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Respectfully Submitted by American Lung Association, Clean Air Task Force, Chesapeake Bay Foundation, Earthjustice, Environment America, Environmental Defense Fund, Environmental Law & Policy Center, National Parks Conservation Association, Natural Resources Defense Council, Sierra Club, and Union of Concerned Scientists

Dear Acting Administrator Nishida,

On December 18th, the Environmental Protection Agency finalized its review of “National Ambient Air Quality Standards for Particulate Matter,” otherwise known as the “PM NAAQS,” 85 Fed. Reg. 82,684 et seq. (Dec. 18, 2020).

American Lung Association, Clean Air Task Force, Chesapeake Bay Foundation, Earthjustice, Environment America, Environmental Defense Fund, Environmental Law & Policy Center, National Parks Conservation Association, Natural Resources Defense Council, Sierra Club, and Union of Concerned Scientists respectfully petition EPA to convene a proceeding for reconsideration of these standards under Section 307(d) of the Clean Air Act, 42 U.S.C. § 7607(d), and in light of President Biden’s recent Executive Orders, because the 2020 review did not set standards at the levels the statute’s directive demands, despite a coherent body of evidence which mandates strengthening revisions to the primary annual and 24-hour PM$_{2.5}$ standards, and the secondary welfare standard, to provide the requisite protection of health and welfare.

The undersigned organizations represent millions of members and supporters across the country who are deeply concerned about the health, environmental, and economic impacts of air pollution and support setting strong, science-based National Ambient Air Quality Standards (“NAAQS”) that ensure public health and the environment are protected.

I. Introduction

The overriding purpose of the Clean Air Act is to “protect and enhance” air quality, 42 U.S.C. § 7401(a), and mitigate the “mounting dangers to the public health or welfare” caused by air pollution. 42 U.S.C. § 7401(a)(2). To that end, the Clean Air Act establishes “National
Ambient Air Quality Standards,” or NAAQS, for some of the most common “criteria” pollutants in the “ambient air.” 42 U.S.C. § 7409; see also 40 C.F.R. part 50.

Primary NAAQS must be set at a level “requisite to protect the public health” with “an adequate margin of safety.” Id. § 7409(b)(1). Any primary NAAQS that EPA promulgates must be adequate to protect public health and provide an adequate margin of safety, in order to prevent not only any known or anticipated health-related effects from polluted air, but also those that are scientifically uncertain or that research has not yet uncovered. Further, the statute makes clear that there are significant limitations on the discretion granted to EPA in selecting a level for the NAAQS. In exercising its judgment, EPA must err on the side of protecting public health, and “taking account of the “preventative” and “precautionary” nature of the act… the Administrator must then decide what margin of safety will protect the public health from the pollutant’s adverse effects – not just known adverse effects, but those of scientific uncertainty or that “research has not yet uncovered.” 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).

Importantly, the NAAQS must be set at levels that are not simply adequate to protect the average member of the population, but must also protect against adverse effects in vulnerable subpopulations, such as children, the elderly, socially disadvantaged, and people with heart and lung disease. The D.C. Circuit has repeatedly found that if a certain level of a pollutant “adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.” Am. Lung Ass’n, 134 F.3d at 390 (citation omitted); see also Coal. of Battery Recyclers Ass’n v. EPA, 604 F.3d 613, 618 (D.C. Cir. 2010); Am. Farm Bureau Fed’n v. EPA, 559 F.3d 512, 524 (D.C. Cir. 2009). EPA must also build into the NAAQS an adequate margin of safety for these sensitive subpopulations. See Am. Farm Bureau Fed’n, 559 F.3d at 526.¹

The Clean Air Act requires that secondary NAAQS “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.” 42 U.S.C. § 7602(h). 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). Senator Muskie, one of the prime architects of the Act, in speaking about the amendments for public welfare during the Senate debates, noted that the protections for public welfare “are especially important because some pollutants may have serious effects on the environment at levels below those where health effects may occur” and will be set to be “protective against any know or adverse environmental effects.” Legislative History of Clean Air Act Amendments of 1970 at 227 (Senate Debate on S. 4358, Sept. 21, 1970). The congressionally mandated “ongoing, periodic review and revision process set up by Congress . . . ensure[s] that regulatory guidelines and standards which protect human safety and welfare are kept abreast of rapid scientific and technological developments[.]” Lung Ass’n v.

¹ Petitioners direct the Agency to, and incorporate by reference, our comments on the underlying standards, at Doc. ID No. EPA-HQ-OAR-2015-0072-0973 A full discussion of the Agency’s authority with respect to the NAAQS is found at pp. 3-8.
Browner, 884 F. Supp. 345, 347 (D. Ariz. 1994), and that “as the contours and texture of scientific knowledge change . . . EPA’s NAAQS review necessarily changes as well[].” Mississippi v. EPA, 723 F.3d 246, 255-56 (D.C. Cir.), amended and superseded on reh’g, 744 F.3d 1334 (D.C. Cir. 2013).

A. 2020 PM NAAQS Review

EPA last updated the annual PM standard in 2012, revising the PM$_{2.5}$ standard to $12 \mu g/m^3$ (micrograms per cubic meter), and retaining the 24-hour PM$_{2.5}$ standard, at $35 \mu g/m^3$, set in 2006. Prior to 2012, the Agency last updated the annual PM$_{2.5}$ standard in 1997. In 2018, then-EPA Administrator Pruitt announced a “back to basics” policy for the NAAQS that truncated scientific review processes and stacked review boards with industry appointees.\footnote{Memorandum from E. Scott Pruitt, Former Administrator, U.S. Environmental Protection Agency, on Back to Basics for Reviewing the National Ambient Air Quality Standards to EPA Assistant Administrators (May 9, 2018) (“2018 Pruitt NAAQS Memo”) at 3, available at https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf}

The Trump Administration followed this approach in the PM review, and proposed to maintain the 2012 standards in April 2020. EPA allowed only 60 days for public comment (and denied requests to extend the comment period amidst the Covid-19 pandemic), and finalized the standards on December 7, making the rule effective immediately on publication in the Federal Register. “Review of the National Ambient Air Quality Standards for Particulate Matter,” 85 Fed. Reg. 24,094 (Apr. 30, 2020) (Proposed Rule); “National Ambient Air Quality Standards for Particulate Matter,” 85 Fed. Reg. 82,684 et seq. (Dec. 18, 2020) (Final Rule).

B. Authority for Reconsideration

As provided for under Section 307(d) of the Clean Air Act, 42 U.S.C. § 7607(d), EPA must immediately undertake a reconsideration proceeding of the 2020 PM standards. The Agency’s final decision meets the test for reconsideration, as outlined herein. Reconsideration also is warranted because of the Agency’s failure to set standards at the levels the statute’s directive demands, despite a coherent body of evidence which mandates strengthening revisions to the primary annual and 24-hour PM$_{2.5}$ standards, and the secondary welfare standard, to provide the requisite protection of health and welfare. Clean Air Act section 307(d)(7)(B) provides:

Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator 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). Therefore, a reconsideration proceeding must be convened when a person demonstrates that an objection was impracticable to raise during the comment period and the objection is of central relevance to the outcome. This provides members of the public with an opportunity to comment on aspects of a final rule that they were not given adequate notice of previously. “The first element’s impracticability prong - rather than the ‘arising after’ prong - is met ‘when the final rule was not a logical outgrowth of the proposed rule.’” Chesapeake Climate Action Network v. EPA, 952 F.3d 310, 319 (D.C. Cir. 2020) (internal citation omitted). “A final rule is the ‘logical outgrowth’ of a proposed rule if ‘interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period.’” Clean Air Council v. Pruitt, 862 F.3d 1, 10 (D.C. Cir. 2017) (internal citation omitted).

An objection is of central relevance if it “provides substantial support for the argument that the regulation should be revised.” Coal. for Responsible Regulation v. EPA, 684 F.3d 102, 125 (D.C. Cir. 2012), aff’d in part, rev’d in part on other grounds sub. nom. Util. Air Regulatory Grp. v. EPA, 573 U.S. 302 (2014); see also 42 U.S.C. § 7607(d)(7)(B).

As this Petition will demonstrate, the 2020 PM standards are in tension with EPA’s core duty to protect public health and welfare in carrying out obligations in the Clean Air Act, and in setting the NAAQS with an adequate margin of safety. The final rule also differs significantly from the proposal in ways that do not represent a logical outgrowth of the proposal, making it impracticable to raise objections to certain issues prior to the final rule. The Administrator must therefore “convene a proceeding for reconsideration of the rule” in accordance with the requirements of the Act. Id. § 7607(d)(7)(B). But not all aspects of the rule are necessarily subject to mandatory reconsideration, and, because of the seriousness of the harms PM causes and the urgency of action to address those harms, Petitioners reserve their right to pursue litigation even without EPA action on this petition.

Similarly, the Biden Administration has pledged an ambitious, broad-based, “whole-of-government” approach to addressing environmental injustices. As EPA renews its commitment to environmental justice and civil rights, EPA must reconsider its decision to maintain outdated standards for particulate matter that disproportionately harm Black and brown communities.3 Section 2 of Executive Order 13990 mandates that:

The heads of all agencies shall immediately review all existing regulations, orders, guidance documents, policies, and any other similar agency actions (agency actions) promulgated, issued, or adopted between January 20, 2017, and January 20, 2021, that are or may be inconsistent with, or present obstacles to, the policy set forth in section 1 of this order. For any such actions identified by the agencies, the heads of agencies shall, as appropriate and consistent with applicable law, consider suspending, revising, or rescinding the agency actions.⁴

These executive orders affirm that a reconsideration of EPA’s 2020 PM standards is necessary.

II. EPA must grant swift reconsideration on the primary standard

A. EPA’s Final Action Introduces Issues of Central Relevance Regarding Treatment of Scientific Evidence and Provisional Consideration of Certain Studies that were Impracticable to Raise During the Comment Period

In the final action, EPA deviated from its proposed explanation for retaining the existing primary standard in ways beyond the limits of a logical outgrowth, and it was therefore impracticable to raise objections during the public comment period regarding two important issues in the final action that are of central relevance to the decision. EPA gave no indication of these changes to the Agency’s rationale for retaining the standard, and therefore these are not changes that parties could or should have anticipated. Specifically, EPA provided a new explanation for why the available scientific evidence supposedly did not justify tightening the standard, and introduced what was referred to as “provisional consideration” for certain recent studies in the final decision. Because the Agency relied on this new explanation, these issues are of central relevance to the outcome of the rule, and objections were impracticable to raise during the comment period due to lack of notice prior to their introduction in the final action, EPA must convene a reconsideration proceeding for this action under section 307 of the CAA.

1. EPA’s Consideration and Treatment of Scientific Evidence

EPA’s final action introduces an important new explanation for the former Administrator’s decision not to revise the PM NAAQS despite compelling scientific evidence. Specifically, the EPA Administrator attempts to diminish the value of the epidemiological evidence by making a number of specious claims:

(1) The reported mean concentration in the majority of the key U.S. epidemiological studies using ground-based monitoring data are above the level of the current annual standard; (2) the mean of the reported study means (or medians) (i.e., 13.5 μg/m³) is above the level of the current standard; (3) air quality analyses show the study means to be lower than their corresponding design values by 10-20%; and (4) that these analyses must be considered in light

of uncertainties inherent in the epidemiological evidence. When taken together, the Administrator judges that, even if he were to place greater weight on the epidemiological evidence, this information would not call into question the adequacy of the current standards.

85 Fed. Reg. at 82717. Underpinning this attempt is the former Administrator’s also novel dismissal of studies that relied on hybrid modeling approaches to develop their mean/median PM2.5 levels in favor of the ones that used ground-based monitors to develop their means/medians. 85 Fed. Reg. at 82,710/1-12/1, 82,714/1, 82,716/3-17/1. And clearly the final decision depends on ignoring this science, which supports a tighter standard. Public commentors could not have objected to these claims because the Administrator’s specious criticism and hypothetical conclusion are significant departures from—and not a logical outgrowth of—the proposal. The epidemiological studies provide important evidence about health effects below the current standards, and therefore their consideration and the weight given to them are of central relevance to setting the standard.

Rather than focusing on this criticism of the epidemiology, the Proposal relied on “broader concerns regarding the lack of experimental studies examining PM$_{2.5}$ exposures typical of areas meeting the current standards” as an explanation for the Administrator’s judgment that there was considerable uncertainty regarding increased public health protection of a tighter standard. 85 Fed. Reg. at 24,120. The significant addition to EPA’s explanation may have been an effort to bolster the Agency’s explanation in the face of criticism received with regard to its approach. EPA’s rationale, specifically the “broader concerns” about lack of experimental studies at lower exposure levels, were strongly rebuked by the Centers for Disease Control and Prevention in the interagency review process. The CDC was highly critical of the Proposal, stating:

EPA has not provided sufficient justification for discounting experimental evidence – both from controlled human exposure studies and animal toxicological studies. There is a large body of scientific literature describing why it is appropriate to conduct these studies at concentrations higher than what is measured under ambient conditions. Results from these studies can, and should, be used to directly inform the health effects of pollutant exposures and are invaluable for proper interpretation of epidemiologic findings. As written, the rationale is not scientifically defensible and is inconsistent with established practice within the EPA and other scientific agencies and organizations.

EPA-HQ-OAR-2015-0072-1229. Regardless of the impetus for the change, it is clear that EPA made a significant change to its rationale for maintaining the existing primary standard in the final action. Members of the public could not have known to object to this rationale and criticism of the epidemiological evidence during the comment period because they were introduced in the final action and not a logical outgrowth of the proposal. EPA’s treatment of this scientific

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evidence is of central relevance to its decision regarding the level of the standard, and therefore warrants reconsideration of this action.

Further, EPA’s new claims are spurious. For example, they rest on the former Administrator’s arbitrary dismissal of the epidemiologic studies that relied on hybrid modeling approaches. See 85 Fed. Reg. at 82,711/1-3 (citing purported remaining uncertainties and imperfections in hybrid modeling approach when throwing out such studies). The thoughtful, well-founded advice given by the Independent Particulate Matter Review Panel makes clear the Administrator’s irrationality. The Panel praised the hybrid modeling approach’s performance as “quite good” and explained that the approach’s “substantial improvements” marked a “substantial advancement” that “enables epidemiologic studies of large cohorts not served by the ambient monitoring network,” with the resulting new studies (which the Administrator dismissed without notice) being “groundbreaking” and “highly compelling.” Advice from the Independent Particulate Matter Review Panel, EPA-HQ-OAR-2015-0072-0037 at B-7 to -8, B-14 to -15. The Administrator gave no rational explanation for why any remaining concerns about the approach called for entirely dismissing every single one of these powerful, profoundly important studies in assessing a requisite level of protection. Had EPA’s new claims been subject to comment, their lack of rational basis would have been further exposed.

2. EPA’s provisional consideration of new studies

In the final action, “EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria” and states that “[i]n the present case, the EPA's provisional consideration of ‘new’ studies concludes that, taken in context, the ‘new’ information and findings do not materially change any of the broad scientific conclusions regarding the health and welfare effects of PM in ambient air made in the air quality criteria. For this reason, reopening the air quality criteria review would not be warranted.” 85 Fed. Reg. at 82,691. EPA did not include this conclusion regarding its “provisional consideration” of the new studies in the proposal, and therefore public commentors did not have an opportunity to raise objections to the Agency’s conclusion regarding the lack of impact that this information would have on important scientific conclusions regarding health and welfare effects of particulate matter. Therefore, these objections were both impracticable to raise during the comment period and centrally relevant to setting the PM NAAQS. Further, EPA’s response is not rational itself. First, it is not clear what EPA means by “broad scientific conclusions.” Second, and relatedly, even if the new studies “do not materially change any of the broad scientific conclusions” about PM’s health and welfare effects, they can have significant implications for key scientific conclusions, like whether the current standards are inadequately protective under the Act with respect to individual health effects.

3. Scientific Underpinnings of Provisional Assessment

As in previous reviews, EPA established a cutoff date for studies to be included in the first draft of the ISA. The final ISA noted the cutoff was about January 2018, or about nine months before release of the first draft. In past reviews, if particularly significant new or otherwise missed studies appeared during the review of the ISA, they could be identified by
CASAC and added during the preparation of the second draft, which would then be reviewed by CASAC. The so-called “streamlined” new NAAQS review process outlined by the “Back to Basics” memo precluded second reviews of the ISA and PA by CASAC and the public, missing the normal opportunity for inclusion of potentially significant new studies.

As an example of past practice, on December 14, 2012 EPA published its *Provisional Assessment Of Recent Studies On Health Effects Of Particulate Matter Exposure*. EPA noted at the time that the report “presents the findings of EPA’s survey and provisional assessment of studies published since the completion of the 2009 PM ISA. EPA has screened and surveyed the recent literature and developed a provisional assessment that places those studies of potentially greatest relevance to the current PM NAAQS review in the context of the findings of the 2009 PM ISA.” Such a thorough provisional assessment of peer-reviewed studies published too recently to be included in the December 2019 PM Integrated Science Assessment was not executed by EPA prior to finalization of the PM NAAQS proposal.

Moreover, given the continuing explosion of research on fine particles since the 1997 standards, recent PM proposals have announced and conducted “provisional assessment” of studies published after the cutoff date for the science (criteria) assessment, reflecting the Clean Air Act 108(a)(2) requirement that such assessments accurately reflect “the latest scientific knowledge.” Though many relevant studies have been published since the January 2018 cutoff date, EPA ignored this step and its obligations under Clean Air Act section 108(a)(2). The Agency did not acknowledge this deviation from its past practice, much less provide a reasoned explanation for it. Further, by accepting CASAC’s recommendation to consider a secondary reference on accountability studies that was published online in late 2019 and published in February 2020, EPA cannot now close the door to adding a number of important new studies that are far more relevant to the particulate matter NAAQS. A sample of important recent studies the Agency failed to adequately consider include:

**Abu Awad et al. 2019. Change In PM$_{2.5}$ Exposure And Mortality Among Medicare Recipients. Environmental Epidemiology 3:e054.** [http://journals.lww.com/01984727-201908000-00002](http://journals.lww.com/01984727-201908000-00002)

Investigators examined PM$_{2.5}$ changes for over 12 million U.S. Medicare beneficiaries, who moved to a new zip code. The investigators conclude that “This study provides evidence of likely causal effects at concentrations below current limits of PM$_{2.5}$.”


This study used inverse probability weighting based on propensity scores, to examine the relationship between PM$_{2.5}$, and total and cardiovascular mortality in a cohort of 635,000 US individuals in the NHIS database. Long-term air quality reflected a 17-year average (1999-2015). The analysis included multiple covariates as confounders. “Covariate-adjusted estimated
relative risks per 10 μg/m³ increase in PM exposure were estimated to be 1.117 (1.083, 1.152) for all-cause mortality and 1.232 (95% CI: 1.174-1.292) for cardiopulmonary mortality.” The investigators concluded that “These results provide evidence that long-term exposure to PM contributes to increased mortality risk in US adults and that the estimated effects are generally robust to modeling choices… Estimated confounding due to measured covariates appears minimal in the NHIS cohort, and various distributional assumptions have little bearing on the magnitude or standard errors of estimated causal associations.”


The authors found that prenatal exposure to PM₂.₅ in late pregnancy reduced gestational age at delivery among Massachusetts neonates, especially among preterm/early-term births, male neonates, and neonates of younger and African American mothers. Importantly, low-exposure analyses yielded similar results, restricting to areas with PM₂.₅ levels under US ambient annual standard of 12 μg/m³.

Rhee, Jongeun, Francesca Dominici, Antonella Zanobetti, Joel Schwartz, Yun Wang, Qian Di, John Balmes, and David C Christiani. “Impact of Long-Term Exposures to Ambient PM₂.₅ and Ozone on ARDS Risk for Older Adults in the United States.” Chest 156, no. 1 (2019): 71–79. https://doi.org/10.1016/j.chest.2019.03.017

This observational study was conducted to estimate air pollution exposures at the ZIP code level and hospital admissions with ARDS among US Medicare beneficiaries aged ≥65 years from 2000 to 2012. There were a total of 1.16 million hospital admissions with ARDS in the cohort. Increases of 1 μg/m³ in annual average PM₂.₅ were associated with increases in annual hospital admission rates for ARDS of 0.72% (95% CI, 0.62-0.82). In low-pollution regions (annual average PM₂.₅ level < 12 μg/m³), the same annual increase in PM₂.₅ was associated with increases in annual hospital admission rates for ARDS of 1.50% (95% CI, 1.27-1.72).


This study used propensity score causal modeling that analyzed directly the effect of PM₂.₅ on life expectancy for nearly 17 million Medicare beneficiaries in the Northeast and Mid-Atlantic states. Investigators found that “estimated mean age at death for a population with an annual average PM₂.₅ exposure of 12 μg/m³ was 0.89 years less (95% CI: 0.88-0.91) than estimated for a counterfactual PM₂.₅ exposure of 7.5 μg/m³.”

Shi, Liuhua, Xiao Wu, Mahdieh Danesh Yazdi, Danielle Braun, Yara Abu Awad, Yaguang Wei, Pengfei Liu, et al. “Long-Term Effects of PM2.5 on Neurological Disorders in the American Medicare Population: A Longitudinal Cohort Study.” The Lancet Planetary
Authors conducted longitudinal cohort study in which they constructed a population-based nationwide open cohort including all fee-for-service Medicare beneficiaries (aged ≥65 years) in the contiguous United States (2000–16) with no exclusions. They reported that, for each 5 μg/m³ increase in annual PM2·5 concentrations, the hazard ratio was 1.13 (95% CI 1.12–1.14) for first hospital admission for Parkinson’s disease and 1.13 (1.12–1.14) for first hospital admission for Alzheimer’s disease and related dementias. The mean PM2.5 concentration for the whole cohort was 9.7 µg/m³.


Authors assessed causal associations of long- and short-term PM2.5, O3, and NO2 exposures with all-cause mortality among Medicare beneficiaries in Massachusetts, 2000–2012. Per 10 million person-days, each 1 μg/m³ increase in long- and short-term PM2.5 levels was associated with 35.4 (95% CI: 33.4, 37.6) and 3.04 (95% CI: 2.17, 3.94) excess deaths, respectively. The authors indicate that within their study, air pollution was causally associated with mortality, even at levels below national standards. The mean long-term PM2.5 level was 9.0 μg/m³ and ranged from a minimum of 3.3 μg/m³ to maximum of 16.4 μg/m³. The mean long-term PM2.5 level was 8.9 μg/m³ and ranged from a minimum of 0.1 μg/m³ to maximum of 65.3 μg/m³.


Authors estimated the causal effect of long-term exposure to PM2.5 on mortality in New England Medicare beneficiaries for the period from 2000 to 2012. They found that exposure to moderate levels of PM2.5 (8 -10 μg/m³) caused a 2.8% (95% CI: 0.6%-3.6%) increase in all-cause mortality compared to low exposure (PM2.5 ≤ 8 μg/m³).” Although not evaluating reductions, this study using advanced causal methods, found a substantial increase in mortality risk when comparing PM2.5 concentrations below 8 μg/m³ and “higher” concentrations in a range between 8 and 10 μg/m³.


Analyzing 68.5 million Medicare enrollees over 16 years, the authors provide strong evidence of the causal link between long-term PM2.5 exposure and mortality under a set of causal inference assumptions. Using five distinct approaches, investigators found that a decrease in PM2.5 (by 10 micrograms per cubic meter) leads to a statistically significant 6 to 7% decrease in mortality risk. Based on these models, lowering the air quality standard to 10 micrograms per cubic meter
would save 143,257 lives (95% CI: 115,581-170,645) in one decade. The study provides the most comprehensive evidence to date of the link between long-term PM$_{2.5}$ exposure and mortality, even at levels below current standards.

_Wu, X, RC Nethery, MB Sabath, D Braun, and F Dominici._ “Air Pollution and COVID-19 Mortality in the United States: Strengths and Limitations of an Ecological Regression Analysis.” _Science Advances_ 6, no. 45 (2020): eabd4049. [https://advances.sciencemag.org/content/6/45/eabd4049](https://advances.sciencemag.org/content/6/45/eabd4049)

This study is an ecological analysis analyzing the relationship between long-term PM$_{2.5}$ exposure and county-level COVID-19 mortality rates, using air pollution data from 2000-2016 and COVID-19 death rates through 18 June 2020. After adjusting for multiple confounding variables, investigators reported an increase of 1 µg/m$^3$ in the long-term average PM$_{2.5}$ was associated with a statistically significant 11% (95% CI: 6-17%) increase in the county’s COVID-19 mortality rate. The average reported PM$_{2.5}$ level amongst the counties was 8.4 µg/m$^3$.

_Yitshak-Sade, Maayan, Rachel Nethery, Yara Abu Awad, Fabrizia Mealli, Francesca Dominici, Itai Kloog, and Antonella Zanobetti._ “Lowering Air Pollution Levels in Massachusetts May Prevent Cardiovascular Hospital Admissions.” _Journal of the American College of Cardiology_ 75, no. 20 (May 26, 2020): 2642–44. [https://doi.org/10.1016/j.jacc.2020.03.056](https://doi.org/10.1016/j.jacc.2020.03.056)

This study used a differences-in-differences method for Medicare deaths and PM$_{2.5}$ in the Northeast and Mid-Atlantic states, finding a significant association between PM$_{2.5}$ and mortality.

**B. EPA’s Decision to Leave the PM NAAQS Unchanged is Inconsistent with Recent Executive Actions**

The final PM NAAQS decision is also inconsistent with a number of recent executive actions on protecting public health and the environment, racial equity, and scientific integrity that were issued after the public comment period for this action. EPA should convene a proceeding to reconsider this action in order to determine where it may be inconsistent with both the statutory requirements of the CAA and the directions and policies discussed in these executive actions.

On January 20, 2021, President Biden issued Executive Order 13990, entitled _Protecting Public Health and the Environment by Restoring Science to Tackle the Climate Crisis_, which states that it is the Biden Administration’s policy “to improve public health and protect our environment; to ensure access to clean air and water; . . . and to prioritize both environmental justice and the creation of the well-paying union jobs necessary to deliver on these goals.” 86 Fed. Reg. at 7,037. Executive Order 13990 directs federal 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 that conflict with these important national objectives . . . .” _Id_. For actions inconsistent with these policies, “the heads of agencies shall . . . consider suspending, revising, or rescinding the agency actions.” _Id_.

In addition to the relevant general policies and directions, Executive Order 13990 has important implications for this particular action because it revoked the Presidential Memorandum of April 12, 2018 (Promoting Domestic Manufacturing and Job Creation Policies and Procedures Relating to Implementation of Air Quality Standards). As discussed above, the PM NAAQS review process was influenced by the Back-to-Basics Memorandum put in place by Administrator Pruitt, which was supposed to “help EPA meet its statutory obligations consistent with . . . President Trump’s Memorandum on Promoting Domestic Manufacturing and Job Creation- Policies and Procedures Relating to Implementation of Air Quality Standards.” Back-to-Basics Memorandum at 2. The quick revocation of the Trump Memorandum suggests the principles outlined in the Back-to-Basics Memorandum, which is referenced in the final action and had a significant impact on the NAAQS review process, may not be consistent with the Biden Administration’s policy priorities, and that the final decision should be reconsidered. In light of the new administration’s focus on following the science and protecting public health and the environment, EPA should ensure that the NAAQS was done properly and without improper political interference with the science.

Similarly, Executive Order 14008, Tackling the Climate Crisis at Home and Abroad, issued on January 27, 2021 also states that “[w]e must listen to science—and act. We must strengthen our clean air and water protections. We must hold polluters accountable for their actions. We must deliver environmental justice in communities all across America.” 86 Fed. Reg. at 7622. Executive Order 14008 also requires that “Agencies shall make achieving environmental justice part of their missions by developing programs, policies, and activities to address the disproportionately high and adverse human health, environmental, climate-related and other cumulative impacts on disadvantaged communities,” 86 Fed. Reg. at 7629, and that it is the Administration’s policy to “to secure environmental justice and spur economic opportunity for disadvantaged communities that have been historically marginalized and overburdened by pollution.” Id. This final action fails to strengthen clean air protections despite compelling scientific evidence supporting a stronger standard.

On January 20, 2021, President Biden issued Executive Order 13985, entitled Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, which requires that the head of each agency conduct an equity assessment reviewing programs and policies and submit a report on a number of issues, including “[w]hether new policies, regulations, or guidance documents may be necessary to advance equity in agency actions and programs.” The disproportinate burden from air pollution placed on communities of color is well documented, and EPA acknowledges this to some degree in the final action, noting that the “ISA additionally notes that stratified analyses (i.e., analyses that directly compare PM-related health effects across groups) provide support for racial and ethnic differences in PM exposures and in PM-related health risk (U.S. EPA, 2019, section 12.5.4),” Fed. Reg. 82,703, and that based on those studies “the ISA concludes that ‘[t]here is strong evidence demonstrating that black and Hispanic populations, in particular, have higher PM exposures than non-Hispanic white populations’ and that ‘there is consistent evidence across multiple studies demonstrating an increase in risk for nonwhite populations’ (U.S. EPA, 2019, p. 12-38).” 85 Fed. Reg. at 82,703. EPA admits that “in evaluating the primary PM standards, an important consideration is the potential for additional public health improvements in these populations.” Id. Yet in the final action the Agency states that “EPA believes that this action does not have disproportionately
high and adverse human health or environmental effects on minority, low-income populations and/or indigenous peoples,” 85 Fed. Reg. at 82,745, and fails to adequately address disparities in the health burden of air pollution. EPA should reconsider this action in order to achieve the goals of racial equity and environmental justice discussed in President Biden’s Executive Orders.

This action is inconsistent with President Biden’s Executive Orders because it fails to improve air quality and public health despite EPA’s determination in the policy assessment that available scientific evidence calls into question the adequacy of the standards, particularly the annual standard for fine particulate matter. Rather than following the science, the previous administration chose to lean on specious arguments to ignore or devalue the significance of the available scientific research. Furthermore, this action has significant environmental justice implications, as the disproportionate risk to fenceline and frontline communities, particularly those with large populations of people of color, due to exposure to particulate matter pollution, is well established. This issue is one of the largest environmental justice concerns, and strengthening the NAAQS should be a priority to achieve the environmental justice and racial equity goals discussed in the Executive Orders. As discussed in section II.E, the robust scientific evidence and the conclusions in the Policy Assessment are indicative of a lack of an adequate (or perhaps any) margin of safety in the existing standard.

Furthermore, on January 27, 2021, President Biden issued the Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, which states that “It is the policy of my Administration to make evidence-based decisions guided by the best available science and data. Scientific and technological information, data, and evidence are central to the development and iterative improvement of sound policies, and to the delivery of equitable programs, across every area of government.” EPA’s treatment of scientific evidence in this final action strongly suggests that the decision was not made based on the best available science and data, and instead the previous Administrator appears to have attacked and diminished the significance of the scientific evidence.

This final action has significant implications for public health, the environment, racial equity, and scientific integrity. In light of these executive actions and the new administration’s priorities, EPA should swiftly reconsider this decision.

C. EPA’s failure to properly include a margin of safety, especially for vulnerable populations, warrants Reconsideration

EPA has failed to explain how retaining the PM NAAQS protects vulnerable groups with an adequate margin of safety. The Proposal was devoid of any such discussion. The final rule makes a few bare mentions of the margin of safety, but fails to rationally explain how the existing standard provides an adequate margin of safety for anyone, much less sensitive populations, in view of the strengthened evidence that PM$_{2.5}$ exposure at levels the current standards allow results in adverse effects. See 85 Fed. Reg. at 82,717/3-18/1 (contending current standards have margin of safety by looking solely at epidemiologic studies that rely on ground-based monitoring exclusively); see supra Section II.B (explaining how EPA arbitrarily dismissed epidemiologic studies that used hybrid modeling approach). Notably, too, EPA fails to consider
how the uncontroverted finding that PM2.5 is a non-threshold pollutant combines with the strengthened evidence of PM2.5’s indisputably adverse effects at levels at and below the current NAAQS, strongly supporting a strengthened NAAQS. In all these failures, EPA has violated the Act, and its decision merits reconsideration.

With respect to sensitive populations, numerous studies have identified major respiratory health risks to older Americans from PM2.5 pollution at levels below the current NAAQS. These risks are especially urgent as the previous decline in exposures to PM2.5 appears to have levelled off, in part due to the increasing burden of wildfire smoke. There is substantial evidence in the record of mortality and cardiovascular effects in older adults. There is strong evidence of PM-related cardiovascular effects in people with pre-existing cardiovascular disease. Likewise, there is strong evidence of PM-related respiratory effects in people with pre-existing respiratory disease, particularly asthma. In a study by Liu et al. (2017), short-term exposure to wildfire-specific PM2.5 was associated with heightened risk of respiratory diseases in the elderly population in the Western United States.


Rhee, Jongeun, Francesca Dominici, Antonella Zanobetti, Joel Schwartz, Yun Wang, Qian Di, John Balmes, and David C. Christiani. 2019. “Impact of Long-Term Exposures to Ambient PM2.5 and Ozone on ARDS Risk for Older Adults in the United States.” *Chest* 156 (1): 71–79. [https://doi.org/10.1016/j.chest.2019.03.017](https://doi.org/10.1016/j.chest.2019.03.017).


7 ISA sections 11.1, 11.2, 6.1 and 6.2.

8 ISA section 6.1.

9 ISA section 5.1.

Similarly, the implications of the retained standard to potentially exacerbate racial disparities in air pollution exposures\textsuperscript{11, 12, 13, 14} are not addressed by the Administrator, despite evidence that racial minorities experience disproportionate air pollution burdens. Most dramatically, the seminal Medicare chronic mortality study (Di et al. 2017a) showed three times higher relative risk (hazard ratio) for Black populations compared to the general population (a hazard ratio of 1.21 per 10\(\mu g/m^3\) increase in PM\(_{2.5}\)).\textsuperscript{15} A study by Thind et al. (2019)\textsuperscript{16} identified high air pollution exposures among African Americans from electricity generation. In that study, disparities by race/ethnicity were observed for each income category, indicating that the racial/ethnic differences hold even after accounting for differences in income.\textsuperscript{17}

The ISA notes specifically that analyses that directly compare PM-related health effects across groups -- i.e. stratified analyses -- indicate that minority populations have higher PM2.5 exposures than white populations, contributing to adverse health risk in non-white populations.\textsuperscript{18} Coupled with the fact that multiple epidemiologic studies show adverse effects -- including premature mortality -- in many areas of the country with air quality allowed by the current NAAQS, it is evident, as the Policy Assessment finds, that the groups at increased risk “represent a substantial portion of the total U.S. population.” Policy Assessment at 3-44. The final rule notes these studies in the ISA, yet entirely ignores all of these issues -- the Administrator literally does not discuss them. 85 Fed. Reg. at 82,703. This is antithetical to both evidence of record, and to the protective and precautionary requirements of section 109(d) of the Act. Specifically, the

\begin{itemize}
  \item \textsuperscript{15} IPMRP Advice, at B-12.
  \item \textsuperscript{17} ISA section 11.
  \item \textsuperscript{18} ISA section 12.5.4.
\end{itemize}
“Administrator cannot fulfill [their] responsibility under the Clean Air Act to establish NAAQS ‘requisite to protect the public health,’” if they do not “describe[] the standard under which” they have “arrived at this conclusion, supported by a ‘plausible’ explanation.” Am. Lung Ass’n v. E.P.A., 134 F.3d 388, 392 (D.C. Cir. 1998). In addition, the Response to Comments document directly acknowledges these disproportionate impacts, noting that “to the extent that the public health burden of PM air pollution is disproportionately affecting minority or low-income populations, reaching attainment with existing standards will effectively reduce that disparity.” RTC, at 41. This entirely misses the point of the margin of safety mandate of the Act, and underscores that the Agency should swiftly grant reconsideration.

D. EPA Failed to Assess Environmental Justice Impacts

Compounding the error of disregarding the Act’s requirements to provide requisite protection and adequate margin of safety to susceptible sub-populations, the final rule also ignores the significant inequities and environmental justice impacts resulting from the inadequate standard. While the final rule claims the action maintains the status quo and thus has no environmental justice implications, the disproportionate impacts of particle pollution are well-established and founded in EPA’s own record. EPA’s review documents note that there is “strong evidence for racial and ethnic differences in PM$_{2.5}$ exposures and in PM$_{2.5}$-related health risk. Such analyses indicate that minority populations such as Hispanic and non-Hispanic black populations have higher PM$_{2.5}$ exposures than non-Hispanic white populations, thus contributing to adverse health risk in non-white populations” (U.S. EPA, 2019, section 12.5.4). Likewise, a 2018 study by EPA scientists published in the American Journal of Public Health found that “Non-White populations overall experienced 1.28 times the 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.”

While nearly half of all Americans breathe unhealthy air on a daily basis, disadvantaged communities and communities of color suffer disproportionately. EPA’s most recent literature review of the science related to the health and welfare effects of particle pollution concluded that nonwhites, particularly Blacks, are at a greater risk for health impacts from fine particles, as are low socioeconomic populations. ISA at 12-31 to 12-38. African Americans and Hispanics tend to live in places where they are exposed to greater levels of air pollution. And numerous studies

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have found that Hispanics, Asians, and especially Blacks have a higher risk of premature death from particle pollution than whites do.\(^{21}\) 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.\(^{22}\) And the risk of dying and likelihood for asthma increase in populations with higher unemployment, higher use of public transportation and among people eligible for Medicaid.\(^{23}\)

EPA also squarely acknowledges that the 2011 PM NAAQS review, which the agency now draws on heavily, made certain adjustments to the standard based on disproportionate effects on certain disadvantaged populations, including on the issue of spatial averaging. 85 Fed. Reg. at 24,104 (“An analysis of air quality and population demographic information indicated that the highest PM\(_{2.5}\) concentrations in a given area tended to be measured at monitors in locations where the surrounding populations were more likely to live below the poverty line and to include larger percentages of racial and ethnic minorities (U.S. EPA, 2011, p. 2–60).”) As the D.C. Circuit explained, in upholding the elimination of spatial averaging, “spatial averaging would enable some portions of a compliance area – particularly those areas where sensitive individuals are likely to live – to exceed the NAAQS for periods of time . . . EPA reasonably concluded that allowing those excess emissions under all the circumstances here was inconsistent with EPA’s goal of ensuring that the NAAQS provides requisite protection for all individuals.”\(^{24}\) But the Agency has undertaken no similar effort during the 2020 review to update aspects of the standard based on similar continuing disparities.

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\(^{22}\) Zeger, Scott L., Francesca Dominici, Aidan McDermott, and Jonathan M. Samet. "Mortality in the Medicare population and chronic exposure to fine particulate air pollution in urban centers (2000–2005)." Environmental Health Perspectives 116, no. 12 (2008): 1614-1619. See above noting that Di et al. (2017a) showed chronic mortality risk three times higher for African Americans. The study, as noted above, involved air quality distributions allowed by the current NAAQS.


\(^{24}\) Nat’l Ass’n of Mfrs. v. EPA, 750 F. 3d 921, 925 (D.C. Cir. 2014) (Kavanaugh, J.).
Notwithstanding the Agency’s attempt to characterize the rule as merely maintaining the status quo, and in addition to obligations mentioned above under the new executive mandates, the studies contained in EPA’s own record are sufficient to trigger EPA’s responsibility under E.O. 12,898, to assess whether health harms from maintaining the current PM standard are disproportionately borne by vulnerable communities and, if so, how EPA should address this disparity. As clearly prescribed by the Clean Air Act: the standards must be revised to provide requisite protection to this susceptible subpopulation. EPA’s failure to do so is a violation of its legal requirement under E.O. 12,898 review.

Likewise, EPA has not considered the emerging literature on the association between exposures to PM \( \text{2.5} \) and risk of more severe adverse COVID-19 health impacts. As noted in section II, recent peer-reviewed science suggests, at the county level, a possible association between long-term exposure to PM\( \text{2.5} \) and statistically significant increases in COVID-19 death rates. Wu et al. (2020)\(^{25}\) reported an increase of 1 \( \mu g/m^3 \) in the long-term average PM\( \text{2.5} \) was associated with a statistically significant 11% (95% CI: 6-17%) increase in the county’s COVID-19 mortality rate. The average reported PM\( \text{2.5} \) level amongst the counties analyzed in that study was 8.4 \( \mu g/m^3 \). Prior to the pandemic, researchers also identified a statistically significant link between long-term PM\( \text{2.5} \) exposure levels (in a restricted analysis to areas with levels below the current NAAQS) and risk of acute respiratory distress syndrome in older adults.\(^{26}\) Because low-income communities and communities of color are more likely to experience higher long-term PM\( \text{2.5} \) pollution burdens,\(^{27}\) they may also be suffering disproportionate mortality burden of COVID-19 due to lung disease and respiratory distress inflicted by chronic exposure to PM\( \text{2.5} \) air pollution.

III. EPA Should Grant Swift Reconsideration on the Secondary Standard

EPA should also grant reconsideration of the secondary standard because the Biden Administration’s recent Executive Order to deliver environmental justice in program implementation, which became available after the comment period closed, confirms that it is necessary for EPA to replace the methodology it used to assess visibility impairment.\(^{28}\) The peer-reviewed scientific report published by Malm et al. in 2019 presented a new methodology that uses the “visual range” and scene viewed by the public and thus would include all views,


\(^{26}\) Rhee, Jongeun, Francesca Dominici, Antonella Zanobetti, Joel Schwartz, Yun Wang, Qian Di, John Balmes, and David C Christiani. “Impact of Long-Term Exposures to Ambient PM\( \text{2.5} \) and Ozone on ARDS Risk for Older Adults in the United States.” Chest 156, no. 1 (2019): 71–79. https://doi.org/10.1016/j.chest.2019.03.017


\(^{28}\) Executive Order on Tackling the Climate Crisis at Home and Abroad, § 201 (Jan. 27, 2021) (noting the Administration’s commitment to “deliver[ing] environmental justice”).
including the urban and rural views of minority and low-income populations. Additionally, the new methodology is far superior and a more consistent predictor of “acceptable” visibility in comparison to the current one-size-fits-all approach, which relies on atmospheric extinction, and does not take into consideration what the public views.

EPA must consider the Malm et al. study because, as it acknowledged in its final action, “[t]he meta-analysis by Malm et al. (2019) was published after the cutoff date for the literature search for the ISA, and therefore, was not included in the ISA.” Id. at 82,739. EPA only “provisionally considered” the study and, without considering the recent EO, reached the arbitrary—and confusing—conclusion that it “did not materially change the broad scientific conclusions of the ISA regarding welfare effects, including visibility impairment.” Id. (emphasis added). EPA decided that it would wait five years until “the next review of the PM NAAQS” to consider the new, more inclusive methodology. Id. This cannot be permitted. Given the relevance and importance of the study, EPA should grant reconsideration and reassess PM’s visibility impacts based on the methodology of Malm et al. (2019).

The importance of good visual air quality is well documented. Studies show that the inability to see and appreciate landscape features that reflect some sort of natural setting evokes feelings of anxiety and stress, and also result in an increased number of sick days and increasing post-operative recovery time. Other studies demonstrate that emergency calls for psychiatric disturbances have increased as visual air quality decreased. Studies have also reported reduced altruism and increased hostility and aggression during periods of poor air quality. Finally, the importance of visual air quality includes the sky, as it has been found that clouds have positive effects on feelings of well-being.

People regularly spend time viewing their surroundings whether outside or in an office setting. Visibility-acceptability studies clearly show that visibility becomes less acceptable to people as haze increases. However, there are large variations in the preference levels for different scenes when haze indicators, such as atmospheric extinction (the current approach), visual range (the Malm, et al., methodology), or deciview are used to express visibility conditions. This demonstrates the importance and need of revising the indicator used in the secondary standard so that it reflects and protects the welfare of all members of the public.

EPA’s evaluation of the secondary visibility standard found that the primary PM2.5 standard is protective of urban visibility. This assessment was arbitrarily based on a haze threshold derived from the Washington, D.C. acceptability study with a relatively near scene. Had a more distant scene been used in the Washington, D.C. study, or thresholds derived from other acceptability studies been used, it is likely the primary standard would not have been found

30 Velarde et al. (2007)
31 Rotton and Frey (1982)
32 Cunningham, 1979; Jones and Bogat, 1978; Rotton et al., 1979.
33 Stefani et al. (2012).
sufficiently protective of urban visibility. EPA should grant reconsideration in order to undertake this analysis and ensure that public welfare is adequately protected.

IV. Conclusion

For the above reasons, Petitioners request that EPA swiftly conduct reconsideration proceedings and stay the effectiveness of the Rule during reconsideration for 90 days.

Sincerely,

AMERICAN LUNG ASSOCIATION,
CLEAN AIR TASK FORCE,
CHESAPEAKE BAY FOUNDATION,
EARTHJUSTICE,
ENVIRONMENT AMERICA,
ENVIRONMENTAL DEFENSE FUND,
ENVIRONMENTAL LAW & POLICY CENTER,
NATIONAL PARKS CONSERVATION ASSOCIATION,
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