act 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.

Id. § 7409(b)(2). Just as with the primary standards, EPA cannot lawfully consider costs in the standard-setting process. *Whitman*, 531 U.S. at 471 n.3 ("For many of the same reasons described in the body of the opinion, as well as the text of § [74]09(b)(2), which instructs the EPA to set the standards at a level 'requisite to protect the public welfare from any known or anticipated adverse effects <u>associated with the presence of such air pollutant in the ambient air</u>' (emphasis added), we conclude that the EPA may not consider implementation costs in setting the secondary NAAQS.'").

Under the Act, "[t]o ensure that the NAAQS take account of the current science," EPA must complete a thorough review of the standards "at least once every five years." 42 U.S.C. § 7409(d)(1); *Nat'l Ass'n of Mfrs.*, 750 F.3d at 923 ("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."). During this review, EPA must revise the criteria and standards or promulgate new standards as appropriate. 42 U.S.C. § 7409(d)(1). 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." *Id.* § 7409(b)(2); *Am. Farm Bureau Fed'n*, 559 F.3d at 530. 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." 42 U.S.C. § 7602(h).

In speaking about the amendments for public welfare during the Senate debates, one of the prime architects of the Act, Senator Muskie 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[n] or adverse environmental effects." Legislative History of Clean Air Act Amendments of 1970 at 227 (Senate Debate on S. 4358, Sept. 21, 1970). The "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," *American Lung*, 884 F. Supp. at 347, and that "as the contours and texture of scientific knowledge change…EPA's NAAQS review necessarily changes as well." *Mississippi v. EPA*, 744 F.3d 1334, 1344 (D.C. Cir. 2013); *see also* discussion and caselaw cited above. The CASAC is chartered to offer recommendations on the secondary as well as the primary NAAQS.

B. Public Welfare Impacts from $PM_{2.5}$

The wide range of harms $PM_{2.5}$ causes for public welfare is well-established. We describe three of the welfare values $PM_{2.5}$ harms below: ecosystems; visibility; and materials.

1. Ecosystems

Fine particle pollution is made of many different compounds, which are independently harmful to ecosystems. $PM_{2.5}$ can be directly deposited on land and 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 organisms both directly and through their role in acidification and affiliated heavy metal contamination. These metals, such as aluminum, are toxic to aquatic life.

Fine PM nitrogen pollution has ecological and water quality impacts. As anthropogenic nitrogen enters ecosystems it can contribute to a "nitrogen cascade" disrupting natural nutrient cycling. Damage to ecosystems that are typically nitrogen limited are particularly concerning where biodiversity can be reduced, and invasive species can be favored. For example, atmospheric deposition of nitrogen is a significant source of pollution affecting water quality in the Chesapeake Bay and contributing to persistent eutrophication in the estuary.[63] EPA's Chesapeake Bay Program reports that

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[63] *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

ammonia emissions account for an increasing amount of the total nitrogen from atmospheric deposition entering the Bay and its tidal rivers.[64] Ammonia emissions also contribute to the formation of PM.[65]

Fine PM can be 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

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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."); *id.* at 4-33 (noting that "[a]ir sources contribute about one-third of the total nitrogen loads delivered to the Chesapeake Bay"); *see also* Linker, Lewis C., et al., *Computing Atmospheric Nutrient Loads to the Chesapeake Bay Watershed and Tidal Waters*, Journal of the American Water Res. Ass'n. (JAWRA), 2013, 1-17, https://doi.org/10.1111/jawr.12112, https://d38c6ppuviqmfp.cloudfront.net/documents/Atmo_Dep__CB_TMDL_10-13.pdf.

[64] 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"); *see also* Keith N. Eshleman, et al., *Declining nitrate-N yields in the Upper Potomac River Basin: What is really driving progress under the Chesapeake Bay restoration?*, Atmospheric Environment, Vol. 146, pp. 280-289 (Dec. 2016), https://doi.org/10.1016/j.atmosenv.2016.07.004.

[65] *See* Battye, W., et al., (2017), *Is nitrogen the next carbon?*, Earth's Future, 5,894–904, https://doi.org/10.1002/2017EF000592; Behera, S.N., 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), https://doi.org/10.1007/s11356-013-2051-9; 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.

deposition like depletion of soil nutrients, aluminum mobilization, and acidification in waters that lead to accelerated plant die-off and 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 long-distance pollution transport. The formation of secondary $PM_{2.5}$ from gaseous precursors like sulfur dioxide, nitric acid, and ammonia helps transport these sulfur and nitrogen 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 sulfur and nitrogen 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 manifest values of our democracy in safeguarding our natural, cultural, and historic heritage.

2. Visibility

There is clear causality between $PM_{2.5}$ air pollution and visibility degradation. Visibility in many areas throughout the country is deteriorated by $PM_{2.5}$ and is unquestionably unacceptable to the general public.[66] 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 national parks and wilderness areas.[67] Despite progress in reducing haze causing pollution, not a single one of the 156 designated "Class I" areas has achieved the statutory goal of natural visibility conditions. Visibility-impairing pollution travels far

[66] Malm, WC, et al., *Which Visibility Indicators Best Represent a Population's Preference for a Level of Visual Air Quality?*, 69 J. Air & Waste Mgmt. Ass'n 145 (2019), https://doi.org/10.1080/10962247.2018.1506370 ("(Malm et al. 2019)").

[67] 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 addition to national parks and wilderness areas, forests and wildlife refuges).

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 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.

3. Materials

EPA has long acknowledged that PM damages and soils materials like metals, paint, stone, concrete, and glass. ISA Supplement at 2-40 tbl.2-3. In this way, PM harms important welfare values—it harms the materials and damages property, for example. ISA at 13-77 to -81; 42 U.S.C. § 7602(h). Information has recently been developing on the negative effects of PM on solar panels and energy efficiency, as well. ISA Supplement 2-39.

C. EPA's proposal not to strengthen the secondary standards is unlawful and arbitrary

Here, EPA proposes to do nothing about any of the well-established welfare harms $PM_{2.5}$ causes. On ecosystems, it punts to a separate NAAQS review on ecosystems that is now subject to court-ordered deadlines. *See* Order, *Ctr. for Biological Diversity v. Regan*, No. 4:22-cv-2285-HSG (Oct. 12, 2022) (entering consent decree); EPA-HQ-OGC-2022-0447-0002 (proposed consent decree). On materials, it declines to set standards, claiming too profound uncertainties. For visibility, EPA proposes no change to the secondary standard, though it indicates its openness to changing the 24-hour $PM_{2.5}$ secondary standard. As we explain below, EPA must strengthen the secondary standards to protect important welfare values.

1. EPA's proposal to retain the secondary 24-hour standard is unlawful and arbitrary

i. EPA fails to rationally justify 30 deciviews as the visibility index target

CASAC's advice on the draft PA was that EPA needed to justify any decision to select 30 deciviews ("dv") as the target level of protection. EPA failed to make this justification in the proposed rule. The Administrator claimed uncertainties and limitations in the preference studies as a rationale to use the upper end of the range of 20-30 dv that 50% of the survey respondents found acceptable visibility. 88 Fed. Reg. at 5659-60. But, as described below, without explanation, EPA failed to take steps recommended by CASAC to reduce such purported uncertainties and instead relied on the fundamentally flawed review process that resulted in the 2020 decision that EPA is reconsidering here. The 2020 rationale is irrational for the reasons given by the outside panel of experts who reviewed the original draft PA.

a. EPA fails to use the latest science to develop a visibility index level

In the reconsideration, CASAC expressly advised EPA that "[t]he final PA should consider using an 'acceptable' contrast value to help develop the secondary PM standards." CASAC Letter on PA 22. CASAC explained that the draft ISA Supplement made clear that "contrast rather than total light extinction appears to make the level of acceptable visual air quality more uniform across different locations." *Id.* An individual CASAC panel member put it succinctly:

> I suggest that the Policy Assessment more fully consider new research explaining regional differences in visibility preferences, which was presented in the ISA Supplement. Visibility preferences are better explained by contrast than concentration.

Id. at A-91. As EPA already knows, the key research at issue is Malm et al. (2019), an important meta-analysis of visibility preference studies.[68] EPA itself was able to draw conclusions from that study about how to relate contrast to acceptable visibility preferences. ISA Supplement at 4-5 to -6.

Yet, in the proposal, EPA fails to consider the alternative ("contrast of distance") methodology. EPA summarizes Malm et al. (2019) but then ignores its findings, *see* 88 Fed. Reg. at 5649, even though it utilizes the same visual preference studies EPA relies on and that are included in past reviews. EPA's analysis summarizes the study but goes on to ignore the Independent Particulate Matter Review Panel's ("IPMRP") important finding that "addresses the limitations with the concept that there is any specific level of light extinction that is universally acceptable."[69] More specifically, the Malm et al. (2019) study evaluates a large number of visibility preference indicators and finds that the apparent contrast of distant, prominent but not necessarily dominant, scene elements is a much better and more consistent predictor of "acceptable" visibility than any specific level of light extinction. The IPMRP further suggested the methodology EPA can use to develop viewing distances across different areas and regions:

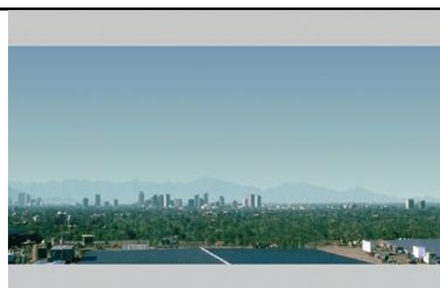
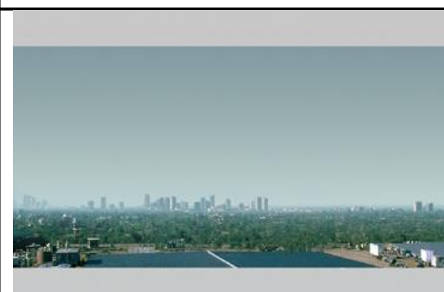
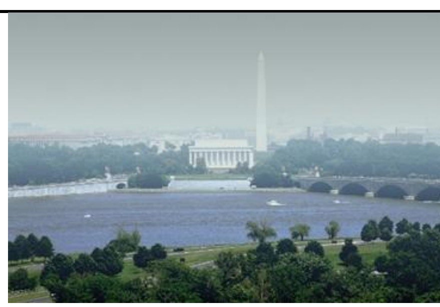
> Across all the currently available visibility preference studies, as the apparent contrast of distant, prominent scene elements approached an apparent contrast level of about -0.04 (i.e. very little contrast), 50% of respondents found the visibility unacceptable. <u>In simpler terms, as the visual range approaches the distance of distant scenic elements, people everywhere find the visibility unacceptable.</u> 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.[70]

[68] *See, e.g.*, ISA Supplement 4-5 to -6; Letter from Dr. Elizabeth A. (Lianne) Sheppard, Chair, Clean Air Scientific Advisory Committee, to Michael S. Regan, Adm'r, EPA, at A-45 (EPA-CASAC-22-001, Mar. 18, 2022) ("CASAC Letter on ISA Supplement").

[69] IPMRP Letter at B-34.

[70] *Id*. (emphasis added).

The IPMRP's suggestion further illustrates that EPA's departure from CASAC's advice to consider the Malm et al. (2019) study in setting the secondary standard is irrational. Indeed, EPA cannot rationally ignore this study, for it suggests that replacing the current indicator with the contrast of distant scenic elements would be a significant improvement and more accurately evaluate public preferences.

Location	Contrast Method (varying dv)	30 dv
Denver	 60 km / 18.75 dv  130 km / 11.02 dv	 19.48 km / 30 dv
Phoenix, AZ	 42 km / 22.32 dv	 19.48 km / 30 dv
Washington, DC	 8 km / 38.9 dv	 19.48 km / 30 dv

Grand Canyon, AZ	 170 km / 9.38 dv	 21.64 km / 30 dv

Table 2: Images from WinHazeWeb depicting the contrast method results vs. 30 dv proposed by EPA

EPA's sole basis in the proposal for its refusal even to consider contrast is its claim that that there are not many studies using contrast "to evaluate public preference information," and EPA thinks it is therefore "difficult to evaluate them as an alternative to the light extinction approach." 88 Fed. Reg. at 5649-50. But EPA itself describes Malm et al. (2019) as evaluating the results of "six visibility preference studies" (in Washington, DC; Phoenix, AZ; Chilliwack, BC; Abbotsford, BC; Denver, CO; and the Grand Canyon, AZ), and summarizes the contrast analysis results for five "studies" (Phoenix, AZ; Chilliwack, BC; Abbotsford, BC; Denver, CO; and the Grand Canyon, AZ).[71] And, in the ISA, EPA indicates there are only "four North American visibility studies" regarding "visibility preference,"[72] addressing nearly the same areas (Washington, DC; Phoenix, AZ; Chilliwack, BC; Abbotsford, BC; and Denver, CO).[73] EPA thus leaves unexplained why essentially the same set of studies is adequate for analysis under a light extinction approach, but not under a contrast approach. This unexplained differential treatment is arbitrary.

As a result of EPA's departure from CASAC's advice, EPA's proposal instead falls back on the approach it took in the 2020 PA (as well as invoking purported uncertainties and limitations, which we address below). But that review lacked a proper

[71] ISA Supplement at 4-3, 4-6 fig.4-2.

[72] EPA's inconsistency in discussing the number of studies makes it quite difficult to understand what exactly it considered at various points in time and what its point is now.

[73] ISA at 13-42 (relying on 2009 PM ISA); *see also* EPA-HQ-OAR-2015-0072-1184 at 9-67 to -71 (2009 PM ISA).

external CASAC review panel. *See supra* § III. Within that review, an outside panel of experts that reviewed drafts of the 2020 PA found the current 24-hour secondary standard was not adequate to protect against visibility effects and explained how the PA must analyze options for alternative secondary standards, offering detailed recommendations regarding alternative indicators, averaging times, forms, and levels that should be considered.[74] The detailed comments further disregarded 30 dv as anything near protective of visibility.[75]

b. EPA's interpretation of the visibility preference studies irrationally leaves a tiny minority of study respondents accepting EPA's visibility target

While we agree that comparing across visual assessment studies can be problematic as identified by Malm et al. (2019), those results can provide insight into what percentage of overall respondents would find acceptable visibility in the range of 20-30 dv at each location. The table below from EPA's 2010 Urban-Focused Visibility Assessment shows that of the four studies examined in the 2012 review, and revisited in this review, a 30 dv standard would leave under 10% of the respondents in each study other than the Washington, DC, one accepting visibility condition >29 dv. A target of 30 dv thus results in the irrational outcome of leaving the vast majority of people dissatisfied with the resulting visibility, especially irrational when EPA purports to be aiming for 50% satisfaction. Certainly, EPA has not explained how it reasonably complies with EPA's statutory duty or is reasonable decision-making.

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[74] IPMRP Letter at 5, B-33 to-36 (citing especially comments from Richard Poirot).

[75] *Id.* at C-88 to -95 ("The combination of daily average, 90th percentile, 30 dv, filter-based reconstructed PM light extinction is a substantially weaker secondary standard than those considered by EPA staff and supported by CASAC in all previous (1987, 1997, 2006 and 2012) PM NAAQS reviews.").

Table 2-3. Logit Model Estimated VAQ Values Corresponding to Various Percent Acceptability Values for the Four Cities

	Denver	British Columbia	Phoenix	Washington, DC
90% Acceptability criteria	14.21	16.80	24.15	23.03
75% Acceptability criteria	17.05	19.63	21.80	26.03
50% Acceptability criteria	**19.90**	**22.45**	**24.15**	**29.03**
25% Acceptability criteria	22.74	25.28	26.51	32.03
10% Acceptability criteria	25.59	28.10	28.87	35.03

EPA, Particulate Matter Urban-Focused Visibility Assessment 2-29 tbl.2-3 (EPA 452/R-10-004, July 2010) ("UFVA").

Similarly, Malm et al. (2019) summarizes these same studies with one additional site in the Grand Canyon, AZ, and by separating the British Columbia studies into two sites. Here the units are in light extinction Mm-1. The results indicate the same issue that only 10% of respondents in 5 out of 6 studies found >191 Mm-1 (near 30 dv) acceptable, leaving 90% finding this threshold unacceptable visibility impairment. It is not difficult to see why this is the case. Table 3 below shows the visibility conditions at 30 dv using WinHazeWeb for all other available urban sites.

Based on these studies, a 75% acceptability is requisite to protect visibility resources. As explained in comments filed in the 2012 review,

> There is no question that using a logit regression to fit binary data is a proper method, and that 50% represents the data inflection point. However, EPA provides no rationale for why 50% is an appropriate metric for the secondary standard. We are concerned that leaving 50% of the public with perceived visibility impairment does not properly protect the public welfare under the CAA….

EPA-HQ-OAR-2007-0492-9562 at 8. Using the light extinction terms in Malm et al. (2019) Table 3, a 75% acceptability criterion would be on average 84.3 Mm-1, or approximately 47 km visual range and about 21 dv.

Table 3. Percentile acceptability levels and associated uncertainties, expressed in atmospheric extinction terms of Mm^{-1}, for each of the scenes studied.

Percentile acceptability	10%	25%	50%	75%	90%
Washington	263.1 ± 1.0	227.5 ± 1.0	191.8 ± 0.7	156.1 ± 0.6	120.4 ± 0.4
Phoenix	186.4 ± 1.5	147.2 ± 1.3	116.2 ± 1.0	91.8 ± 0.8	72.5 ± 0.6
Denver	100.1 ± 2.4	87.4 ± 2.1	74.8 ± 1.7	62.1 ± 1.4	49.4 ± 1.0
Chilliwack	155.5 ± 2.1	134.7 ± 1.8	113.8 ± 1.5	93.0 ± 1.2	72.2 ± 0.9
Abbotsford	153.7 ± 2.3	130.6 ± 1.9	107.5 ± 1.6	84.4 ± 1.3	61.2 ± 1.0
Grand Canyon	32.6 ± 2.3	27.9 ± 2.0	23.2 ± 1.7	18.5 ± 1.3	13.8 ± 1.0

Though this would not be as clean as the contrast method indicates, which is approximately on average 61 km, 64 Mm-1, or 18 dv, either value is strikingly better protective than EPA's choice of 30 dv, as shown in Table 3 below.

Boston, MA **Visibility:** **64.13 Mm^{-1} / 61 km / 18.58 dv** 	**Boston, MA** **Visibility:** **83.23 Mm^{-1} / 47 km / 21.19 dv** 	**Boston, MA** **Visibility:** **200.86 Mm^{-1} / 19.48 km / 30 dv** 
Dallas, TX **Visibility: 64.13 Mm^{-1} / 61 km / 18.58 dv** 	**Dallas, TX** **Visibility: 83.23 Mm^{-1} / 47 km / 21.19 dv** 	**Dallas, TX** **Visibility: 200.86 Mm^{-1} / 19.48 km / 30 dv** 
Durango, CO **Visibility: 64.13 Mm^{-1} / 61 km / 18.58 dv** 	**Durango, CO** **Visibility: 83.23 Mm^{-1} / 47 km / 21.19 dv** 	**Durango, CO** **Visibility: 200.86 Mm^{-1} / 19.48 km / 30 dv** 
Fort Collins, CO	**Fort Collins, CO**	**Fort Collins, CO**

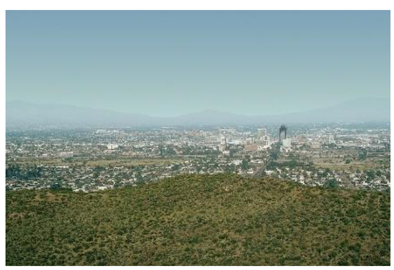
Visibility: 64.13 Mm^{-1} / 61 km / 18.58 dv 	**Visibility: 83.23 Mm^{-1} / 47 km / 21.19 dv** 	**Visibility: 200.86 Mm^{-1} / 19.48 km / 30 dv** 
Las Vegas - Red Mountain Wilderness, NV **Visibility: 64.13 Mm^{-1} / 61 km / 18.58 dv** 	**Las Vegas - Red Mountain Wilderness, NV** **Visibility: 83.23 Mm^{-1} / 47 km / 21.19 dv** 	**Las Vegas - Red Mountain Wilderness, NV** **Visibility: 200.86 Mm^{-1} / 19.48 km / 30 dv** 
Tucson, AZ **Visibility: 64.13 Mm^{-1} / 61 km / 18.58 dv** 	**Tucson, AZ** **Visibility: 83.23 Mm^{-1} / 47 km / 21.19 dv** 	**Tucson, AZ** **Visibility: 200.86 Mm^{-1} / 19.48 km / 30 dv** 

Table 3: WinHazeWeb images from urban sites comparing different visibility.

c. EPA illegally and arbitrarily relies on claimed uncertainties and concerns over overprotectiveness to propose a weaker visibility index target

Having irrationally dismissed the new science discussed above, EPA falls back on tired, meritless arguments for refusing to set a more protective standard.[76] EPA says (1) there are "significant questions about how to set a national standard for visibility that is not overprotective for some areas of the U.S," and proposes that (2) "the uncertainties and variability inherent in the public preference studies warrant setting a higher target level of protection than if the underlying methods and results from the public preference studies were more consistent." 88 Fed. Reg. at 5660. EPA then concludes that, (3) because the standard "is intended to address visibility impairment across a wide range of regions and circumstances" and there's a Regional Haze program, EPA proposes to use the upper end of the 20-30 dv range as a target. *Id.*

Each of these three arguments is inconsistent with the Act and irrational. EPA's purported concern about being "overprotective for some areas" ignores the governing text of the Act: a secondary standard must "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 word "any" sweeps broadly. *New York v. EPA*, 443 F.3d 880, 885 (D.C. Cir. 2006) ("any" has an "expansive reach" in the Act). Thus, if EPA identifies an effect that is known or anticipated to be adverse in portions of the country (outside Class I areas, at least), that effect remains known or anticipated to be adverse even if it may not constitute a known or anticipated adverse effect in some other portion of the country. Accordingly, EPA must set the standard to protect against it.

[76] *Cf. Murray Energy*, 936 F.3d at 618-20 (EPA's reliance on purported "'uncertainties and complexities'" did not rationally justify its refusal to set secondary standard to protect against adverse welfare effect); *Mississippi*, 744 F.3d at 1360 (rejecting EPA's decision, based on evidence being purportedly "limited and uncertain," to set secondary standard equal to primary standard); *Am. Farm Bureau*, 559 F.3d at 529-30 (rejecting EPA's decision, based on evidence being purportedly "uncertain," to set secondary standard equal to primary standard).

Further, EPA's proposal cannot and does not rationally explain why setting the standard at a level that does not protect against known or anticipated adverse welfare effects in portions of the country is requisite to protect the public welfare from any known or anticipated adverse effects. The proposal fails to mention, much less rationally explain how its concern about purported overprotectiveness is consistent with the statutory text or EPA's correct position on primary standards. And EPA's purported concern about overprotectiveness irrationally fails to consider the flip side: an <u>under</u>-protective standard.

EPA's "uncertainties" argument is also inconsistent with the Act and arbitrary. Similar to the primary standards, on secondary standards, the Act pushes for protection through its "preference for preventative…regulation." *Ctr. for Biological Diversity v. EPA*, 749 F.3d 1079, 1090 (D.C. Cir. 2014). It commands that EPA act not only when it might have "perfect information" or be able to predict adverse effect certainly, but to protect against "anticipated adverse effects," "suggesting that EPA must act as soon as it has enough information (even if crude) to 'anticipate[]' such effects." *Am. Trucking Ass'ns*, 283 F.3d at 380 (alteration in original); *see Ctr. for Biological Diversity*, 749 F.3d at 1090 & n.18. EPA's proposed decision to resolve purported uncertainties in favor of less protection is inconsistent with the Act's protective direction. EPA makes no attempt to show otherwise, which is itself arbitrary. Nor could it do so rationally.

The "uncertainties" argument is also irrational because EPA cannot "merely recite the terms 'substantial uncertainty' as a justification for its actions." *State Farm*, 463 U.S. at 52; *Murray Energy*, 936 F.3d at 619. As explained above, other experts, including CASAC, have suggested ways to overcome the uncertainties EPA claims cut against stronger protections. *E.g.*, IPMRP Letter at C-93 ("If this kind of approach were applied across multiple urban/suburban areas throughout the country, it would be clear that people in many diverse regions would likely find visibility impairment of 30 dv to be unacceptable."). Further, EPA gives no reason why it should resolve "uncertainties and variability" in favor of less protection rather than more, 88 Fed. Reg. at 5660.

Finally, for similar reasons, EPA's third argument—that it should set a visibility target at the upper end of the 20-30 dv range because there are many "regions and circumstances" for the secondary standard to operate and there is also a Regional Haze Program, *id.*—is arbitrary. There are two pieces to this. First is that the standard will operate in many regions and circumstances. For the reasons given above in addressing

EPA's concerns about purportedly being overprotective and about uncertainties, EPA's reliance on this point for targeting the upper end of the dv range is irrational and illegal.

Second is the Regional Haze Program. EPA identifies no rational connection between the Regional Haze Program and EPA's proposal to set the visibility target at the high end of the deciview range. The Regional Haze Program addresses Class I areas. *Id.* at 5658; *see Am. Corn Growers Ass'n v. EPA*, 291 F.3d 1, 2-4 (D.C. Cir. 2002); *Am. Trucking Ass'ns*, 175 F.3d at 1056 ("Congress required the EPA to implement a regional haze program specifically in order to address adverse visibility effects that persist in class I areas after attainment of the secondary NAAQS."), *overruled in other parts sub nom. Whitman*, 531 U.S. 457 (2001). EPA proposes in this very same notice to rely exclusively on the Regional Haze Program to protect visibility in Class I areas and give visibility in such areas no weight in its consideration of the secondary standard. 88 Fed. Reg. at 5658 ("the Administrator proposes to conclude that addressing visibility impairment in Class I areas is beyond the scope of the secondary PM NAAQS"). Thus, the Regional Haze Program provides no rational basis—certainly EPA identifies none—for EPA to select a visibility target in the upper end of its range. Moreover, even if it is rational for EPA not to rely exclusively on the secondary standard to address visibility in Class I areas, that hardly makes it rational to entirely ignore visibility in such areas in setting the secondary standard.

ii. EPA fails to rationally justify the 3-year average, 90th percentile form of the visibility index

EPA wrongly says CASAC didn't give feedback on the 3-year, 90th percentile aspect of the target, 88 Fed. Reg. at 5659 ("the Administrator notes that the CASAC did not provide advice or recommendations related to the form of the visibility index."). To the contrary, as with the target level, CASAC explicitly recommended that EPA justify its selection of metric and form.[77] EPA still has not done so, and its proposal thus arbitrarily departs from CASAC's recommendations and comments.

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[77] CASAC Letter on PA at 22 ("The final PA should provide a robust justification for the daily light extinction percentile used in the analysis).

When EPA finally confronts the advice CASAC expressly provided regarding the form of the visibility index, it must find that 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).

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.[78]

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. 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.[79]

EPA also 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 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.[80] EPA's proposal lacks consideration of the 98th percentile. Even if EPA wanted to follow the regional haze

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[78] 88 Fed. Reg. at 5651; *accord id.* 5659 & n.147.

[79] IPMRP Letter at C-94.

[80] *Id.*

approach, the question is to first identify the worst impaired days and then require pollution on those days be reduced.

EPA points back to the 2010 Urban-Focused Visibility Assessment, for justifying the 90th percentile. 88 Fed. Reg. at 5651; *see also id.* at 5659. But that document compared a completely different metric than the 24-hour average being considered now. It instead used an estimate of daily maximum daylight 1-hour PM_{10} light extinction value in each year, comparing the 90th percentile of that maximum to the 98th percentile of all hours in a day.[81] Here, EPA only points back to outdated and irrelevant analyses and thus has not rationally justified its use of the 90th percentile in this reconsideration.

2. EPA must set a protective secondary 24-hour standard

Poor visibility impacts humans in a variety of ways, including their productivity, and mental status. Clear causality between $PM_{2.5}$ air pollution and visibility impairment requires EPA to act. Previous reviews have set forth alternative secondary standards based on $PM_{2.5}$ filter-based speciated reconstructed light extinction. Setting the target level of protection from visibility impairment must be linked to its harm rather than be pre-defined by the viable monitoring metrics. It is appropriate to translate the target level to a measured air quality metric as long as the standard set is the measure of protection against the harm. If harm is defined as the visibility levels that a percentage of the population find acceptable/unacceptable then the best information we have using the contrast method is an average of 61 km visual range. It is fair then to look at all scenes available at this visual range and move from there to the dv or $\mu g/m^3$. Considering the information above, approximately 20 dv, or about 25 $\mu g/m^3$ would be an appropriate strengthening of the standard, whereas 35 $\mu g/m^3$ is unacceptable.

3. EPA fails to justify how the annual standard is sufficient to protect against any welfare impacts

As explained above, and as is clear throughout the proposal, $PM_{2.5}$ causes serious welfare harms and the 24-hour and annual standard work together to limit that pollution and the harms it causes, both on a chronic and a more acute basis. *E.g.*, 88 Fed. Reg. at 5655-56. Though harms to visibility stem most obviously from sub-daily or daily

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[81] *See* UFVA 4-4 to -6.

peak $PM_{2.5}$ levels, chronically elevated $PM_{2.5}$ still diminishes views.[82] Damage to materials and climate results from exposure to $PM_{2.5}$ over time, not merely (or even perhaps principally) on a daily basis. Accordingly, a current CASAC member and the IPMRP recommended EPA consider strengthening the annual standard to at least match the primary standard.[83]

Yet EPA's proposal is virtually silent on the annual $PM_{2.5}$ secondary standard. *See* 88 Fed. Reg. at 5561. The PA is, too. Likewise, EPA's final decision in 2020. Here, though, CASAC warned that "evidence to support a 15 µg/m^3 annual secondary standard needs to be provided."[84] EPA's unexplained failure to do so is arbitrary.

4. EPA illegally and arbitrarily refuses to identify the level requisite to protect against other important welfare harms

Although EPA's proposal explains that "the available evidence continues to support the conclusion that there is a causal relationship between PM deposition and materials effects," 88 Fed. Reg. at 5650, 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 in the PA 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 information to inform quantitative analyses assessing materials effects to inform consideration of a national PM standard on materials." *Id.* at 5654-55. Furthermore, we disagree with EPA's assertion that quantitative relationships have not been established for PM-related soiling and corrosion and frequency of cleaning or repair that further the understanding of the public welfare implications of materials effects. *Id.* at 5650. For example, there is evidence on the cost of soiling from air pollution (*e.g.*, Besson et al., 2017; Grøntoft et al., 2019), and while the studies were conducted outside the U.S., the materials studied are used in the U.S. and thus the results should be fully considered by EPA.

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[82] *See* EPA-HQ-OAR-2015-0072-0973 at 130 fig.1 (illustrating visibility impairment current annual secondary standard allows).

[83] IPMRP Letter at 5; CASAC Letter on PA at A-3.

[84] CASAC Letter on PA at 22.

- Besson *et al.* found that the effect of soiling on photovoltaic ("PV") systems negatively impacts their 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.[85]
- Grøntoft *et al.* estimated maintenance-cleaning costs, cost savings and cleaning interval increases for structural surfaces and windows in Europe obtainable by reducing air pollution. The study considered a hypothetical 50% reduction in air pollution to determine savings in these cleaning costs. The study further observed that the reduction in 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 cleaning cost savings are significantly higher than previously reported for the weathering of Portland limestone ornament and zinc monuments.[86]

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[85] P. Besson, et al., Long-Term Soiling Analysis for Three Photovoltaic Technologies in Santiago Region, IEEE Journal of Photovoltaics, 7 (6): 1755-1760 (2017), https://ieeexplore.ieee.org/abstract/document/8057771.

[86] 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), https://doi.org/10.3390/atmos10040167.

Additionally, EPA fails to provide a basis for many assertions in the proposal. For example, EPA proposes to conclude that it has "consider[ed] the evidence for PM-related impacts on climate and on materials and concludes that it is generally appropriate to retain the existing secondary standards." 88 Fed. Reg. at 5661. But there is nothing in the proposal that explains how the current standard is appropriate to protect materials from the effects of PM.

Moreover, the proposal asserts that "[w]hile some recent evidence on materials effects of PM is available in the 2019 ISA, EPA notes that this evidence is primarily from studies conducted outside of the U.S. in areas where PM concentrations in ambient air are higher than those observed in the U.S." *Id.* at 5661. The public cannot comment on this and EPA's other bald assertions[87] because EPA fails to provide references to the studies it refers to. EPA has not reasonably explained its do-nothing proposal: it must do more than share unsupported statements; its suggestion that it has exercised reasonable judgment does not make it so.[88] *Murray Energy*, 936 F.3d at 619 ("We defer to EPA's judgment that the available evidence is too uncertain only when the agency reasonably explains its decision.").

Finally, irreversible damage to the surface of materials and potentially higher degradation rates for polymeric materials, plastic, paint, and rubber due to increased oxidant concentrations and solar radiation were not considered in this proposal. In failing to propose a standard that covers materials and addresses the irreversible damage and higher degradation rates, EPA ignores the Act's requirement to set a standard that "specif[ies] a level of air quality requisite to protect the public welfare from any known or anticipated adverse effects." 42 U.S.C. § 7409(b)(2).

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[87] *See, e.g.*, 88 Fed. Reg. at 5657 (referring to "studies examining PM-related effects on the energy efficiency of solar panels and passive cooling building materials, though there remains insufficient evidence to establish quantitative relationships between PM in ambient air and these or other materials effects").

[88] *Id.* at 5662 ("In the Administrator's preliminary judgment, such a suite of secondary PM standards and the rationale supporting not revising the current standards are reasonably judged to reflect the appropriate consideration of the strength of the available evidence and other information and their associated uncertainties and the advice of CASAC.").

VII. AIR QUALITY MONITORING

A. EPA must amend its monitoring network requirements to ensure adequate monitoring of air pollution in at-risk communities, including communities of color and low-income communities

In general, EPA is correct to amend its regulations to make sure that more air quality monitors are placed in at-risk communities. *See* 88 Fed. Reg. at 5673-76, 5709 (proposed to be codified at 40 C.F.R. pt.58 app.D, § 4.7.1(b)(3)). Such an amendment will serve the purposes of the Clean Air Act, including environmental justice, because communities that face elevated levels of $PM_{2.5}$ due to their proximity to high-emitting sources will be less at risk of having their local conditions go unmonitored. *See supra* § V.A.3.iii (explaining how newly operating monitor in community that scores high on environmental justice factors is recording highest $PM_{2.5}$ concentrations in the Houston area thus far).

In taking final action, EPA must make various changes and clarifications to its proposal to have air quality monitoring networks better address at-risk communities. First, EPA must amend its proposed regulatory text, which currently reads, "For areas with additional required SLAMS, a monitoring station is to be sited in an at-risk community, particularly where there are anticipated effects from sources in the area (e.g., a major port, rail yard, airport, industrial area, or major transportation corridor)." 88 Fed. Reg. at 5709 (proposed to be codified at 40 C.F.R. pt.58 app.D, § 4.7.1(b)(3)). This language neither requires the monitor be sited in an area of poor air quality, nor for the monitor to be <u>actually</u> in an area that is anticipated to experience poor air quality from unspecified (and thus potentially relatively insignificant) sources in the area. It thus leaves open the possibility that, to meet this requirement, a regulator could site a monitor in an at-risk community that does not also have poor air quality. *Cf.* 40 C.F.R. pt.58 app.D, § 4.7.1(b)(3) ("For areas with additional required SLAMS, a monitoring station is to be sited in an area of poor air quality."). Notwithstanding its draft regulatory language, we do not believe that this was EPA's intent. But to eliminate this possibility, EPA should add a clear statement in the preamble to that effect and, especially, stronger regulatory language. For example, EPA could add the following to the regulatory text: "For areas with additional required SLAMS, a monitoring station is to be sited in an at-risk community <u>where air quality is expected to be poor and,</u>

especially, where there are anticipated effects from sources in the area (e.g., a major port, rail yard, airport, industrial area, or major transportation corridor)."

Second, EPA's preamble and regulatory language appear to be in tension regarding the areas to which its new proposed language would apply. EPA's preamble makes it seem like the new requirement would apply only to third monitors in MSAs with populations above 1 million. *See* 88 Fed. Reg. at 5674-75. And while it would apply to these monitors, portions of EPA's regulations that it does not propose to revise (and that it should not revise) delineate the precise numbers of required monitors and siting requirements for them, and, coupled with EPA's proposed language, indicate that the new requirement would apply in other situations, as well, just as the existing requirement does. EPA's regulations require two monitors in a metropolitan statistical area ("MSA") with a population of 500,000 to 1,000,000 with a design value within 85% of any $PM_{2.5}$ NAAQS. 40 C.F.R. pt.58 app.D tbl.D-5. For such an area, one monitor must be located "in an area of expected maximum concentration," but the second monitor is not required to be a near-road monitor. *Id.* § 4.7.1(b)(1)-(2). Instead, it currently must be "sited in an area of poor air quality" because it is "an additional required SLAMS" beyond those EPA's other siting requirements apply to. *Id.* § 4.7.1(b)(3) ("For areas with additional required SLAMS, a monitoring station is to be sited in an area of poor air quality."). EPA's proposed amendment applies in exactly the same circumstance: where there is "an additional required SLAMS" beyond those EPA's other siting requirements apply to. 88 Fed. Reg. at 5709 (proposed to be codified at 40 C.F.R. pt.58 app.D, § 4.7.1(b)(3)). EPA must clarify its final preamble to make it consistent with what its regulatory text actually requires.

Third, EPA should require—rather than just recommend—that the at-risk site use continuous federal equivalent methods ("FEMs"). *See* 88 Fed. Reg. at 5675. As EPA explains, continuous FEMs provide better, more actionable data, in the places it's especially necessary. *Id.* By contrast, federal reference method ("FRM") monitors may be operated as infrequently as every three—or even six—days. 40 C.F.R. § 58.12(d)(1)(i); *see also id.* § 58.12(d)(1)(ii). If such intermittent monitoring is an option for monitors required to be sited in at-risk communities, there is a serious risk that pollution levels will be elevated on days without monitoring and misleadingly depressed on days when the monitor operates.[89] Communities would thus be deprived of the benefit of the monitor. Continuous FEMS would mitigate this risk.

Fourth, EPA's proposed changes, though generally laudable, leave out many communities because they would have impacts only in larger metropolitan areas where pollution levels are already known to be at or near dangerous levels. There are many communities throughout the country that may very well have dangerously elevated $PM_{2.5}$ levels, but are not part of an MSA that EPA's rule applies to and/or that lack monitoring that a state or EPA would deem reliable enough to conclude that $PM_{2.5}$ levels are within 85% of a $PM_{2.5}$ NAAQS.[90] That EPA's changes would leave out these communities does not mean EPA should not finalize improvements to its proposal, but it does mean that EPA must make other changes to ensure that these communities know what levels of $PM_{2.5}$ pollution they are exposed to and ensure that, if those levels are unsafe, they get their dirty air cleaned up. To help do this, EPA should require states to ensure that at least some monitors located outside MSAs of the size the rule amendments cover are sited in at-risk communities, as well.

Fifth, consistent with the GAO reports cited above, EPA should extend its new siting requirement—that when the regulations require additional monitors, at least one monitor is located in an at-risk community where air quality is expected to be poor—to the monitoring network requirements for other standards, with such siting done in consultation with environmental justice communities, wherever possible, to advance environmental justice goals.

Sixth, more broadly, to more fully realize the goal of the NAAQS program, the monitoring network needs to be built out beyond what EPA proposes to require here. This would require more monitors in more locations with at-risk populations. EPA

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[89] *See* Eric Yongchen Zou, *Unwatched Pollution: The Effect of Intermittent Monitoring on Air Quality*, 111 Am. Econ. Rev. 2101 (2021), available in alternatively paginated version at https://static1.squarespace.com/static/56034c20e4b047f1e0c1bfca/t/603afc5c6607da3e67640175/1614478432535/monitor_zou_202101.pdf.

[90] *See* GAO, *Opportunities to Better Sustain and Modernize the National Air Quality Monitoring System*, at 38 (current monitoring "system is unable to meet needs for information on…air quality in rural areas"), 67-68 (similar, and addressing wood smoke); *accord* GAO, *Need Remains for Plan to Modernize Air Monitoring*, at 8.

should encourage states to do so and ensure that EPA's funds to support state-run monitoring are used to supplement state funding, not replace it. Proactive maintenance of regulatory monitors and verification that monitors are providing accurate information is also extremely important.

Finally, community engagement in monitor siting decisions is vitally important. EPA thus should make sure that states provide genuine opportunities for public involvement in monitoring siting (including providing notice in alternative languages, consistent with Title VI guidance) and that EPA's review of monitoring network plans provides opportunities for public involvement.

B. EPA should take steps to ensure that data resulting from new technologies for assessing real-world $PM_{2.5}$ pollution levels factors into regulatory decision-making that will reduce dangerous pollution levels

Incorporating new technologies for assessing real-world $PM_{2.5}$ pollution levels is a critical step toward national improvements in air quality. Regulatory air quality monitors are limited in number and often only monitor intermittently, resulting in both geographic and temporal gaps in monitoring—the existing network does not fully account for pollution hotspots and transient pollution events.[91] Though it is well established that, among other things, disparities in air quality render vulnerable communities significantly more at-risk of adverse health effects, *see, e.g.*, ISA at 2-1, monitoring gaps make it difficult to assess the actual number of people exposed to dangerous pollution and the true degree of disparity between population groups. As EPA recognizes, the capital investment and costs of operating FRM and FEM monitors for criteria pollutant measurements may be substantial. Further, when there is no regulatory acknowledgment of dangerous levels of $PM_{2.5}$ air pollution, there is no assurance that the harmful levels will be addressed on the Clean Air Act's required timelines, if they are addressed at all. Accordingly, EPA should employ supplemental technologies and systems to increase coverage of the regulatory monitoring network

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[91] *See, e.g.*, Genna Reed et al., Environmental Racism in the Heartland: Fighting for Equity and Health in Kansas City 4 (2021), https://www.ucsusa.org/sites/default/files/2021-11/ucs-mr-KC-10.21-Engl-web.pdf.

and obtain more complete data to further protect public health and address environmental injustice in air pollution exposure.

Emerging technologies and data sources create opportunities to strengthen and improve the existing monitoring network and the development of state implementation plans, including through siting decisions for regulatory monitors and determinations of nonattainment areas. They can also help identify when regulatory monitors may not be fully and accurately reporting air quality, allowing for timely improved reliability of regulatory monitoring data, and when regulatory monitors may miss episodes of elevated air pollution.[92] They also have helped shed light on the severity of disparities in air pollution exposures.[93] These technologies include satellites, low-cost sensors, models, and hybrid methodologies. Cumulatively, they support expanding the air quality monitoring paradigm from one based on "expensive, complex, stationary equipment, which limits who collects data, why data are collected, and how data are accessed" to a more widespread and accessible system that provides nearly real-time data.[94]

1. Advancements in satellite and sensor technologies offer EPA opportunities to supplement data from the existing monitoring network

i. Satellite-derived data

Satellite-derived atmospheric composition data is available for use in measuring air pollutant concentrations, including levels of $PM_{2.5}$ along with other air pollutants including nitrogen dioxide, sulfur dioxide, ammonia, carbon monoxide, and certain

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[92] *See* Paul English et al., *Performance of a Low-Cost Sensor Community Air Monitoring Network in Imperial County, CA*, 20 Sensors 3031, at 7, 9-10 (2020).

[93] Revesz, *Air Pollution and Environmental Justice*, at 200-01; *see also id.* 222-23.

[94] Emily G. Snyder et al., *The Changing Paradigm of Air Pollution Monitoring*, 47 Env't. Sci. & Tech. 11,369, 11,369 (2013).

volatile organic compounds.[95] These data are collected by numerous satellites using a variety of sensors, and launches of several additional satellites are already planned.[96]

All air quality monitoring technologies, including satellites, have inherent strengths and limitations. Researchers have noted caveats to satellite-derived data: that data accuracy depends in part on calibration with ground monitors; satellite outputs must be scaled to pollutants based on local conditions; and on cloudy, dusty, or smoky days, satellites are unable to measure ground level conditions at all.[97] For these reasons, satellite-derived data are most accurate over longer timescales, as averaging large quantities of the data can overcome many of the issues that would pose challenges if satellite data was used only on an hourly or daily basis.

Satellite-derived data present a unique opportunity to improve ground monitoring networks because their strengths and limitations are complementary to those of the existing ground monitoring network. As a result, they can create a more accurate and holistic monitoring network when employed in tandem with existing ground monitors. For example, the existing 1-in-3 or 1-in-6 day $PM_{2.5}$ FRM ground

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[95] Bryan N. Duncan et al., *Satellite Data of Atmospheric Pollution for U.S. Air Quality Applications: Examples of Applications, Summary of Data End-User Resources, Answers to FAQs, and Common Mistakes to Avoid*, 94 Atmospheric Envt. 647, 648 (2014); see also Laura Gladson et al., *Evaluating the Utility of High-Resolution Spatiotemporal Air Pollution Data in Estimating Local $PM_{2.5}$ Exposures in California from 2015-2018*, 13 Atmosphere 2022, 85, 86 (2022); Aaron Van Donkelaar et al., *Global Estimates of Fine Particulate Matter Using A Combined Geophysical-Statistical Method With Information From Satellites, Models, And Monitors*, 50 Env't Sci. & Tech. 3762, 3762-3772 (2016).

[96] *See* Nat'l Sci. & Tech. Council, *Air Quality Observation Systems in the United States*, app.H (2013), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/NSTC/air_quality_obs_2013.pdf; NASA, *Earth Science Mission Profile* (last revised Feb. 4, 2022), https://eospso.nasa.gov/files/mission_profile.pdf.

[97] Daniel M. Sullivan & Alan Krupnick, Using Satellite Data to Fill the Gaps in the US Air Pollution Monitoring Network 2, 10 (Res. for the Future, Working Paper 18-21, 2018), https://media.rff.org/documents/RFF20WP-18-21_0.pdf; *see also* 88 Fed. Reg. at 5679.

monitoring network, at its best, can provide accurate snapshots of site-level pollution concentrations but has limited temporal and geographic coverage. Conversely, satellite pollution sensing allows for higher temporal resolution and greater spatial coverage than ground monitors without the need for manual sampling, but at the cost of measurement precision and lost coverage during cloudy days.[98]

Other challenges associated with satellite-derived data can be overcome by combining the data with statistical methods and models. For example, statistical methods, such as land use regression and geographically weighted regression, have been used to improve the accuracy of $PM_{2.5}$ estimates derived from satellite data.[99]

In sum, incorporating satellite-derived data into regulatory decision-making can help identify areas where existing ground-based monitoring is lacking, whether temporally or spatially, and allow for better identification of pollution-burdened communities.

ii. Air sensor data

Low-cost sensors can also help fill in temporal and geographic monitoring gaps, provided that their implementation incorporates strategies both to maximize the accuracy of sensor networks and to prioritize the ability of environmental justice communities to obtain and use sensors. The term "low-cost sensors" is used to describe sensors with a maximum cost in the hundreds-of-dollars range (as opposed to thousands or tens of thousands of dollars for FRM or FEM monitors).[100] These sensors

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[98] Laura Gladson et al., *Evaluating the Utility of High-Resolution Spatiotemporal Air Pollution Data in Estimating Local $PM_{2.5}$ Exposures in California from 2015-2018*, 13 Atmosphere 2022, 85, 86 (2022).

[99] Aaron Van Donkelaar et al., *Global Estimates of Fine Particulate Matter Using a Combined Geophysical-Statistical Method with Information from Satellites, Models, and Monitors*, 50 Env't Sci. & Tech. 3762, 3762-3772 (2016).

[100] Presentation, Ron Williams, Air & Energy Research Program, EPA, *New Paradigm for Air Pollution Monitoring: 2014-2018 Progress Report* (Apr. 30, 2018), https://www.epa.gov/sites/production/files/2018-03/documents/final_em-3_master_slide_set.pdf.

are designed to operate at high temporal frequencies and, because of their low cost, can potentially be deployed in large numbers.[101] Many low-cost sensors can report data at one-second intervals, and some vendors, such as the PurpleAir network, are already providing coverage of broad swaths of the United States.[102]

Regarding concerns about the accuracy of sensor data, accuracy can be improved by calibrating sensors to FRM or FEM monitors and incorporating other sources of information. The potentially overwhelming amount of data produced by sensors may present an additional challenge to communities without the resources or expertise to analyze it. Cost is another concern, as the initial cost of the sensor alone is not indicative of the total cost of operation, which can include costs of Wi-Fi and servers. Accordingly, environmental justice considerations must be prioritized when incorporating air sensors into air monitoring plans.

Despite these potential challenges to incorporating air sensor data into regulatory decision-making, integrating sensors into the air quality monitoring framework presents a unique opportunity to supplement monitoring data through a low-cost technology that provides large-scale data to monitor and improve air quality nationwide.

2. EPA should address temporal gaps in monitoring by reducing the use of intermittent monitoring and using data from supplemental technologies to fill gaps

EPA currently requires $PM_{2.5}$ manual samplers generally to operate on a minimum of a 1-in-3-day basis. 40 C.F.R. § 58.12(d). However, operating schedules for manual $PM_{2.5}$ monitors may be reduced to a 1-in-6-day sampling frequency upon receipt of waiver from the EPA Regional Administrator. *Id.* Pollution levels have been

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[101] *Id*.

[102] *See* Real Time Map, PurpleAir, https://map.purpleair.com/1/mAQI/a10/p604800/cC0#3.35/37.53/-99.41.

found to increase on days when intermittent monitors do not operate, suggesting that temporal gaps in monitoring actually result in increased pollution.[103]

To address the temporal gaps in $PM_{2.5}$ monitoring, EPA should issue a plan to ultimately move all instruments to continuous monitoring. In the interim, EPA should eliminate the 1-in-6 day sampling waivers granted by EPA Regional Administrators and, to the extent such waivers are considered, provide an opportunity for public comment before such a waiver can be issued. Further, as discussed above, EPA should require the use of supplemental technologies such as satellites and sensors to assess whether missing air quality data from the regulatory monitoring network results in incomplete or biased data.

3. To fill gaps in the regulatory monitoring network, EPA should incorporate data from supplemental monitoring technologies and methods into its NAAQS attainment decisions

EPA should take data derived from satellites, low-cost sensors, and/or hybrid methodological approaches into account through a weight-of-the-evidence analysis when making NAAQS designations either when areas would otherwise be deemed "unclassifiable" or when data derived from supplemental technologies indicates nonattainment but FRM/FEM-data would permit an attainment designation. In addition, EPA should explore options for expanding the regulatory conceptualization of FEMs so that large-data approaches such as networks of low-cost sensors, satellite data, or model-measurement assimilations could qualify. Specifically, EPA should undertake a review of 40 C.F.R. Part 53 with the aim of designing protocols for designating large-data approaches as FEM.

Data from new monitoring technologies and hybrid modeling approaches has already shown how the current FRM and FEM approaches may not capture hotspots where pollution levels are higher than the NAAQS.[104] For instance, in an effort to

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[103] Eric Yongchen Zou, *Unwatched Pollution: The Effect of Intermittent Monitoring on Air Quality*, 111 Am. Econ. Rev. 2101 (2021).

[104] Ann E. Carlson, *The Clean Air Act's Blind Spot: Microclimates and Hotspot Pollution*, 65 UCLA L. REV. 1036, 1060-67 (2018). Hotspots are microclimates, which due to land use,

identify potential hotspots missed by regulatory monitoring, EDF and its partners mounted air pollution sensors on Google street view cars that were driven on every street and highway in a study region in Oakland, CA to collect nearly three million unique air quality measurements.[105] The study found that NO, NO_2, and black carbon concentrations could vary by a factor of 8 times or more within a single neighborhood or city block.[106] Notably, the median concentrations of these pollutants across the study area differed 32-60% when compared to measurements taken by a regional monitor in Oakland.[107]

Hotspots typically occur near roadways and in fenceline communities, exposing residents in these areas to potentially dangerous levels of unmonitored air pollution. Millions of people live near highly trafficked roadways[108]—especially in urban areas where "a large fraction of the population typically lives within 1.5-2 km of a freeway"[109]—and are likely to be exposed to elevated levels of multiple pollutants, including $PM_{2.5}$, NO, NO_2, and black carbon, from vehicle emissions.[110]

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geography, or the built environment have relatively high levels of air pollution. *Id.* at 1041.

[105] Joshua S. Apte et al., *High-resolution Air Pollution Mapping with Google Street View Cars: Exploiting Big Data*, 51 Envt. Sci. & Tech. 6999, 6999 (2017).

[106] *Id.* at 7003-04, 7006.

[107] *Id.* at 7006.

[108] A 2013 study found that about 11.3 million people live within 150 meters of a major highway. Tegan K. Boehmer et al., *Residential Proximity to Major Highways—United States, 2010, in* Centers for Disease Control & Prevention, CDC Health Disparities and Inequalities Report — United States, 2013, at 46-50 (2013), https://www.cdc.gov/mmwr/pdf/other/su6203.pdf.

[109] Wonsik Choi et al., *Prevalence of Wide Area Impacts Downwind of Freeways Under Pre-Sunrise Stable Atmospheric Conditions*, 62 Atmospheric Env't 318, 318, 326 (2012).

[110] *See* Health Effects Inst., *Traffic-Related Air Pollution: A Critical Review of the Literature on Emissions, Exposure, and Health Effects* 3-3 (2010) ("the highest direct exposures to

The Oakland study described above found that actual levels of NO, NO_2, and black carbon on busier streets and highways were substantially elevated compared to measurements taken by regulatory monitors, with median highway black carbon exceeding urban background levels by a factor of 2.7, NO by a factor of 4.8, and NO_2 by a factor of 1.8.[111] Pollutant concentrations on city-designated truck routes linking highways to industrial areas were 1.9-3.6 times higher than on other surface streets.[112] In addition, in a study of 41,000 Oakland residents, near-road elevated pollution levels were associated with an increased risk of heart attack, requiring heart surgery, and/or dying due to coronary heart disease.[113] Other studies have found near-road pollution to elevate the risk of asthma hospitalizations and emergency room visits.[114]

With leadership from resident led, community-based environmental justice organization West Oakland Environmental Indicators Project, data from the Oakland mobile monitoring campaign were utilized by West Oakland residents and the Bay Area Air Quality Management District to designate areas of West Oakland with elevated pollution as "impact zones" prioritized for exposure mitigation through the

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traffic-related emissions are likely to occur at the local scale, that is, in a vehicle traveling in traffic or on a roadside out to a few hundred meters.").

111 Apte et al., *High-resolution Air Pollution Mapping*, at 7004.

112 *Id.*

113 Stacy E. Alexeeff et al., *High-resolution Mapping of Traffic Related Air Pollution with Google Street View Cars and Incidence of Cardiovascular Events Within Neighborhoods in Oakland, CA*, 17 Env't Health (2018).

114 S. Alexeeff et al., *Google Street View Car Measurements of Traffic Related Air Pollution Within Neighborhoods and Asthma-Related Emergency Department Visits and Hospitalizations*, 3 Env't Epidemiology 406 (2019); *see also* Sarah E. Chambliss et al., *Local- and Regional-scale Racial and Ethnic Disparities in Air Pollution Determined by Long-term Mobile Monitoring*, 118 PNAS e2109249118 (2021) (detailing racial and ethnic disparities in air pollution exposure in parts of San Francisco Bay area).

West Oakland Community Action Plan, adopted by the California Air Resources Board in 2019.[115]

In addition, since 2019, the resident-led organization Achieving Community Tasks Successfully ("ACTS") has managed the operation of a community-designed and community-owned network of lower-cost air pollution sensors in the Pleasantville neighborhood of Houston, Texas. Pleasantville is a historically Black neighborhood impacted by multiple air pollution sources, including congested freeways, truck-attracting warehouses and manufacturing facilities, rail, cement facilities, and the Houston Ship Channel and Port of Houston. In 2021, data from the community-owned network was used to demonstrate in comments to the Texas Commission on Environmental Quality ("TCEQ") that average concentrations of $PM_{2.5}$ at sensitive locations in the Pleasantville neighborhood, including an elementary school, were consistently higher than concentrations measured at a sensor co-located with the nearest regulatory monitor, two miles from Pleasantville. This data supported successful advocacy by Pleasantville residents to place a new regulatory monitor in their neighborhood—TCEQ is working with ACTS leadership to site the regulatory monitor where the community requested, adjacent to Pleasantville elementary school. Deployment is anticipated in the fourth quarter of 2023.

Future data collected by community groups selected will likely provide local insights not captured by regulatory monitors. EPA should issue guidance as soon as possible to ensure that data collected consistent with this guidance, using new technologies and hybrid approaches, may factor into regulatory decision-making. For example, Appalachian Voices was awarded a grant from EPA to expand particulate matter monitoring work in communities impacted by coal mining and combustion and by other polluting industries across Kentucky, Pennsylvania, Virginia, West Virginia, and Tennessee, in collaboration with local grassroots groups. Rural communities in these states are often far from the nearest regulatory monitor. Data collected by EPA funding awardees could fill in the gaps between regulatory monitors and guide solutions to reduce dangerous pollution.

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[115] Owning Our Air: The West Oakland Community Action Plan – Volume 1 (2019), https://www.baaqmd.gov/~/media/files/ab617-community-health/west-oakland/100219-files/final-plan-vol-1-100219-pdf.

One particularly important application of large-data approaches is advancements in the identification and characterization of air pollution sources. Inverse modeling methods can help identify sources of air pollution. Running models backward to trace concentrations of air pollution to sources is inherently uncertain. Using multiple data inputs is a way to reduce that uncertainty and start to narrow down both locations of specific sources, and even actual emissions rates. EDF, working with partners in Salt Lake City, has a paper under review that demonstrates a method to identify the "exact" (down to 200 meters) location of an unknown source given many concentration data points around that source, plus meteorological data. With known source locations, it is believed that emissions rates can be estimated.

VIII. AIR QUALITY INDEX

We agree with EPA that the air quality index ("AQI") is an important tool for communicating to the public whether the air is healthful to breathe on any given day. *See* 88 Fed. Reg. at 5637-38. The AQI allows individuals to understand easily what threats they may face to their health and, if necessary, tailor their behavior accordingly.[116]

Thus, we further agree with EPA's proposal to require daily AQI reporting seven days a week. *See* 88 Fed. Reg. at 5563, 5642. As EPA cogently explains, technological advances make this not just possible to do but routinely done. *Id.* at 5642; *see also, e.g.*, https://www.airnow.gov/state/?name=texas (select "Historical Air Quality" and select any recent weekend day to see that AQI values were reported); https://www.airnow.gov/state/?name=new-york (same).

Similarly, EPA is correct to at the very least strongly recommend states to report the AQI sub-daily and submit hourly monitoring data, where the monitor supports it. 88 Fed. Reg. at 5642-43. EPA should strongly consider making such reporting and submission a requirement, given the importance to the public of the information and the lack of any obvious downside to such a requirement: by EPA's own statements, "the

[116] Of course, the fundamental promise and goal of the Clean Air Act is that <u>everyone</u>, even those who may be especially at risk of harmful effects from elevated air pollution levels, can go outside and engage in their everyday activities without facing such threats. *See supra* § II.

public has come to rely on" "near-real time AQI reporting," and "[m]any…air agencies" already do such reporting," both of which indicate that such reporting and submission is generally feasible. *Id.*

We recognize that there may be some individual air agencies that may lack resources to transition to such reporting. Recent statutes, however, have charged EPA with distributing grants to improve air quality monitoring, and EPA should consider how its recent and ongoing grant-making can fill such resource gaps, ease air agencies' paths forward, and thus improve a vital tool for the public. *See, e.g.*, https://www.epa.gov/inflation-reduction-act/delivering-cleaner-air; https://www.epa.gov/arp/direct-awards-arp-enhanced-air-quality-monitoring; EPA, Enhanced Air Quality Monitoring Direct Awards (Nov. 7, 2022), https://www.epa.gov/system/files/documents/2022-11/Enhanced%20Air%20Quality%20Monitoring%20Direct%20Awards%2011-02-2022.pdf.

IX. OTHER ISSUES

EPA's proposal raises several issues that are not legally relevant to the rulemaking. We comment on several of them nonetheless.

A. EPA must expeditiously conclude this reconsideration with final action

As explained below, strengthening the $PM_{2.5}$ standards will be hugely beneficial, with the benefits vastly outweighing the costs, which, again, are legally irrelevant. *See also supra* §§ II, V, VI (explaining EPA's legal obligations in setting standards and how strong the scientific basis is for strengthening the standards). The sooner EPA finalizes its action, the sooner those benefits can begin accruing. *See also infra* § IX.B (explaining why EPA must hasten the designations process and how it can do so).

We are aware polluters have made arguments about considering costs in deciding whether EPA should proceed with this reconsideration, pointing to the 2008 ozone NAAQS reconsideration. Several of our groups were deeply involved in that reconsideration. There is no basis whatsoever for a repetition of that experience.

As an initial matter, the polluters' argument is legally baseless. The sole factors relevant to EPA's decision in reviewing a NAAQS are health and welfare. EPA's decision to reconsider the PM standards was based on those—the sole relevant—

factors. Indeed, concerns about costs would provide no basis for the agency to undertake a review of standards. EPA's decision on reconsideration must also be based solely on health and welfare. There simply is no room here for consideration of costs.

We note also that the decision to terminate the 2008 ozone NAAQS reconsideration was never judicially reviewed. Instead, the D.C. Circuit dismissed a challenge to the termination decision on procedural grounds. Order, *American Lung Ass'n v. EPA*, No. 11-1396, at 2 (Feb. 17, 2012). Thus, the polluters' argument has never been judicially tested, much less confirmed.

Further, even if costs could be lawfully considered, the circumstances here are significantly different from the ones at play in the 2008 ozone NAAQS reconsideration process. For one, EPA's regular review of the ozone NAAQS had commenced about a year before EPA announced it was reconsidering the 2008 NAAQS. *See* 73 Fed. Reg. 56,581 (Sept. 29, 2008) (announcing initiation of regular review). That context was key—undergirding the first and second points the Office of Information and Regulatory Affairs "emphasize[d]" in explaining the 2011 decision to terminate the reconsideration. Letter from Cass Sunstein, Adm'r, Off. of Info. & Reg'y Affairs, to Lisa P. Jackson, Adm'r, EPA, at 1 (Sept. 2, 2011), https://www.reginfo.gov/public/return/EPA_Return_Letter_9-2-2011.pdf. Here, EPA has not initiated its review of the PM standards at issue. Not seeing this reconsideration through would result in substantial and pointless delay. That delay would profoundly harm people throughout this country, especially those who are especially at risk. There would be no justification for that.

Moreover, here, EPA still has before it several petitions for reconsideration of the 2020 NAAQS decision under § 7607(d)(7)(B). *E.g.*, EPA-HQ-OAR-2015-0072-1242 (health and environmental groups); EPA-HQ-OAR-2015-0072-1241 (states and municipalities). These petitions have now been pending for over two years old, and EPA is legally obligated to act on them "within a reasonable time." 5 U.S.C. § 555(b). Among the bases for these petitions was that EPA had failed to rationally consider studies that post-dated the January 2018 cut-off for inclusion of studies in the ISA and that EPA must reconsider the standard under § 7607(d)(7)(B). EPA-HQ-OAR-2015-0072-1242 at 7-11; EPA-HQ-OAR-2015-0072-1241 at 10-19. The review EPA has already done of such studies—finding they strengthen the evidence supporting the conclusion that stronger annual standards are warranted and that stronger 24-hour standards are at least reasonable to consider—confirms the merit of those reconsideration petitions under § 7607(d)(7)(B).[117] Under the Act, when there is a meritorious § 7607(d)(7)(B) reconsideration petition, EPA "shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed." 42 U.S.C. § 7607(d)(7)(B). That decisionmaking process leaves no room for consideration of costs. EPA should promptly grant the reconsideration petitions under § 7607(d)(7)(B) and announce that the instant reconsideration process constitutes its convening of the mandated reconsideration process.

B. EPA must hasten the designations process as much as possible

EPA's promulgation of nonattainment designations is necessary to trigger the Act's nonattainment provisions and bring about the attendant health and environmental benefits in areas with illegally elevated levels of $PM_{2.5}$ air pollution. *See* 88 Fed. Reg. at 5680-82, 5683-84. The Act prescribes the outer attainment deadlines for nonattainment areas: December 31 of six years after the calendar year air quality designations are made, which EPA interprets as the date such designations become effective. 42 U.S.C. § 7513(c)(1); *see* 40 C.F.R. § 51.1000.[118] Thus, if designations go into effect in January 2026, the backstop for polluted areas to come into attainment will be an entire year later than if designations go into effect in December 2025. Moving the backstop back would mean a year's delay in implementing stronger protections and thus an additional year of unnecessary health harms.

EPA must avoid such an outcome by ensuring that designations will take effect before the end of 2025, if not sooner. EPA has not just copious tools but also a statutory obligation to do so. Reflecting the importance of protecting public health, Congress mandated that EPA move the designations process along swiftly, authorizing EPA to direct states to submit recommended designations 4-12 months after EPA promulgates

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[117] We maintain as well that the other arguments in the petitions are meritorious and compel EPA to grant the petitions.

[118] EPA's regulations provide that an area's outer attainment deadline may advance, depending on the contents of its attainment plan. 40 C.F.R. § 51.1004(a)(1); *see also id.* § 51.1002(a).

a revised NAAQS, and directing EPA to promulgate final designations "as expeditiously as practicable." 42 U.S.C. § 7407(d)(1)(A), (B)(i).

EPA acknowledges the importance for "environmental justice" of "promptly issu[ing] designations in accordance with the statutory requirements to ensure expeditious public health protections for all populations, including those currently experiencing disparities in $PM_{2.5}$ exposures and $PM_{2.5}$-related health risk." 88 Fed. Reg. at 5681. EPA should demonstrate not merely that it "intends" to take this vital step, *id.*, but should act on that intent and bind itself to it. Accordingly, there are at least three steps EPA can and must take to protect public health and welfare by advancing the designations process quickly.

First is to sign the final rule as quickly as possible, and, ideally, no later than mid-September 2023. Such a signature date would put the default date-certain deadline for EPA's signature of final designations two years later, in mid-September 2025. *See* 42 U.S.C. § 7407(d)(1)(B)(i) ("Upon promulgation or revision of a national ambient air quality standard, the Administrator shall promulgate the designations of all areas…as expeditiously as practicable, but in no case later than 2 years from the date of promulgation of the new or revised national ambient air quality standard.").

An effective date in December 2025 should then be possible, even with the time that might be taken to have the designations published in the Federal Register and for the designations then to take effect. Of course, EPA could and should seek expedited publication in the Federal Register. *See* Off. of the Fed. Register, *Document Drafting Handbook* 8-4, 8-6 (Jan. 7, 2022) (agency can request emergency or immediate filing for public inspection and publication in the Federal Register of a document), https://www.archives.gov/files/federal-register/write/handbook/ddh.pdf. Notably, the Administrative Procedure Act's default of a 30-day effective date delay does not apply here because the Clean Air Act exempts designations from that provision of the Administrative Procedure Act. 42 U.S.C. § 7407(d)(2)(B) (5 U.S.C. § 553 does not apply to designations under 42 U.S.C. § 7407(d)(1)); *see* 5 U.S.C. § 553(d). But, if EPA insisted on such a delay, it could and should shorten that delay to the extent necessary to avoid losing a year's time in implementation. *See* 77 Fed. Reg. 34,221, 34,221 (June 11, 2012) (making certain initial nonattainment designations under 2008 ozone NAAQS effective in under 60 days from publication); *see also* 83 Fed. Reg. 25,776, 25,783 (June 4, 2018) (initial nonattainment designations under 2015 ozone NAAQS are not a "major rule" under the Congressional Review Act).

Second is for EPA to exercise its authority to require states to submit recommended designations sooner than a year after signature of the final standards. 42 U.S.C. § 7407(d)(1)(A). Doing so would ensure EPA has adequate time to review and make the modifications to the recommendations that it might deem necessary while still finalizing designations expeditiously, as the Act requires it to do. *Id.* § 7407(d)(1)(B).

Finally is for EPA to follow the legal command to promulgate final designations "as expeditiously as practicable." *Id.* § 7407(d)(1)(B)(i). EPA should ensure it does so by establishing a binding legal deadline for itself to sign those final nonattainment designations that is indeed as expeditiously as practicable and no later than mid-September 2025. *See id.* § 7601(a)(1) ("The Administrator is authorized to prescribe such regulations as are necessary to carry out his functions under this chapter.").

C. EPA must ensure the standards are properly implemented

Strengthened standards will result in more areas of the country being required to remedy unhealthy air. When an air agency seeking to carry out its legal obligations to clean the air needs resources and support to do its lawful work effectively, to the extent EPA can, we encourage it to provide the necessary resources and support. If additional assistance beyond what EPA can provide is necessary, we urge EPA to help the air agency in obtaining them.

Other air agencies have been more recalcitrant and have failed to timely implement all the measures they know can and must be used to improve air quality. For example, the San Joaquin Valley Air Pollution Control District, in California, has repeatedly refused for years to implement known measures that would reduce the extremely high $PM_{2.5}$ levels in the area, only eventually to take the steps it previously claimed were infeasible. *E.g.*, Letter from Tom Frantz, Ass'n of Irritated Residents, et al. to Michael S. Regan, Adm'r, EPA, attach.A at 2, attach.C at 9 (May 18, 2022). The San Joaquin Valley has repeatedly failed to attain the 1997 annual standard, has the highest annual design value of any area of the country, and also violates the 24-hour standard. *Id.* attach.C at 89; EPA, $PM_{2.5}$ Design Values, 2021, tbls.1a, 1b, 1c, 2a. The San Joaquin Valley's population is disproportionately low-income, high-poverty, and Latino compared with California's. Letter from Frantz et al. to Regan, attach.C at 94-95. EPA must timely exercise oversight over the regulators who do not effectively carry out their legal responsibilities to timely implement the NAAQS. Such failings severely burden the health and well-being of residents, and they are counting on EPA to remedy past injustice by swiftly finalizing stronger standards and ensuring they are rapidly and effectively implemented.

D. EPA cannot lawfully include a grandfathering provision in its final action

EPA correctly recognizes that, after the new standards go into effect, the Clean Air Act requires that a preconstruction prevention of significant deterioration permit cannot issue without a demonstration that the new or modified source of $PM_{2.5}$ will not cause or contribute to violations of the new standards, 88 Fed. Reg. at 5685-86. 42 U.S.C. § 7475(a)(3); *see Murray Energy*, 936 F.3d at 625-27. Though EPA may have included a grandfathering provision in a prior iteration of its PM NAAQS, the legal bar on including one here still applies. *Murray Energy*, 936 F.3d at 626-27; *see also* 88 Fed. Reg. at 5686 n.200.

E. Impacts from concerns touching on issues like exceptional events must be addressed only in implementing stronger standards

Any concerns touching on exceptional events or similar programs, such as prescribed burns, relate solely to implementing the standard and thus are irrelevant to the standard-setting process. Moreover, however beneficial to ecosystems prescribed burns might be, concerns over such an implementation issue (or any other) must not affect anything—substantive or timing-wise—about setting health or welfare standards under the Clean Air Act. Emissions that result from prescribed burns can still harm human health and the welfare considerations protected by secondary standards. People have the right to know whether the air they are breathing is harmful.

1. EPA may not consider background emissions levels, including from wildfires and international man-made sources, when setting NAAQS

As discussed earlier in these comments, it is well established that the only lawful consideration in setting NAAQS is the effect of the pollutant in the ambient air on health and welfare—not the cost or feasibility of implementing the standard, or any other implementation-related concern. *See supra* §§ II.B.3, VI.A. Indeed, the courts have already heard and rejected precisely an argument that background ozone pollution levels—including from wildfires—could lawfully be considered in the standard-setting process. *Murray Energy*, 936 F.3d at 622-24 (citing "wildfire" as an example of "background" ozone pollution and holding "the Clean Air Act prohibits EPA from adjusting for background ozone in setting the NAAQS"); *see* Industry Pet'rs' Final Joint Opening Br. at 23, 2016 WL 5390603 (using wildfires as example of contributor to background ozone pollution levels). Allowing the standard to be weakened on account of background ozone pollution "would mean that, if the level of background ozone in any part of the country exceeds the level of ozone that is 'requisite to protect the public health,' EPA must set the NAAQS at the higher, unhealthy level," an outcome that could not be squared with the statute's command that the standard be "requisite to protect the public health" or longstanding precedent interpreting it. *Murray Energy*, 936 F.3d at 623-24. Even though the pollutant at issue here is different, the legal analysis is not: EPA may not somehow make room for these emissions when setting NAAQS.

Notably, in rejecting the background ozone arguments, it was immaterial to the *Murray Energy* court whether the legally irrelevant considerations arose from international or domestic emissions, or from man-made or natural sources. The court recognized that all these considerations were <u>implementation</u> concerns, and therefore legally improper concerns during EPA's <u>standard-setting</u> process. Responding to (hyperbolic) arguments by petitioners that "the presence of background ozone will make it impossible to achieve attainment," the court noted that "rather than watering down the nationally applicable standards" during the <u>standard-setting</u> process, Congress had designed a series of <u>implementation</u> flexibilities and responses, in the form of three statutory programs: (1) the "Exceptional Event" program; (2) the "International Transport" program; and (3) the "Rural Transport" program. *Murray Energy*, 936 F.3d at 623. The last does not apply for $PM_{2.5}$, but the rest, as well as additional programs, do. The court rightly observed that "[t]hese provisions make little sense under Petitioners' reading of the Act," concerning background ozone levels. *Id.* State Petitioners had argued that "it is more difficult to meet the terms of these exceptions than EPA asserts," *id.*, but the court found this argument unavailing, holding that "the fact remains that Congress decided that EPA should account for background ozone during enforcement, not when setting standards." *Id.*

2. EPA's proposal properly rejects considering prescribed fires during standard setting

As part of its 2023 rulemaking process, EPA properly concludes that the lawful way to address any impacts of prescribed fires on NAAQS attainment is through the Act's implementation programs, not through the health- and welfare-standard setting process in the instant rulemaking: "such issues are outside the scope of this proposal," and "these topics may arise in the context of implementation of any revised $PM_{2.5}$ NAAQS." 88 Fed. Reg. at 5570. As with previous rulemakings, EPA appropriately acknowledges and directs such concerns to the exceptional events rule. That rule is the proper venue for implementation matters related to prescribed fires and, "EPA is not proposing changes to implementation as part of this proposal." 88 Fed. Reg. at 5570.

The Act authorizes EPA to regulate how and when air monitoring data showing an exceedance or violation of the NAAQS that is clearly caused by an exceptional event may be excluded from regulatory attainment determinations. 42 U.S.C. 7619(b). The Act defines an "exceptional event" as an event that "(i) affects air quality; (ii) is not reasonably controllable or preventable; (iii) is an event caused by human activity that is unlikely to recur at a particular location or a natural event; and (iv) is determined by the Administrator through the process established in the regulations promulgated under paragraph (2) to be an exceptional event." *Id.* § 7619(b)(1)(A). EPA has twice issued regulations to implement its authority, and in both its 2007 and its superseding 2016 regulations, it specifically allowed prescribed fires to qualify[119] as exceptional events. 80 Fed. Reg. 68,216, 68,251-56 (Oct. 3, 2016); 72 Fed. Reg. 13,560, 13,566-67 (Mar. 22, 2007); *see* 40 C.F.R. § 50.14(b)(3) (current regulation). This program thus provides a pathway to address concerns about how prescribed burns affect attainment and nonattainment designations. That program offers the appropriate process, not this rulemaking.

[119] We say "qualify" because an "exceptional event" only exists under the Act and EPA's implementing regulations if the event is linked to elevated ambient pollution levels. *See* 42 U.S.C. § 7619(b)(1)(A)(iv), (3)(B)(ii); 40 C.F.R. § 50.1(j). Because whether emissions from a prescribed fire matter for regulatory purposes cannot be known in advance—and ideally they will not matter for regulatory purposes because ambient levels remain low—a prescribed fire can only qualify to later become an exceptional event.

Regarding the concerns of how wildfire and prescribed wildfire will impact NAAQS attainment designations, the proposal notes "EPA has already issued guidance addressing development of exceptional events demonstrations for both wildfire and prescribed fires on wildland." *Id.* at 5682. EPA acknowledges that prescribed fire is a valuable tool for managing fire-dependent ecosystems in order to reduce the frequency and magnitude of wildfires due to climate change by way of reducing fuel load. *Id.* at 5570. And EPA reiterates that "[t]hough such issues are outside the scope of this proposal, the EPA acknowledges that these topics may arise in the context of implementation of any revised $PM_{2.5}$ NAAQS and intends to work with stakeholders to address these issues." *Id.*

Elsewhere, the proposal notes:

> Under the 2016 Exceptional Events Rule, an air agency may submit to the EPA a demonstration with supporting information and analyses for each monitor and day the air agency claims should be excluded from design value calculations for regulatory purposes. The EPA has provided a number of tools to assist air agencies in preparing their demonstrations and will continue to work with air agencies as they identify, prepare and submit exceptional events demonstrations.

Id. at 5681 (footnote and citation omitted). Rules like the exceptional events rule that address implementation are the appropriate avenue to take up issues related to attainment of $PM_{2.5}$ health and welfare standards and the practice of prescribed fire.[120] The standard-setting process is an inappropriate and indeed unlawful avenue.

3. EPA must decline any suggestion, from federal departments or agencies or any other parties, that EPA may consider prescribed fires when setting $PM_{2.5}$ health and welfare standards

The docket for the instant rulemaking contains an undated four-page document that appears to have been authored by the Department of Interior's ("DOI") Office of Wildland Fire. *See* EPA-HQ-OAR-2015-0072-1627 (attach.1) ("DOI Comments"). In

[120] Other Clean Air Act implementation programs, like general conformity, also make allowances for prescribed fire. *E.g.*, 40 C.F.R. § 93.153(i)(2).

context, it is evident that DOI submitted the comments to EPA, via OMB, during the inter-agency review process concerning the draft proposal. The DOI "request[ed] a dialogue" with EPA concerning its comments. DOI Comments, at 1. This material is doubly irrelevant here. First, it is not part of the record for purposes of judicial review (and we do not attach or otherwise incorporate it herein). *See* 42 U.S.C. § 7607(d)(1)(A) (NAAQS revisions are subject to special rulemaking provisions of § 7607(d)), (d)(4)(B)(ii) (requiring interagency review materials to be placed in the docket), (d)(7)(A) (excluding interagency review materials from the record for judicial review).

Second, those comments pertain to and rely on implementation issues and discussions. The comments point to EPA discussions related to implementation topics in EPA's 2016 rule regarding $PM_{2.5}$ NAAQS implementation and in EPA's 2015 ozone NAAQS rule, which also discussed topics concerning transportation and general conformity, and the interstate and international transport of air pollution. The comments assert that the portions of those rules DOI cites are merely "primarily related to rule implementation," and thus DOI professes its misguided belief that those implementation rules and concerns somehow pertain to standard setting. *See* DOI Comments at 1-2 (internal citations omitted). DOI further urges EPA to consider implementation issues, including materials not contained in the "Policy Analysis [*sic*] or Integrated Science Assessment," contending without basis that this rulemaking has somehow been rushed. *Id.* at 1. DOI also notes it "supports clean air efforts for the protection of public health as well as our firefighters that respond to wildfires." *Id.* at 1.

The DOI comments wrongly claim the citations to the two earlier EPA rules were "primarily related to rule implementation." *Id.* The passages in the two EPA rules that the DOI comments referenced are entirely related to rule implementation, namely, implementation of the $PM_{2.5}$ and ozone NAAQS, respectively—not setting primary or secondary standards for $PM_{2.5}$ or ozone under the NAAQS program. Indeed, in the 2015 final rule for the ozone NAAQS cited in the DOI comments, it is clear that EPA included the referenced discussions as background for understanding future implementation of the newly revised ozone standard, not as any factors that EPA did or could consider when setting NAAQS. *See, e.g.*, 80 Fed. Reg. 65,292, 65,434 (Oct. 26, 2015) ("This section provides background information for understanding the implications of the revised O_3 NAAQS and describes the EPA's plans for providing revised rules or additional guidance on some subjects in a timely manner to assist states with their implementation efforts under the requirements of the CAA" (emphasis added)). EPA did not and could not have, consistent with the Act and governing caselaw, taken into account implementation-related considerations when setting primary and secondary NAAQS. Thus, the DOI Comments are wrong to suggest that the cited passages were merely "primarily related to rule implementation."

Further, as explained above, the DOI Comments are mistaken that the "context" of those two earlier rules and the discussions in DOI's own comments "ha[ve] far broader applicability, including the setting of an implementable standard and a wide range of associated context." DOI Comments at 2 (emphasis added). The DOI Comments do not attempt to justify this incorrect and unlawful suggestion. The plain language of the Clean Air Act, the court decisions in *Whitman* and *Murray Energy*, and over five decades of consistent EPA practice all contradict the suggestion. *Whitman*, 531 U.S. at 465; *Murray Energy*, 936 F.3d at 623.

Similarly, nor is there any lawful basis for EPA here to consider materials outside the Policy Assessment and Integrated Science Assessment that pertain to implementation. As discussed herein, the DOI Comments are mistaken in the belief that such information is a relevant or permissible consideration when EPA sets primary and secondary NAAQS.[121] None of the implementation-related topics listed in the DOI

[121] The DOI Comments are further out-of-bounds in claiming that there was any "compressed review period" for the draft rulemaking proposal. DOI Comments at 1-2. Indeed, DOI's request for further "dialogue" with EPA—to raise issues that are unlawful and impermissible considerations during standard-setting—itself caused significant delays in signature and publication of a vital public health rulemaking. *See id.* at 1.

The DOI Comments are similarly wrong in alleging that EPA is engaging in an "an off-cycle review of NAAQs [*sic*]." *Id.* at 2. On January 20, 2021, President Biden's "Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis" directed all departments and agencies "to immediately review and, as appropriate and consistent with applicable law, take action to address the promulgation of Federal regulations and other actions during the last 4 years" of the then-Trump administration that conflicted with the Biden-Harris administration's commitment to public health, the environment, and environmental justice. Exec. Order 13,990, § 1, 88 Fed. Reg. 7037, 7037 (Jan. 25, 2021). And, as the proposal notes, "[a]n

Comments is a permissible consideration when EPA sets standards that honestly, and in an enforceable manner, determine how much $PM_{2.5}$ air pollution is unsafe for people to breathe on an annual and daily basis, and how much $PM_{2.5}$ pollution harms the public welfare.

The *Murray Energy* ruling anticipates and rejects the arguments in the DOI Comments that the EPA Administrator can or should consider emissions from prescribed fires that contribute to background pollution levels or themselves cause monitored violations of a NAAQS: "the fact remains that Congress decided that EPA should account for background ozone during enforcement, not when setting standards." 936 F.3d at 623. And the reason for this is the same as the court's rationale for rejecting the arguments of Industry and State Petitioners in that case. Paraphrasing the decision's holding: accepting that argument would mean that, if the level of background $PM_{2.5}$ in any part of the country exceeds the level of $PM_{2.5}$ that is "requisite to protect the public health," "EPA must set the NAAQS at the higher, unhealthy level." *Id.* This outcome both harms public health and violates the Clean Air Act. EPA must continue to decline appeals to do so.

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accompanying fact sheet provided a non-exclusive list of agency actions that agency heads should review in accordance with that order, including the 2020 Particulate Matter NAAQS Decision." 88 Fed. Reg. at 5567. DOI knew that during the inter-agency review period. The White House understands that it is in the public's interest to reconsider completion of a $PM_{2.5}$ NAAQS review by the Trump EPA Administrator that ignored clear medical evidence and health hazards, and ended with the conclusion that it was appropriate to maintain unsafe $PM_{2.5}$ health and welfare standards for Americans. EPA is undertaking the current $PM_{2.5}$ NAAQS rulemaking using a long-established procedure for reconsidering administrative rules, when justified; indeed, the Department of Interior has used this administrative tool itself. Charging falsely that EPA is engaged in an "off-cycle review of NAAQS," in the course of advancing unlawful arguments, does a disservice to the Department and the public.

F. Even accounting for costs, stronger standards will be an immense benefit for the United States

In proposing to revise the primary standards, EPA developed a Regulatory Impact Analysis to evaluate the incremental costs and benefits of meeting the alternative $PM_{2.5}$ standards. Although the Clean Air Act prohibits EPA from considering costs in actually setting the NAAQS,[122] the RIA presents estimates of the incremental costs and benefits of meeting the proposed $PM_{2.5}$ NAAQS relative to meeting the existing standards in 2032, when EPA assumed moderate nonattainment areas under any proposed NAAQS would likely have to attain the standard.[123] To evaluate the costs of meeting the proposed alternative standards relative to existing $PM_{2.5}$ NAAQS, EPA first developed a future-year emissions inventory reflecting effects of finalized rules and other factors in 2032.[124] EPA then conducted a multistep modeling analysis to estimate the emissions reductions and associated costs of various control strategies that would be needed to meet the proposed new standards relative to the existing $PM_{2.5}$ NAAQS.[125] EPA then compared those projected, incremental compliance costs to the human health and economic benefits (or avoided adverse health and economic costs) associated with meeting the proposed, alternative standards.[126] The RIA demonstrates that stronger standards than those EPA proposed would easily pass any cost-benefit test. Indeed, the costs are likely overestimated, and polluters' dire warnings about projected costs echo prior warnings that have not proven true and thus should be discounted now.

1. The benefits of stronger standards vastly outweigh the costs

While the Clean Air Act and Supreme Court precedent make clear that EPA cannot consider costs in setting the NAAQS, the benefits of reducing $PM_{2.5}$ concentrations as a result of revising the standards far outweigh the costs of

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[122] *Whitman*, 531 U.S. at 471 ("the CAA as a whole, unambiguously bars cost considerations from the NAAQS-setting process").

[123] RIA at ES-2, 2-1.

[124] *Id*. at ES-3.

[125] *Id*. at ES-4; 2-1 to -2.

[126] *Id*. at ES-14 to -15.

implementation. Historically, the monetized value of reducing ambient concentrations of $PM_{2.5}$ has been particularly large due to the associated health benefits, especially of averted premature mortality. In a study of the benefits and costs of the Clean Air Act from 1990 to 2020, EPA noted that, for the Clean Air Act Amendments of 1990, "a very high percentage of the benefits is attributable to reduced premature mortality associated with reductions in ambient particulate matter and ozone"[127] and more specifically that "$1.7 trillion of the $2.0 trillion total benefit estimate in 2020, or 85 percent, is attributable to reductions in premature mortality associated with reductions in ambient particulate matter."[128]

The emissions reduced by control strategies identified by EPA in the RIA to achieve an annual standard of 8 $\mu g/m^3$ amount to quantified and monetized benefits of either $46 billion or $95 billion in 2032 (depending on the hazard ratio used), compared to costs of $1.8 billion. RIA at 5-35 tbl.5-6, 8-3. Therefore, net benefits would be either $44 billion or $93 billion. *Id.* at ES-26 tbl.ES-10. The benefits of control strategies assessed by EPA for achieving an annual standard of 8 $\mu g/m^3$ include avoiding up to 9,200 premature mortalities, up to 580,000 lost work days, 1.6 million cases of asthma symptoms, 4,100 emergency room visits, and 3.4 million days of restricted activities. RIA at 5-34 tbl.5-5. It is also worth noting that the cost estimate in EPA's RIA is likely a significant overestimate, as discussed further in §§ IX.F.2-3.

Furthermore, if all areas actually achieve an annual primary $PM_{2.5}$ NAAQS of 8 $\mu g/m^3$ through ways beyond the control strategies identified by EPA, the RIA estimates that this would result in avoiding 15,000 mortalities, 1 million lost work days, 2.9 million cases of asthma symptoms, 7,000 emergency room visits, and 5.9 million restricted activity days. RIA at 5A-3 tbl.5A-1. The value of these benefits could exceed $160 billion. *Id.* at 5A-6 tbl.5A-4.

Several other studies support the conclusion that stronger standards will be an economic benefit:

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[127] EPA, *The Benefits and Costs of the Clean Air Act from 1990 to 2020*, at 7-7 (2011), https://www.epa.gov/sites/default/files/2015-07/documents/fullreport_rev_a.pdf.

[128] *Id.* at 7-3.

- Lauri Myllyvirta, Centre for Research on Energy and Clean Air, *Quantifying the Economic Costs of Air Pollution from Fossil Fuels* (2020), https://energyandcleanair.org/wp/wp-content/uploads/2020/02/Cost-of-fossil-fuels-briefing.pdf.
- Antoine Dechezleprêtre et al., *The Economic Cost of Air Pollution: Evidence From Europe* (OECD Economics Department Working Papers, No. 1584, 2019), doi:10.1787/56119490-en.
- Peter Tschofen et al., *Fine Particulate Matter Damages and Value Added in the US Economy*, 116 PNAS 19,857 (2019), doi:10.1073/pnas.1905030116
- Victor Lavy et al., *The Impact of Short Term Exposure to Ambient Air Pollution on Cognitive Performance and Human Capital Formation* (National Bureau of Economic Research Working Paper 20648, 2014), http://www.nber.org/papers/w20648.

Finally, even if costs were lawful to consider, the draft RIA makes clear that the net benefits are greatest for the strongest standards analyzed (8 $\mu g/m^3$ (annual), with no change to the 24-hour standard). RIA at ES-26 tbl.ES-10. For no analyzed standard combination would there be a negative net benefit, and, with the exception of the 10/35 and 10/30 combination, there is no overlap in the range of projected net benefits. *Id.* Thus, cost-benefit analysis here would favor <u>stronger</u> standards, not weaker ones. *See* Michael A. Livermore & Richard L. Revesz, *Rethinking Health-Based Environmental Standards*, 89 N.Y.U. L. Rev. 1184, 1188-89, 1236-1246, 1258-66 (2014).

2. Existing and proposed EPA rules, in addition to significant changes in federal tax law and funding provisions, will likely make compliance with the particulate matter NAAQS easier than EPA assumed

Although EPA's analysis already indicates that any of the proposed alternative standards would ultimately save billions of dollars in lost economic productivity, respiratory and cardiovascular illness costs, and premature mortality, the RIA almost certainly overestimates the costs of compliance with the proposed alternative standards. Indeed, the RIA overlooks a suite of existing and proposed EPA rules, in addition to significant changes in federal tax and appropriations, that will significantly reduce the local, state, and regional costs of compliance with any new PM standards.

First, the RIA does not account for a number of final EPA and state regulations that will continue the downward trend in particulate matter emissions, especially urban-scale particulate concentrations that tend to remain higher than surrounding areas.[129] In particular, the RIA does not account for EPA's recently-finalized regulations governing NOx from heavy-duty engines and vehicles.[130] EPA estimates that, by 2030, the final rule will result in the reduction of at least 115 tons of direct PM emissions, and more than 5,000 tons of VOCs and nearly 140,000 tons of NOx, thereby reducing secondary PM concentrations across the country.[131] By 2040, direct PM, VOC, and NOx reductions from heavy-duty engines will more than double as a result of the rule.[132] Given the significance of mobile source emissions for particulate matter concentrations, especially in urban areas,[133] those heavy-duty emission reductions are likely to reduce the cost of compliance with any of EPA's proposed PM NAAQS alternatives.

The RIA similarly excludes consideration of likely particulate matter reductions under EPA's Revised 2023 and Later Model Year Light-Duty Vehicle Greenhouse Gas Emissions Standards, 86 Fed. Reg. 74,434 (Dec. 30, 2021), and the Federal Implementation Plan for Managing Emissions from Oil and Natural Gas Sources on Indian Country Lands in Utah, 87 Fed. Reg. 75,334 (Dec. 8, 2022), each of which is expected to result in reductions of thousands of tons of direct and precursor particulate matter emissions. The RIA suggests that the impacts of these two rules are "likely to be small,"[134] but EPA does not explain why that is the case, especially given the significant role that mobile sources play in urban particulate matter concentrations,[135] and that

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[129] RIA at ES-4 n.2.

[130] 88 Fed. Reg. 4296 (Jan. 24, 2023).

[131] *Id*. at 4418 tbl.VI-1.

[132] *Id*.

[133] *See, e.g.*, ISA at 2-9 to 2-12 & fig.2-3 (explaining that heavy-duty vehicles are responsible for between 4-11% of primary $PM_{2.5}$ emissions in several urban areas).

[134] RIA at 2-15 n.4.

[135] ISA at 2-9 to 2-12 & fig.2-3.

areas of the western United States, including the Salt Lake Valley, Utah, experience some of the "highest $PM_{2.5}$ concentrations in the country."[136]

The RIA likewise excludes consideration of California's Advanced Clean Cars regulations, which will rapidly scale down emissions of light-duty passenger cars, pickup trucks and SUVs starting with the 2026 model year through 2035.[137] The regulations are two-pronged. First, the new regulations amend the state's zero-emission vehicle regulation to require an increasing number of zero-emission vehicles, and relies on currently available advanced vehicle technologies, including battery-electric, hydrogen fuel cell electric and plug-in hybrid electric-vehicles, to meet air quality and climate change emissions standards. Second, the low-emission vehicle regulations were amended to include increasingly stringent standards for gasoline cars and heavier passenger trucks to continue to reduce smog-forming emissions. California estimates that the revised regulations will result in hundreds of tons of reduced direct $PM_{2.5}$ emissions annually, and likely significant secondary $PM_{2.5}$ emission reductions as a result of direct NO_X reductions.[138] The California regulations will almost certainly reduce the costs of compliance with any strengthened $PM_{2.5}$ NAAQS, especially given that, at least for the 10/35 analytical option, the "majority" of EPA's assumed compliance costs "are incurred in California because 15 of the 24 counties that need emissions reductions are located in California."[139]

Second, in addition to excluding the likely $PM_{2.5}$ reductions associated with final federal and state rules, the RIA does not include the substantial $PM_{2.5}$ reductions likely to result from a number of proposed and impending rules, some of which have now been finalized, rendering the costs even more conservative. Relevant matters include:

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[136] RIA at 2-6.

[137] *See generally* https://ww2.arb.ca.gov/rulemaking/2022/advanced-clean-cars-ii (to be codified at Title 13, CCR, Chapter 1, Section 1900 *et seq*.).

[138] *See* Final Statement of Reasons for Rulemaking, Including Summary of Comments and Agency Response, Appendix F Updated Costs and Benefits Analysis, at 8-10 (Cal. Air Res. Bd. Agenda Item No.: 22-10-1 Aug. 25, 2022), *available at* https://ww2.arb.ca.gov/sites/default/files/barcu/regact/2022/accii/fsorappf.pdf.

[139] RIA at ES-14.

- EPA's Federal Implementation Plan Addressing Regional Ozone Transport for the 2015 Ozone National Ambient Air Quality Standards, proposed 87 Fed. Reg. 20,036 (Apr. 6, 2022), final version titled "Federal 'Good Neighbor Plan' for the 2015 Ozone National Ambient Air Quality Standards," signed March 15, 2023, prepublication version available at https://www.epa.gov/system/files/documents/2023-03/FRL%208670-02-OAR_Good%20Neighbor_Final_20230314_Signature_ADMIN%20%281%29.pdf. The final version of the Good Neighbor Rule addresses 23 states, requiring nitrogen oxide emission budgets for electric generating units ("EGUs") in 22 states, and non-EGU sources in 20 states, with reductions for EGUs beginning in the 2023 ozone season. EPA estimates that the final rule would reduce direct $PM_{2.5}$ emission from the EGU sector by approximately 1,000 tons per year, and reduce overall $PM_{2.5}$ precursor emissions of SO_2 and NO_X.[140]
- EPA's National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units – Revocation of the 2020 Reconsideration, and Affirmation of the Appropriate and Necessary Supplemental Finding (signed Feb. 15, 2023).[141] Under the rule, EPA reaffirmed the scientific, economic, and legal underpinnings of the 2012 Mercury and Air Toxics Standards ("MATS") Rule for power plants. Although the February 2023 rule does not itself require additional emission reductions, EPA is reconsidering, under 42 U.S.C. § 7412(d)(6), its prior risk and technology review of the MATS Rule to determine whether to impose more stringent standards reflecting developments in technology. Any such review would likely result in additional PM reductions from the EGU sector.
- On June 22, 2021, EPA announced its intent to reconsider its 2020 final rule captioned, "Promulgation of Air Quality Implementation Plans; State of Texas; Regional Haze and Interstate Visibility Transport Federal

[140] Federal 'Good Neighbor Plan' for the 2015 Ozone National Ambient Air Quality Standards at 669-70 tbl.VIII-1.

[141] 88 Fed. Reg. 13,956 (Mar. 6, 2023).

Implementation Plan," 85 Fed. Reg. 49,170 (Aug. 12, 2020).[142] EPA adopted the 2020 emission trading rule in lieu of requiring Texas EGUs to install and operate source-specific "best available retrofit technology," or "BART," as EPA's previous 2017 proposal had contemplated. Under that 2017 proposal, 18 Texas EGUs would have been required to reduce SO_2 emissions by 90-95%, resulting in significant secondary $PM_{2.5}$ reductions.[143] Reconsideration and implementation of source-specific BART controls for Texas EGUs could result in significant PM reductions across the central United States, lowering the cost of compliance with EPA's proposed NAAQS.

- On March 8, 2023, EPA announced a proposed rulemaking to strengthen certain Clean Water Act discharge limitations for Steam Electric Power Generating point sources.[144] Although those Clean Water Act regulations do not directly reduce $PM_{2.5}$ air emissions, the existing regulations allow point sources to commit to retire by 2028, rather than retrofit to comply with the regulation,[145] and the proposed rule and direct final rule that EPA recently released would retain and extend the deadline to select that option.[146] And as reflected in the attached exhibit and EGU notices collected to date, for whatever combinations of reasons, numerous sources have already committed to cease burning coal in lieu of retrofitting wastewater discharge

[142] https://www.epa.gov/system/files/documents/2021-07/tx-rh-bart-fip-response-signed_1.pdf.

[143] 82 Fed. Reg. 912 (Jan. 4, 2017).

[144] EPA, Press Release, Biden-Harris Administration Proposes Stronger Limits on Water Pollution from Power Plants (Mar. 8, 2023), https://www.epa.gov/newsreleases/biden-harris-administration-proposes-stronger-limits-water-pollution-power-plants.

[145] 40 C.F.R. § 423.16(g).

[146] *See* Steam Electric Power Generating Effluent Guidelines – 2023 Proposed Rule (Mar. 8, 2023), https://www.epa.gov/eg/steam-electric-power-generating-effluent-guidelines-2023-proposed-rule.

systems.[147] Allowing point sources to opt to cease burning coal in lieu of retrofitting would result in additional decreased PM emissions and reduce the federal, state, and local costs of complying with the NAAQS.

- Similarly, in October 2020, EPA began reconsidering aspects of the Coal Combustion Residuals ("CCR") Rule, which requires existing coal ash disposal units to have synthetic liners to protect groundwater, or meet other technical specifications.[148] As with EPA's wastewater regulations, the CCR Rule does not directly reduce PM emissions from EGUs, but it does allow power plants to commit to cease burning coal by 2023 or 2028, depending on the size of the power plant's coal ash disposal unit.[149] And as with EPA's wastewater regulations, discussed above, for whatever combinations of reasons, several EGUs have opted to cease burning coal in lieu of retrofitting. Revisions to the CCR Rule, coupled with continuing to allow coal EGUs to opt to cease burning coal, would likely result in additional PM reductions,

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[147] *See* Exhibit 3. Under EPA's Clean Water Act regulations, EGUs opting to retire in lieu of retrofitting were required to submit to their state wastewater permitting authority a "notice of planned participation" in the so-called retirement subcategory. *See* 40 C.F.R. § 423.19(f)(1). We have endeavored in Exhibit 3 to create a complete list of EGUs that have thus far notified their permitting authorities of their planned intent to cease burning coal in lieu of retrofitting to comply with EPA's wastewater rules. Because permitting authorities are not required to post all such notices publicly, however, there may be additional notices not reflected on this list. EPA has also released a direct final rule that would extend the date for existing coal power plants to submit a notice of planned participation until 90 days from the date of publication in the Federal Register, so additional EGUs may also submit notices. Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category—Initial Notification Date Extension (Mar. 7, 2023), https://www.epa.gov/system/files/documents/2023-03/Prepublication FRN_OW_Steam Electric ELG_NOPP Extension_DFRM_03_07_2023_1.pdf.

[148] 85 Fed. Reg. 65,015 (Oct. 14, 2020).

[149] *See* 40 C.F.R. § 257.103(f)(2).

which would further reduce the overall cost of compliance with any revised PM NAAQS.

Third, in addition to overstating the cost of compliance with the $PM_{2.5}$ NAAQS by failing to account for the impact of final and impending rules that will independently result in PM reductions, an examination of EPA's emissions inventory assumptions indicates that the RIA likely overestimates future year EGU emissions by failing to account for actual or planned retirements. As reflected in the RIA, EPA's 2032 EGU emissions assumptions were developed using the agency's Summer 2021 version of the Integrated Planning Model ("IPM"), which, in turn, relies on the agency's National Electric Energy Data System ("NEEDS") database, "NEEDS v6 rev: 1-24-22."[150] Those modeling assumptions, however, are now outdated. On October 14, 2022, EPA released a new version of its NEEDS database, which represents existing EGUs and planned or likely EGU retirements through 2028, whereas EPA's previous, January 2022 NEEDS data reflected only planned retirements through 2023.[151] Comparing EPA's most-recent NEEDS database assumptions to those included in the RIA makes clear that numerous additional, fossil-fuel burning EGUs are now expected to retire before 2032, due to independent economic and environmental compliance factors. Indeed, EPA's most recent database indicates that, by 2028, nearly 400 more fossil-fuel, biomass, or landfill gas EGUs will retire than EPA's RIA assumes. Those retirements will result in significant local and regional PM reductions, thereby reducing the overall cost of PM NAAQS compliance.

It is worth pointing out that EPA's NEEDS database does not appear to account for all the planned EGU retirements linked to EPA's wastewater and CCR regulations, discussed above. Nor does the NEEDS database include EGU retirements beyond 2028, including planned retirements, EGUs that are required to convert from coal to burning gas, and retirements required by consent decrees. Each of those planned changes in operation will result in significant direct and secondary $PM_{2.5}$ reductions, both locally

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[150] RIA app.2A at 2A-2 & n.1; *see also id.* at 2-15.

[151] *Compare* NEEDS-v6_1-24-22, *available at* https://www.epa.gov/system/files/documents/2022-01/needs-v6_01-24-2022-2.xlsx, *with* NEEDS v621_10-14-2022, *available at* https://www.epa.gov/system/files/documents/2022-10/NEEDS%20v621_10-14-2022.xlsx.

and regionally, yet EPA's RIA does not take those into account when quantifying the cost of compliance with the PM NAAQS.

Finally, in addition to underestimating PM reductions likely to occur as a result of existing and proposed rules and planned retirements, the RIA does not incorporate the substantial direct and secondary particulate matter reductions likely to occur under the 2022 Inflation Reduction Act ("IRA"), and thus likely overestimates the direct costs of compliance with the revised $PM_{2.5}$ NAAQS. The IRA contains extensive direct federal funding and tax credits to utilities, municipalities, governmental agencies, tribal authorities, small business, and individuals for clean energy and efficiency investments, which will directly reduce PM pollution, in at least two key ways.

At the outset, the new law provides extensive tax credits and direct funding mechanisms for utilities, municipalities, and non-profit entities to invest in clean energy generation and infrastructure.[152] Those electric sector tax credits and federal funding provisions are expected to result in significant additions of zero-marginal cost clean energy resources to the electric system, which will likely displace generation from higher-cost, fossil fuel resources. Indeed, in organized energy markets, the system operator dispatches lowest-cost resources first, and higher-cost resources are dispatched only as needed to meet demand. One recent electric sector modeling analysis indicates that by 2030, the IRA will increase in the nation's renewable energy generation to 69-75% of the overall mix, displacing significant portions of the country's natural gas and

[152] *See, e.g.*, Inflation Reduction Act, Section 13102 (extension of existing Investment Tax Credit through December 31, 2024); Section 13701, 13702 (creating of a new Clean Electricity Production Tax Credit and Clean Electricity Investment Credit that takes effect on January 1, 2025); Section 13103 (increase in energy credit for solar facilities placed in service in connection with low-income communities); Section 13801 (Elective payment for energy property and electricity produced from renewable energy for tax-exempt entities, including state and local governments, tribes); Section 22001 ($1 billion appropriated for loans to fund renewable energy); Section 22002 (funding for renewable energy and efficiency investments in rural areas); Section 22004 (USDA direct assistance for rural electric cooperatives); Section 50145 (Tribal renewable energy loan program).

coal generation.[153] The substantial shift from fossil-fuel generation to non-emitting renewable resources under the IRA will result in a substantial decline in emissions of SO_2 and NO_X, pollutants that contribute to fine particulate matter. According to that same study, by 2030, the IRA's electric sector tax credits and funding mechanisms will result in a 37-63% decline in SO_2 emissions, and a 36-53% decline in NO_X emissions, from 2022 levels.[154] These changes will likewise substantially cut sulfate- and nitrate-based secondary $PM_{2.5}$ resulting from the electric sector, with serious health benefits.[155] Given the electric sector emission reductions expected under the IRA, the RIA likely overstates the costs of compliance with the updated $PM_{2.5}$ NAAQS.

In addition to electric sector particulate matter reductions, the IRA includes significant tax credits and direct funding for municipalities and governmental entities, tribal governments, small businesses, and individuals to invest in energy efficiency measures, electric vehicles, and electric appliances (*e.g.*, electric stoves, water heaters, dryers, and HVAC systems),[156] each of which will likely reduce direct and secondary particulate matter pollution, especially in urban areas where particulate levels remain stubbornly high.[157] As EPA's ISA indicates, commercial cooking sources, residential oil- and wood-burning heating systems, and light-duty vehicles are each significant sources of urban-scale particulate matter emissions; those sources account for up to 16%, 13%, and 10% of urban $PM_{2.5}$ emissions, respectively.[158] Other studies suggest that gas appliances are responsible for up to 321,000 tons per year of NO_X emissions, and

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[153] Nicholas Roy et al., *Beyond Clean Energy: The Financial Incidence and Health Effects of the IRA* (Resources for the Future Report 22-11, Oct. 2022), https://media.rff.org/documents/Report_22-11_v5.pdf.

[154] *Id*.

[155] *Id*.

[156] *See, e.g.*, Inflation Reduction Act §§ 13301-13304, 30002, 50122-50123, 50131.

[157] RIA at 2-9.

[158] ISA at 2-9 to 2-11 fig.2-3.

approximately 6,200 tons per year of direct particulate matter emissions.[159] After they are emitted from household appliances and heating systems, these NO_X emissions react in the atmosphere to contribute to ground-level smog and secondary particulate matter, primarily in urban areas.[160] The IRA's incentives for building and vehicle electrification will almost certainly reduce nitrate-based particulate matter in many urban areas across the country, thereby reducing costs of ensuring compliance with the standard in those areas. For its part, the RIA emphasizes what it sees as "need for control of local primary $PM_{2.5}$ sources to address the highest $PM_{2.5}$ concentrations in urban area."[161] While we agree that urban-scale particulate matter reductions result in a net benefit, EPA's cost assumptions for urban particulate matter reductions are likely overstated, especially in light of the IRA's tax incentives and direct funding provisions. Indeed, the statute is specifically designed, in part, to reduce the cost of local and regional greenhouse gas and criteria pollution control measures. And given that those incentives are now codified in federal law, it is not reasonable for EPA to assume that compliance with the $PM_{2.5}$ NAAQS will drive or necessitate those investments.

In sum, EPA's RIA almost certainly overestimates the costs of compliance with the proposed, alternative $PM_{2.5}$ NAAQS because the analysis fails to account for recent final federal and state rules, impending federal rules, and the Inflation Reduction Act, each of which will lead to significant reductions in particulate matter pollution, thereby reducing the cost of compliance with any new standard.

3. There are other means for controlling emissions that would be highly effective and efficient

Beyond the actions discussed above, there are other actions that would effectively and feasibly reduce $PM_{2.5}$-precursor emissions and thus help reduce the harms $PM_{2.5}$ causes. A recent study reported that "farms have become the largest

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[159] *See* Dennison, J., *et al*., *How Air Agencies Can Help End Fossil Fuel Pollution from Buildings* (RMI 2021), *available at* https://rmi.org/insight/outdoor-air-quality-brief/; RMI Factsheet, Why EPA Must Address Appliance Pollution (June 4, 2021), https://rmi.org/wp-content/uploads/2021/04/rmi_factsheet_appliance_pollution.pdf.

[160] Dennison, J., et al., *How Air Agencies Can Help End Fossil Fuel Pollution from Buildings*.

[161] RIA at 2-11.

contributor to air pollution damages from $PM_{2.5}$-related emissions."[162] For example, several studies demonstrate that strategies for reducing ammonia emissions from agriculture are among the most effective for reducing $PM_{2.5}$ concentrations, especially during the winter time.[163] Ammonia emissions from dairy production can be reduced through strategies such as improving livestock feed to reduce excreted nutrients, altering manure storage and handling practices to prevent NH_3 emissions, and improving land application practices have been effectively implemented in some operations.[164] Further, various ammonia-reduction strategies are already widely adopted across parts of Europe. Emission control options like these represent another inexpensive, efficient way to reduce ambient $PM_{2.5}$ levels. Full consideration of the broad range of options would likely reduce estimated compliance costs still more.

4. Polluters' repeated cries about costs have historically not been borne out

Complaints about health and environmental standards being purportedly too stringent to justify their costs are hardly new. Former EPA Administrator Lisa P. Jackson noted that they are also wrong:

> The Clean Air Act has faced incessant claims that it will spell economic doom for the American people.

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[162] Peter Tschofen et al., *Fine Particulate Matter Damages and Value Added in the US Economy*, 116 PNAS 19,857, 19,857 (2019).

[163] Robert W. Pinder & Peter J. Adams, *Ammonia Emission Controls as a Cost-Effective Strategy for Reducing Atmospheric Particulate Matter in the Eastern United States*, 41 Environ. Sci. & Tech. 380 (2007); *see* Domingo et al., *Air Quality-Related Health Damages of Food*, 118 PNAS e2013637118 (changes in farming practices, many related to ammonia-emitted activities, could cut $PM_{2.5}$-related mortality in half).

[164] *E.g.*, Sharon L.M Preece et al., *Ammonia Emissions from Cattle Feeding Operations* 6-9 (Tex. A&M Univ. AgriLife Ext., AGEN-PU-063, 2022); Domingo et al., *Air Quality-Related Health Damages of Food*, 118 PNAS e2013637118; Susan Guthrie et al., *The Impact of Ammonia Emissions From Agriculture on Biodiversity* at iv fig.1 (2018), https://royalsociety.org/-/media/policy/projects/evidence-synthesis/Ammonia/Ammonia-report.pdf.

> Today's forecasts of economic doom are nearly identical—almost word for word—to the doomsday predictions of the last 40 years. This "broken-record" continues despite the fact that history has proven the doomsayers wrong again and again.
>
> * * *
>
> As you can see, the Clean Air Act has not only reduced harmful pollution—it has also been particularly effective at proving lobbyists wrong. This law not only respects but thrives on the openness and entrepreneurship of our economy. It creates a "virtuous cycle" in which clean air standards spark new technology—serving our fundamental belief that we can create jobs and opportunities without burdening our citizens with the effects of pollution.
>
> * * *
>
> True to form, the lobbyists have recycled their old predictions of job loss and economic catastrophe with regard to each and every one of these actions. That train's never late….Of course there have been claims about job killing regulations—despite the fact that cost-effective strategies to reduce air pollution should spark clean energy innovation and help create green jobs.

Lisa P. Jackson, Adm'r, EPA, Remarks on the 40th Anniversary of the Clean Air Act, As Prepared (Sept. 14, 2010), https://www.epa.gov/archive/epapages/newsroom_archive/speeches/7769a6b1f0a5bc9a8525779e005ade13.html. Administrator Jackson's faith in this country's ingenuity and American business's inventiveness applies just as strongly now as it did a decade ago.

Certainly, polluters' predictions have continued to be disproven. *See, e.g.*, 88 Fed. Reg. 13,956, 13,975-76 (Mar. 6, 2023) ("Compliance Cost Projections in the 2011 RIA Were Likely Significantly Overestimated"). Many academic studies strenuously support the conclusion that polluters' predictions are overstated, as well. *E.g.*, E. Mark Curtis, 99 J. Envtl. Econ. & Mgmt. 102261 (2020) (assessing impacts of nonattainment designations under 1997 ozone standard and finding "[t]he employment results are not in line with the industry view that these regulations are 'job-killers'"), *available in alternatively* *paginated version at* https://www.sciencedirect.com/science/article/am/pii/S0095069618300494; Janet Currie & Reed Walker, *What Do Economists Have to Say about the Clean Air Act 50 Years after the Establishment of the Environmental Protection Agency?*, 33 J. of Econ. Perspectives 3, 19 (2019) ("One defining feature of the research on the costs of the Clean Air Act is that predicted costs of the regulations are often higher than the costs that actually occur."); Matthew E. Kahn, *The Beneficiaries of Clean Air Act Regulation*, 24 Regulation 34, 36 (2001) (finding no "significant negative effects on employment in the tightly regulated L.A. basin" and citing then-forthcoming study that suggested "local air quality regulations" "probably increased labor demand slightly").

And still, as Administrator Jackson explained and numerous studies also demonstrate, we have substantially improved air quality, saved and bettered many people's lives, and, in sum, resulted in a huge net benefit for our country. *See supra* § IX.F.1; *e.g.*, Currie & Walker, *What Do Economists Have to Say*, at 15 ("the current estimates suggest that the overall costs are likely to have been substantially less than the estimated benefits in terms of health and other outcomes."), 20 ("Although we have emphasized that forecasters have often overestimated the costs of environmental policies, researchers have also sometimes underestimated the benefits.").

X. CONCLUSION

When CASAC commenced reconsidering the $PM_{2.5}$ NAAQS, Administrator Regan spoke at the meeting and, per the minutes, recognized the importance of protecting the most vulnerable by combining science and environmental justice:

> [Administrator Regan] indicated that from the beginning of his time as Administrator, he committed that science would serve as the backbone of everything EPA does to protect people and the environment from pollution….He stated he believes science and environmental justice must go hand-in-hand, to truly fulfill EPA's long-standing mission to protect all human health and the environment, especially those historically marginalized, over-burdened, under-served, and living with the legacy of structural racism. He encouraged the CASAC and the PM Panel to consider these disparities as they conduct their scientific review of EPA's work and that achieving environmental justice must be a collective task.

> He stated that the mission of protected [*sic*] health and the environment could only be achieved if a strong foundation of science were built and then acting on it [*sic*].

Summary Minutes of CASAC Particulate Matter Panel's Oct. 14, 2021, Public Meeting, at 2-3, https://casac.epa.gov/ords/sab/f?p=105:19:5822783535378:::RP,19:P19_ID:961#minutes.

As Administrator Regan said, science and environmental justice truly must go hand-in-hand. In its proposal, however, EPA does not follow the science. And, as a result, the proposal does not adequately advance environmental justice.

Fix one and EPA can fix the other. EPA still has the chance.

* * *

For the foregoing reasons, to fulfill the requirements of the Clean Air Act, and make important, overdue advances in public health and reduce unjust public health disparities, EPA must finalize the primary annual $PM_{2.5}$ standard to be no higher than 8 $\mu g/m^3$ and the primary 24-hour $PM_{2.5}$ standard to be no higher than 25 $\mu g/m^3$. Though stronger standards than 8 $\mu g/m^3$ and 25 $\mu g/m^3$ are justified, 8 $\mu g/m^3$ and 25 $\mu g/m^3$ would represent the minimum improvement necessary to protect public health and make an important advance on environmental justice. To protect public welfare, EPA must also strengthen the secondary 24-hour $PM_{2.5}$ standard to 25 $\mu g/m^3$ and strengthen the secondary annual $PM_{2.5}$ standard.

Just as strengthening the standards is vitally important, so too is ensuring that people know whether the air they are breathing is healthy. Accordingly, EPA must also update its regulations regarding air quality monitoring and the air quality index to help make the promise of the national ambient air quality standards—clean air for all, including vulnerable populations, like children, people with heart and lung disease, and older Black adults—all the more real.

Similarly, EPA must move swiftly and surely to finalize these important public health and environmental protections without further delay. The combination of stronger standards that protect the most at-risk among us, with expeditious, full implementation, is necessary to advance environmental justice.

Sincerely,

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