COMMENTS OF THE ATTORNEYS GENERAL FOR THE STATES OF CALIFORNIA, CONNECTICUT, DELAWARE, ILLINOIS, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEW JERSEY, NEW YORK, OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, WASHINGTON, AND WISCONSIN, THE DISTRICT OF COLUMBIA, AND THE CITY OF NEW YORK

ON

THE EPA ADMINISTRATOR'S RECONSIDERATION OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER, 88 FED. REG. 5558 (JAN. 27, 2023)

March 28, 2023

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I. INTRODUCTION

The Attorneys General of the States of California, Connecticut, Delaware, Illinois, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin, the District of Columbia, and the City of New York submit these comments on the Environmental Protection Agency's ("EPA") Proposed Rule for the Reconsideration the National Ambient Air Quality Standards for Particulate Matter ("2022 Proposed Rule").[1] We herein urge the Administrator of the Environmental Protection Agency ("EPA") to take long-necessary action and adopt national ambient air quality standards ("NAAQS") for particulate matter, or PM, that sufficiently protect the public health and welfare. In particular, this coalition submits these comments to ensure that the final PM NAAQS adequately provide the "margin of safety" required by the Clean Air Act to protect human health in all communities, including sensitive populations in communities that have historically suffered disproportionately severe health impacts from PM exposure and other environmental injustices.[2] Due to the serious health impacts associated with fine PM, or PM smaller than 2.5 micrometers (μm) ("$PM_{2.5}$"), this letter focuses on those $PM_{2.5}$ standards, with a brief discussion of the standards for particulate matter up to 10 μm, or PM_{10}. Specifically, we urge EPA to consider the latest scientific evidence demonstrating that setting the PM NAAQS at the lowest levels under consideration—a primary annual $PM_{2.5}$ standard of 8.0 $\mu g/m^3$ and a primary 24-hour $PM_{2.5}$ standard of 25-30 $\mu g/m^3$—is necessary to fulfill the Clean Air Act's mandate.[3]

Members of this coalition have been advocating for adequately protective PM NAAQS for years. This statutorily required review of the sufficiency of the existing PM NAAQS began in 2014—nearly a decade ago. In 2017, Administrator Pruitt directed EPA staff to pursue a truncated process that failed to adequately consider the latest scientific evidence demonstrating the health impacts of PM and prevented the proper review of the proposed standards by the necessary experts. As a result of this flawed process—in the waning days of the prior Administration—EPA promulgated a Final Rule that did not strengthen any of the existing PM NAAQS ("2020 Final Rule").[4]

Members of this coalition and several other stakeholders subsequently challenged the 2020 Final Rule by filing both petitions for review and petitions for reconsideration. In June 2021, EPA announced its decision to grant the petitions for reconsideration of the 2020 Final

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[1] 88 Fed. Reg. 5558 (Jan. 27, 2023).

[2] 42 U.S.C. § 7409(b); Environmental justice is defined by EPA as the "fair treatment and meaningful involvement of all people regardless of race, color, national origin or income with respect to development, implementation, and enforcement of environmental laws, regulations and policies." EPA, EPA-300-B-1-6004, EJ 2020 ACTION AGENDA: THE U.S. EPA'S ENVIRONMENTAL JUSTICE STRATEGIC PLAN FOR 2016-2020, 1 (Oct. 2016). For the purpose of this comment, the term "environmental justice community" refers to a community of color or community experiencing high rates of poverty that is overburdened by environmental pollution, and the accompanying harms and risks from exposure to that pollution, because of past or current unfair treatment.

[3] The concentration of PM is measured in micrograms per cubic meter of air, or $\mu g/m^3$.

[4] *See* 85 Fed. Reg. 82,684 (Dec. 18, 2020).

Rule, and the D.C. Circuit placed the petitions for review in abeyance pending the Agency's review. As part of its reconsideration, EPA reanalyzed available evidence, including the following documents referenced throughout this letter: (1) the 2019 Integrated Science Assessment ("2019 ISA");[5] (2) the 2022 Supplement to the 2019 Integrated Science Assessment[6] ("2022 ISA Supp."); (3) the May 2022 Policy Assessment ("2022 Policy Assess.");[7] and (4) the advice from the expert Clean Air Scientific Advisory Committee (CASAC) as presented in the March 18, 2022, letter to Administrator Regan ("CASAC Review Letter").[8]

Given the overwhelming evidence of the harms to human health and welfare from PM pollution, EPA must use this reconsideration of the deficient 2020 Final Rule to establish PM NAAQS that protect sensitive populations within an adequate margin of safety. For example, fine PM alone, is estimated to be responsible for about 95 percent of the global public health impacts from exposure to air pollution, and is the largest environmental health risk factor in the United States, responsible for 85,000 to 2000,000 excess deaths per year in the United States.[9] Scientific studies link PM to many serious harms, including premature mortality, cardiovascular effects, respiratory effects, lung cancer; and nervous system effects.[10] And studies continue to show that both short-term and long-term exposure to fine PM is also associated with more serious infections and higher mortality rates for persons with COVID-19.[11]

EPA's Proposed Rule includes the following actions:

- **Lower the primary annual $PM_{2.5}$ standard** from 12.0 μg/m^3 to between 9.0 to 10.0 μg/m^3; EPA is also taking comments on alternative annual standard levels down to 8.0 μg/m^3 and up to 11.0 μg/m^3;

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[5] EPA, Integrated Science Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (Dec. 2019).

[6] EPA, Supplement to the 2019 Integrated Science Assessment for Particulate Matter (May 2022).

[7] EPA, Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (May 2022).

[8] CASAC Review of the EPA's Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (Mar. 2022) [page numbers reference Consensus Response Letter except where noted].

[9] Tessum, et al., *$PM_{2.5}$ polluters disproportionately and systemically affect people of color in the United States* SCI ADV. 7 (2021), https://pubmed.ncbi.nlm.nih.gov/33910895/; Pinto de Moura *et al*., *Inequitable Exposure to Air Pollution from Vehicles in the Northeast and Mid-Atlantic*, Union of Concerned Scientists Fact Sheet p. 2 (June 2019), https://www.ucsusa.org/resources/inequitable-exposure-air-pollution-vehicles; *see also* Tessum, et al., *Inequity in consumption of goods and services adds to racial-ethnic disparities in air pollution exposure*, Proceedings of the National Academy of Sciences 116(13) at 1 (Mar. 11, 2019), https://pubmed.ncbi.nlm.nih.gov/30858319/.

[10] 88 Fed. Reg. at 5580-5591.

[11] Zang et al., *Ambient air pollution and COVID-19 risk: Evidence from 35 observational studies*, ENVIRONMENTAL RESEARCH Vol. 204 112065 (2022), https://www.sciencedirect.com/science/article/pii/S0013935121013608?via%3Dihub.

- **Retain the primary 24-hour $PM_{2.5}$ standard** at a level of 35 $\mu g/m^3$; EPA is also taking comments on revising the level down to 25 $\mu g/m^3$; and
- **Retain the current primary 24-hour PM_{10}** standard without revision.[12]

As explained below, the latest scientific evidence and the plain language of the Clean Air Act require that EPA establish the strongest primary annual and 24-hour $PM_{2.5}$ under consideration here—8.0 $\mu g/m^3$ and 25-30 $\mu g/m^3$, respectively.

Strengthening the standards would also help correct long-standing environmental injustices. Strong evidence exists that non-White racial and ethnic populations as well as low-income populations are disproportionately harmed by PM, with an ever-growing body of evidence supporting such a link since EPA's previous evaluation.[13] The Clean Air Act requires that EPA establish PM NAAQS that sufficiently protect the public health of these vulnerable communities in setting sufficient PM NAAQS within an adequate margin of safety.[14]

The undersigned coalition has a significant interest in ensuring that PM pollution is adequately controlled to protect our residents. State and local governments bear increased costs to treat illness to our residents caused by PM pollution. States and municipalities rely on the EPA's promulgation of strong and lawful NAAQS as a key element of their efforts to prevent these harms and to achieve their air quality goals. We therefore urge EPA to properly consider the most recent scientific evidence and establish primary PM NAAQS at the most protective levels under consideration.

II. BACKGROUND

A. PM, Its Sources and Its Harmful Effects

1. Types and sources

PM encompasses all airborne particles including small liquid and/or solid particles.[15] It originates in two ways. First, it includes particles emitted directly from sources such as factories or automobiles.[16] Second, it includes particles that start out as gaseous emissions, such as sulfur dioxide, nitrogen oxides, and volatile organic compounds, and undergo chemical reactions that produce small particles.[17]

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[12] EPA also proposes retaining the current secondary PM standards, while taking comment on revising the level of the secondary 24-hour $PM_{2.5}$ standard as low as 25 $\mu g/m^3$. This letter focuses on the health impacts of PM and the primary PM NAAQS designed to adequately protect the public health. While we do not specifically address the secondary standards in this letter, we note that the expert scientific panel reviewing EPA's proposal recommended consideration of a secondary 24-hour $PM_{2.5}$ standard in the range of 25-35 $\mu g/m^3$. *See* CASAC Review Letter at 21.
[13] 88 Fed. Reg. at 5592.
[14] 42 U.S.C. § 7409(b).
[15] 88 Fed. Reg. at 5569.
[16] *Id*.
[17] *Id.*

PM comes in sizes ranging from less than 0.1 to more than 10 micrometers ("µm").[18] The NAAQS are designed to limit exposure to two ranges of PM, known as fine PM and thoracic coarse PM. Fine PM is defined as particles with a diameter of 2.5 µm or less and is referred to as $PM_{2.5}$. Thoracic coarse PM is defined as particles with a diameter greater than 2.5 and less than or equal to 10 µm, and is referred to as $PM_{10\text{-}2.5}$. EPA has created a third classification for particulate matter with a diameter less than 10 µm, referred to as PM_{10}, which it uses as a proxy for limiting ambient concentrations of $PM_{10\text{-}2.5}$. While currently not the subject of specific NAAQS, there is also growing evidence and concern about the health and environmental impacts of ultrafine PM, generally defined to have a diameter of 0.1 µm or less.[19]

2. Harms to health and welfare

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

- premature mortality;
- cardiovascular effects, including coronary heart disease, heart failure, stroke, hypertension and atherosclerosis;
- respiratory effects, including asthma, chronic bronchitis, chronic obstructive pulmonary disease (COPD), impaired lung function in children, and accelerated lung function decline in adults;
- lung cancer; and
- nervous system effects, including cognitive impairment and dementia.[20]

In 2011, EPA estimated that among adults alone, reduced exposure to $PM_{2.5}$ and ozone due to the Clean Air Act, including the NAAQS, prevented 160,000 premature deaths in 2010 and would prevent 230,000 premature deaths in 2020, with approximately 85 percent of that avoided mortality due to limiting PM emissions.[21]

B. PM Disproportionately Impacts Communities with Environmental Justice Concerns.

Communities facing environmental injustices experience heightened exposure to PM pollution, and these communities experience disproportionately severe health outcomes as a

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[18] *Id.*
[19] *Id.*
[20] 88 Fed. Reg. at 5592, 5580-91.
[21] EPA, Clean Air Act Overview: Benefits and Costs of the Clean Air Act 1990-2020, the Second Prospective Study, https://www.epa.gov/clean-air-act-overview/benefits-and-costs-clean-air-act-1990-2020-second-prospective-study.

result, with the strongest disparity being death.[22] These communities are generally populated by lower-income and non-White populations that have historically borne the brunt of pollution and endured underinvestment in infrastructure and critical services.[23] In fact, the percentage of people of color in a community has been identified as the most significant variable determining $PM_{2.5}$ exposure.[24] Areas with low-income populations are also consistently exposed to higher average $PM_{2.5}$ levels compared to areas with high income groups.[25] As described below, adopting the strictest standards under consideration is necessary to reduce this unjust disparity.

1. Communities of color suffer disproportionately high exposure to PM.

EPA previously concluded in the 2019 PM ISA that there is sufficient evidence to show that race and ethnicity substantially impact $PM_{2.5}$-related exposure and risk.[26] In the 2022 ISA Supp., EPA cites several additional studies that strengthen the connection between communities of color and higher concentrations of $PM_{2.5}$ exposure. The studies demonstrate that communities of color, at both an individual and neighborhood level, are exposed to disproportionate $PM_{2.5}$ pollution.[27] Specifically, strong evidence demonstrates that Black and Hispanic populations, in particular, have higher $PM_{2.5}$ exposures than non-Hispanic White populations.[28]

In addition to EPA's analysis, several new studies further illuminate the disparate burden that communities of color and low-income populations face. A recent study from Harvard's T.H. Chan School of Public Health analyzed nationwide demographic data and $PM_{2.5}$ data to assess relative disparities across income groups and racial and ethnic groups.[29] The study shows that areas with higher-than-average White populations are exposed to lower average $PM_{2.5}$ levels than areas with higher-than-average Black, Asian, and Hispanic populations. In addition, areas with low-income populations are consistently exposed to higher levels than high-income areas. Overall, the study concludes that "strong, targeted air pollution reduction strategies are necessary not only to reduce overall air pollution levels but also to move closer towards the EPA's aim to provide all people with the same degree of protection from environmental hazards." Another recent study analyzing results in all 50 states over a 20 year period found that in 2010, $PM_{2.5}$ exposures were at least 5% higher than average in 63% of states for non-Hispanic Black populations; in 33% of states for Hispanic populations; and in 26% of states for non-Hispanic

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[22] *See, e.g.*, Mikati, et al., *Disparities in distribution of particulate matter emission sources by race and poverty status*, 108(4) AM. J. PUBLIC HEALTH 480 (Apr. 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5844406/.
[23] *See* White House Website, https://www.whitehouse.gov/environmentaljustice/.
[24] Collins, et al., *Communities of color are disproportionately exposed to long-term and short-term $PM_{2.5}$ in metropolitan America*, 214 ENVIRONMENTAL RESEARCH 7 (2022), https://pubmed.ncbi.nlm.nih.gov/35961542/.
[25] Jbaily, et al., *Air pollution exposure disparities across U.S. population and income groups*, 601 NATURE 228 (Jan. 2022), https://doi.org/10.1038/s41586-021-04190-y.
[26] *See* 2022 ISA Supp. at 3-148.
[27] *Id.*
[28] 88 Fed. Reg. at 5592.
[29] Jbaily, et al., *supra*, at 228.

Asian populations, respectively.[30] In no states did non-Hispanic White populations suffer disproportionate exposure to $PM_{2.5}$.

The disparity in exposure is pervasive throughout the United States and cannot be ascribed to a specific industry or geographical area. A 2021 study found that, when considering $PM_{2.5}$ exposure caused by each emitter type, nearly all major emission categories contribute to the systemic exposure disparity experienced by people of color.[31] These findings were consistent across states, urban and rural areas, and income levels. Such results have been caused in large part by the disparate siting and development of roadways and pollution-emitting facilities in these Black and low-income communities.[32] Emphasizing the systemic nature of disparate exposure levels, a 2022 study overlaid historic redlining practices with present-day air pollution disparities in U.S. cities, finding that current pollution levels have a "consistent and nearly monotonic association" with the grades given that created redlined communities in which these sources of pollution were sited.[33]

This disparity is even more troubling given EPA's findings that these same disproportionately impacted communities of color and low-income populations contribute less to the total $PM_{2.5}$ pollution nationwide.[34] EPA pointed to a recent study that estimated the disparities between the consumption of goods and services that produce $PM_{2.5}$ and the amount of $PM_{2.5}$ to which each racial and ethnic group is exposed, in an attempt to estimate the "pollution inequity" across subpopulations.[35] The results demonstrated extreme disparities between the amount of $PM_{2.5}$ that each group contributed versus the level of exposure, finding that Black populations are exposed to $PM_{2.5}$ levels 56% higher than their relative contribution and Hispanic populations are exposed to 63% more than their contribution.[36] Conversely, White populations were exposed to 17% *less* $PM_{2.5}$ than the amount contributed.[37]

2. Communities of color also experience disproportionate health impacts exacerbated by increased PM exposure.

Not only do communities of color and low-income populations experience heightened exposure, they also endure disproportionate health impacts, even controlling for the increased exposure.[38] EPA has acknowledged that Black populations and residents of majority Black

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[30] Liu, et al., *Disparities in air pollution exposure in the United States by race/ethnicity and income*, 1990–2010, ENVIRONMENTAL HEALTH PERSPECTIVES, 129(12) (Dec. 2021), https://doi.org/10.1289/EHP8584.
[31] Tessum, et al., *supra,* at 1.
[32] *Id.*; *see also* Jbaily, et al, *supra*.
[33] Lane, et al., *Historical Redlining Is Associated with Present-Day Air Pollution Disparities in U.S. Cities*, 9 ENVIRONMENTAL SCIENCE & TECHNOLOGY LETTERS 345 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9009174/.
[34] 2022 ISA Supp. at 2-149, *citing* Tessum, et al., *supra* (2019).
[35] *Id*.
[36] *Id.*
[37] *Id.*
[38] 2022 ISA Supp. at 3-148, 3-153-60.

neighborhoods experience higher levels of $PM_{2.5}$-related health effects than those in non-Hispanic White populations, with the largest disparity being premature death.[39] EPA points to studies showing that communities of color, particularly Black communities, have a significantly higher risk of $PM_{2.5}$-related cardiovascular mortality.[40] Further, EPA's review found troubling evidence that $PM_{2.5}$-related impacts on life expectancy is greatest in states with higher income inequality and larger Black populations.[41] In other words, in addition to experiencing more PM exposure, these same communities also experience the worst health impacts from that PM exposure. This double-whammy of environmental injustice should be addressed by establishing the most health protective standards under consideration.

A new study in the New England Journal of Medicine provides critical insight into disparate levels of exposure and resultant health impacts in racial and ethnic subpopulations.[42] In a comprehensive analysis of data collected from 73 million persons, researchers found both greater exposure to PM and greater susceptibility to disproportionate effects from PM exposure among marginalized subpopulations like Black and low-income populations. The analysis concluded that the increased harm from PM exposure was attributable to social structural forces, rather than any biological differences amongst the study groups. Specifically, the study pointed to the poorer health care access, lack of housing opportunities, and less buffers like health-promoting greenspace that often burden low-income and Black communities as the cause for such disparate impacts.[43]

This new information significantly augments EPA's analysis, providing additional evidence of health benefits that may otherwise have been underestimated by EPA.[44] The results of the study offer additional proof that lowering the primary PM NAAQS to the lowest standards under consideration will lead to large reductions in mortality among the elderly and will produce greater health benefits across a wide array of disproportionately affected low-income populations and communities of color. The results also demonstrate the inverse—failing to establish strengthened NAAQS will continue to place the public health of historically marginalized communities at high risk of $PM_{2.5}$ impacts.

C. Executive Orders Direct EPA to Address These Environmental Injustices.

In its rulemaking process, EPA must consider sensitive communities that have historically borne a disproportionate pollution burden and continue to suffer serious impacts from PM exposure that are not experienced equally across the population. Amongst its first actions in 2021, the Biden Administration issued Executive Order 14008, which calls on federal agencies to make achieving environmental justice part of their missions "by developing programs, policies, and activities to address the disproportionately high and adverse human

[39] *Id*.; *see also* 88 Fed. Reg. at 5592.
[40] *Id*. at 3-154.
[41] 2022 ISA Supp. at 3-157.
[42] Josey, et al., *Air pollution and mortality at the intersection of race and social class*, N. ENGL. J. MED. (Mar. 2023), https://www.nejm.org/doi/10.1056/NEJMsa2300523.
[43] *Id*. at 6.
[44] *Id*. at 8.

health, environmental, climate-related and other cumulative impacts on disadvantaged communities, as well as the accompanying economic challenges of such impacts."[45] Executive Order 14008 commits the Administration "to secure environmental justice and spur economic opportunity for disadvantaged communities that have been historically marginalized and overburdened by pollution and under-investment in housing, transportation, water and wastewater infrastructure, and health care." Further, the Administration issued (1) Executive Order 13985 directing all federal agencies to "work to redress inequities in their policies and programs that serve as barriers to equal opportunity"[46] and (2) Executive Order 13990 directing all executive departments and agencies to address any actions that conflict with the goal of prioritizing environmental justice, among other national objectives.[47] Executive Order 12898 previously established federal executive policy on environmental justice issues. That Executive Order's main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations.[48] We urge EPA to consider these Executive Orders as appropriate in its decision to lower the PM NAAQS.

D. Clean Air Act Authority Relevant to the NAAQS

The Clean Air Act aims "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare."[49] One of the Clean Air Act's principal mechanisms for achieving this goal is the establishment of NAAQS for a set of pollutants known as "criteria" pollutants.[50]

Put simply, NAAQS are the maximum allowable concentrations of pollutants in the atmosphere.[51] With regard to criteria pollutants, the Clean Air Act requires EPA to identify and list specific pollutants that are released from stationary and mobile sources and are anticipated to endanger public health or welfare.[52] These pollutants are known as criteria pollutants because for each such pollutant, EPA is required to issue air quality criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare."[53] Air quality criteria essentially summarize the state of the science regarding

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[45] 86 Fed. Reg. 7619 (Feb. 1, 2021).
[46] 86 Fed. Reg. 7009 (Jan. 25, 2021).
[47] 86 Fed. Reg. 7037 (Jan. 25, 2021).
[48] 59 Fed. Reg. 7629 (Feb. 16, 1994); see also Exec. Order 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011) (directing agencies to select regulatory approaches that maximize net benefits including "distributive impacts[] and equity"); Exec. Order 12,866, 51 Fed. Reg. 51,735 (Oct. 4, 1993) (ordering agencies to consider "distributive impacts[] and equity" in designing regulations).
[49] 42 U.S.C. § 7401(b).
[50] *See* 42 U.S.C. § 7408.
[51] *See, e.g.*, Encyclopedia Brittanica, "National Ambient Air Quality Standard," https://www.britannica.com/science/National-Ambient-Air-Quality-Standards-United-States.
[52] 42 U.S.C. § 7408(a)(1).
[53] *Id.*; § 7408(a)(2).

the pollutant and its impacts on health and the environment. Because of their known well-documented negative impacts to the public health and welfare, EPA has listed $PM_{2.5}$ and PM_{10} as criteria pollutants.[54]

For each criteria pollutant, the Clean Air Act requires the Administrator to establish two types of NAAQS: primary NAAQS, which protect public health, and secondary NAAQS, which protect public welfare.[55] The Act defines primary NAAQS as "ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on [the relevant air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health."[56] The Clean Air Act then defines secondary NAAQS as "specify[ing] a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on [the air quality] criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air."[57] This letter focuses on the public health impacts of PM exposure and accordingly addresses solely the primary standards under reconsideration.

As discussed further below, Congress's mandate that the NAAQS "allow[] an adequate margin of safety" in protecting the public health requires EPA to set standards that "err on the side of caution" in favor of more protective standards when setting NAAQS. In requiring such a "margin of safety," Congress recognized that such complex matters often involve some degree of uncertainty, and that perfect data is not required to establish NAAQS that adequately protect the public health. At the same time, EPA's task is to set standards that are "neither more nor less stringent than necessary."[58]

The Clean Air Act requires EPA to base the standards solely on impacts to public health and welfare and "unambiguously bars cost considerations from the NAAQS-setting process."[59] Further, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards."[60]

To satisfy these statutory requirements, EPA looks at both the short-term and long-term impacts of each criteria pollutant on human health and public welfare.[61] Accordingly, depending on the criteria pollutant targeted, the NAAQS may include a short-term standard, in the form of an hourly or daily average standard, designed to protect against acute exposure, and a long-term standard, in the form of an annual average standard, designed to protect against chronic exposure to lower levels of the pollutant.[62]

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[54] 40 C.F.R. §§ 50.6, 50.7.
[55] 42 U.S.C. § 7409; *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 516 (D.C. Cir. 2009).
[56] *Id*. § 7409(b)(1).
[57] *Id*. § 7409(b)(2).
[58] 88 Fed. Reg. at 5563.
[59] *Whitman v. American Trucking Ass'ns,* 531 U.S. 457, 471 (2001).
[60] *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); *accord Murray Energy Corp. v. EPA*, 936 F.3d. 597, 623-24 (D.C. Cir. 2019).
[61] *See*, *e.g.*, 88 Fed. Reg. at 5580-91.
[62] *See*, *e.g.*, *id.*

After establishing the initial NAAQS, EPA is required to review and revise, as necessary, the air quality criteria and the NAAQS every five years.[63] This mandate underscores the need for EPA to rely on the most up-to-date information and set standards based on the best available science.

To assist this process, EPA is required to appoint a seven-member independent review committee, known as the CASAC. The CASAC consists of relevant experts charged with reviewing the existing air quality criteria and NAAQS and recommending to the Administrator any new NAAQS or revisions of existing NAAQS that may be appropriate, as further described below.[64]

Once the Administrator sets, or revises, the NAAQS for a pollutant, each state must ensure that air quality in areas throughout the state meets that level. Areas whose air quality fails to meet the level set by EPA are designated as "non-attainment" areas, requiring the appropriate state and/or local air pollution agency to impose emission limits on sources of the pollutant within its jurisdiction to satisfy the NAAQS, sometimes with the assistance of pollution controls imposed on sources in upwind states.[65]

E. The Current PM NAAQS Standards

1. Structure of the standards

The NAAQS for each pollutant consists of four basic elements: an indicator, an averaging time, a form and a level.[66] The indicator identifies the substance that is the subject of the NAAQS, that is, the chemical species or mixture for which the concentration is measured.[67] The indicators at issue in this proceeding are $PM_{2.5}$, as an indicator for fine PM, and PM_{10}, as an indicator for thoracic coarse PM. The averaging time defines the period over which the concentration of the indicator is averaged or otherwise evaluated for the purpose of determining compliance with the NAAQS, for example annually or over a 24-hour period.[68] The form is the statistic that is used to evaluate whether an area attains the standard.[69] For example, the form of the annual $PM_{2.5}$ NAAQS is the average of annual mean concentrations over three years.[70] Finally, the level is the threshold value of the form that defines the legally acceptable concentration of the indicator.[71] For example, the level of the current annual primary $PM_{2.5}$ NAAQS is 12 $\mu g/m^3$.[72]

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[63] 42 U.S.C. § 7409(d)(1).
[64] *Id.*; § 7409(d)(2).
[65] *See generally id.* § 7410.
[66] *Am Farm Bureau Fed'n*, 559 F.3d at 516; 2022 Policy Assess. at 1-2.
[67] *Id.*
[68] *Id*.
[69] *Id*.
[70] 2022 Policy Assess. at 1-2 n.3.
[71] *Id*.
[72] *See*, *e.g.*, 88 Fed. Reg. at 5560.

2. The primary standards

EPA has typically focused on the annual $PM_{2.5}$ standard as the principal means of protecting public health against short-and long-term $PM_{2.5}$ exposures.[73] It considers the 24-hour standard as a means of providing supplemental protection against the short-term exposures to peak $PM_{2.5}$ concentrations that can occur in areas with strong contributions from local or seasonal sources, even when overall mean $PM_{2.5}$ concentrations remain relatively low.[74]

EPA first set an annual $PM_{2.5}$ standard in 1997. The annual standard was structured as the three-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors, and set at 15.0 $\mu g/m^3$.[75] EPA strengthened the annual standards in 2012 by setting them at 12.0 $\mu g/m^3$.[76]

EPA first set a 24-hour standard for $PM_{2.5}$ in 1997. The standard was set at 65 $\mu g/m^3$ based on the three-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations within a given area.[77] The standard was intended to provide supplemental protection against days with high peak concentrations, localized hotspots, and risks arising from seasonal emissions that might not be well controlled by an annual standard.[78] The form of the standard was selected to provide a balance between limiting the occurrence of peak 24-hour $PM_{2.5}$ concentrations and identifying a stable target for risk management programs.[79]

In 2006, EPA increased the stringency of the 24-hour $PM_{2.5}$ standard to its current level of 35 $\mu g/m^3$.[80] EPA explained that this decision was based primarily upon an expanded body of short-term $PM_{2.5}$ exposure studies that reported statistically significant associations with mortality, hospital admission, and respiratory symptoms at levels around 39 $\mu g/m^3$.[81]

EPA Administrators have maintained the annual primary standard for PM_{10} at 150 $\mu g/m^3$ since 1997.[82] In 2006 and 2012, the Administrator determined that the existing annual PM_{10} standard continued to be adequate to protect the public health.[83]

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[73] *See* 88 Fed. Reg. at 5561; 2022 Policy Assess. at 3-13. For example, while EPA did not further lower the 24-hour $PM_{2.5}$ standard in 2012, it explained that, by lowering the *annual* $PM_{2.5}$ standard from 15.0 $\mu g/m^3$ to 12.0 $\mu g/m^3$, the annual standard would also provide additional health protection from *short-term* $PM_{2.5}$ exposure. 78 Fed. Reg. 3086, 3163 (Jan. 15, 2013).
[74] *Id.*
[75] 62 Fed. Reg. 38,652, 38,671-74 (July 18, 1997).
[76] 88 Fed. Reg. at 5566.
[77] 62 Fed. Reg. at 38,652.
[78] *Id.* at 38,669.
[79] *Id.*
[80] 88 Fed. Reg. at 5566.
[81] 71 Fed. Reg. 61,144, 61,155 (Oct. 17, 2006).
[82] 62 Fed. Reg. at 38,658.
[83] 71 Fed. Reg. at 61,202; 78 Fed. Reg. at 3089.

F. The 2020 Review of the PM NAAQS and Subsequent Legal Challenges

In 2020, EPA's prior Administrator completed the review of the existing PM NAAQS and promulgated the 2020 Final Rule retaining all of the existing primary and secondary standards.[84] This decision was based on a flawed analysis and truncated review process that failed to adequately consider the latest scientific evidence regarding the public health impacts from PM.[85]

The 2020 Final Rule was based on the Administrator's assessment that the latest scientific evidence did not call into question either the existing annual or the existing 24-hour PM standards. Specifically, the Administrator asserted that there was "considerable uncertainty" in the potential for additional public health benefits by lowering the ambient $PM_{2.5}$ concentrations achieved through the current standards. He therefore contended that lowering the PM NAAQS was unnecessary to protect the public health within an adequate margin of safety.[86] Ultimately, the Administrator claimed that purported limitations and uncertainties in the public health evidence led him to conclude that the existing standards did not need to be lowered to protect public health within an adequate margin of safety.[87]

On January 13, 2021, the States of California, Connecticut, Delaware, Illinois, Maryland, Michigan, Minnesota, New Jersey, New York, Oregon, Rhode Island, Vermont, Washington, and Wisconsin, the Commonwealths of Massachusetts, Virginia, and Pennsylvania, and the City of New York filed a petition for review of the 2020 Final Rule. See *State of California et al. v. EPA*, Case No. 21-1014, filed Jan. 13, 2021 (*consolidated with American Lung Assoc., et al. v. EPA*, Case No. 21-1027, and *Center for Biological Diversity, et al. v. EPA*, Case No. 21-1054). Petitioners explained that the Administrator's decision to retain the existing PM NAAQS failed to adequately protect the public health and welfare within the requisite margin of safety as mandated by the Clean Air Act.

On February 16, 2021, the same coalition of States filed a petition for reconsideration of the 2020 Final Rule with the EPA. The reconsideration petition argued that EPA should reevaluate the 2020 Final Rule due to its failure to provide adequate protection of the public health and welfare as required by the Clean Air Act. The petition further cited to multiple new studies that bolstered the link between PM exposure and significant health impacts. Multiple other stakeholders also filed similar petitions encouraging EPA to reconsider the 2020 Final Rule.

To evaluate the petitions for reconsideration, EPA moved for multiple abeyances of the consolidated petitions for review, and the consolidated cases are being held in abeyance until October 31, 2023.

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[84] "Review of the National Ambient Air Quality Standards for Particulate Matter," 85 Fed. Reg. 82,684 (Dec. 18, 2020)
[85] *See* 2022 Policy Assess. at 1-12.
[86] *See* 85 Fed. Reg. 82,717.
[87] 88 Fed. Reg. at 5579.

G. EPA's Current Reconsideration of the PM NAAQS

In June 2021, EPA granted the petitions for reconsideration and initiated this rulemaking process. As part of its review, EPA reanalyzed and updated the scientific available regarding the adequacy of the PM NAAQS. EPA updated the 2019 ISA with the 2022 ISA Supp., which includes a review of the most recent evidence available, including additional experimental studies conducted at near-ambient concentrations, epidemiologic studies employing alternative methods for confounder control or conducted accountability analyses, studies that assess the relationship between $PM_{2.5}$ exposure and COVID-19 death, and studies that examine disparities in $PM_{2.5}$ exposure and the risk of health effects. EPA also published a new Policy Assessment for the Reconsideration of the PM NAAQS ("2022 Policy Assess."), drawing directly from the 2019 ISA and 2022 ISA Supp. to analyze the policy implications of the new scientific evidence and quantitative analysis. Further, per the Clean Air Act's mandate, the expert CASAC panel evaluated the new material, and the majority determined, amongst other things, that in order to adequately protect the public health, EPA should reduce the primary annual $PM_{2.5}$ standard to 8.0 $\mu g/m^3$ and the 24-hour standard to 25-30 $\mu g/m^3$.

III. THE ADMINISTRATOR SHOULD ADOPT THE LOWEST STANDARDS CONSIDERED IN THE PROPOSED ACTION IN ORDER TO PROTECT THE PUBLIC HEALTH WITHIN THE ADEQUATE MARGIN OF SAFETY.

After reconsideration of the 2020 Final Rule, the Administrator proposes to strengthen the primary annual $PM_{2.5}$ standard, while leaving other standards in place. Specifically, EPA proposes to:

1. **Strengthen the primary annual $PM_{2.5}$ standard**, averaged over three years, from 12.0 $\mu g/m^3$ to between 9.0 to 10.0 $\mu g/m^3$, while taking comment on alternative annual standard levels down to 8.0 $\mu g/m^3$ and up to 11.0 $\mu g/m^3$;.

2. **Retain the current primary 24-hour $PM_{2.5}$ standard** with a 98th percentile form, averaged over three years, at a level of 35 $\mu g/m^3$, while taking comment on strengthening the level as low as 25 $\mu g/m^3$;

3. **Retain the current primary 24-hour PM_{10} standard**, without revision; and

4. **Retain the current secondary PM standards**, while taking comment on strengthening the level of the secondary 24-hour $PM_{2.5}$ standard as low as 25 $\mu g/m^3$.

88 Fed. Reg. at 5560.

This coalition previously urged EPA to adopt more health protective NAAQS based on the scientific evidence presented in order to meet the Clean Air Act's mandate.[88] Now, with even

[88] *See* Comments of the Attorneys General of New York, California, Illinois, Connecticut, Delaware, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, Oregon, Pennsylvania,

more proof of the serious health impacts from PM exposure, the disproportionate burden of those health impacts on communities with environmental justice concerns that will be reduced through lower thresholds, and the remainder of analysis presented, we urge EPA to adopt the lowest PM standards under consideration.

A. Given the Substantial Evidence in Support of Adopting the Most Protective Standards, the Clean Air Act Directs EPA to Adopt Those Standards Despite Whatever Limited Uncertainties Remain.

The Clean Air Act requires that primary NAAQS "protect the public health" with an "adequate margin of safety"—directing EPA to set standards low enough to *ensure* that the public health is protected.[89] In other words, EPA must "err on the side of caution" in favor of more protective standards when setting NAAQS.[90] While the totality of the evidence is overwhelming that the existing PM NAAQS should be made more protective, the Clean Air Act recognizes that some scientific uncertainty may always remain and requires that EPA strengthen the PM NAAQS even in the face of imperfect data. The Clean Air Act's unambiguous direction to not only broadly "protect the public health" but do so with an "adequate margin of safety" is specifically intended to address uncertainties at the time of establishing NAAQS associated with scientific and technical information available. Congress's "margin of safety" mandate is also intended to provide a reasonable degree of protection against potential unidentified hazards for which research has not yet been developed.[91] When establishing primary PM NAAQS that meet the Clean Air Act's requirements, EPA must seek to prevent pollution levels at which harm has been demonstrated but also to prevent harm at lower pollution levels for which "the risk is not precisely identified as to nature or degree."[92]

Challenges to insufficient public health standards have borne this out. As the D.C. Circuit has stated:

> Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect…. [I]n such cases, the Administrator may

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Rhode Island, Vermont, Virginia, Washington, and Wisconsin filed June 29, 2020, regarding the Review of the NAAQS for PM by the Administrator of the U.S. EPA ("2020 AG Comments"), 85 Fed. Reg. 24094 (Apr. 30, 2020); *see also* Comments of the City of New York filed June 29, 2020, regarding the Review of the NAAQS for PM by the Administrator of the U.S. EPA, 85 Fed. Reg. 24094 (Apr. 30, 2020).

[89] 42 U.S.C. § 7409(b)(1).

[90] *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980).

[91] 2022 Policy Assess. at 1-4*; see Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), *cert. denied*, 449 U.S. 1042 (1980); *Am. Petroleum Inst. v. Costle*, 665 F.2d at 1186 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982); *Coal. of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 617-18 (D.C. Cir. 2010); *Mississippi v. EPA*, 744 F.3d 1334, 1353 (D.C. Cir. 2013).

[92] *See* 2022 Policy Assess. at 1-4.

> assess risks… The Administrator may apply his expertise to draw conclusions from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as 'fact,' and the like.[93]

Here, given the overwhelming evidence supporting strengthening the PM NAAQS, EPA must not use the small number of remaining uncertainties identified to evade the Clean Air Act's mandate. To the extent uncertainty remains regarding the precise level of PM regulation necessary to create a standard that protects the public health within an adequate margin of safety, such uncertainty warrants a more, not less, protective standard.

B. EPA Should Set the Strongest PM NAAQS Under Consideration to Meet the Statutory Mandate to Protect Sensitive Populations.

EPA must consider the disparate impacts of PM exposure on susceptible populations—not simply the "average" person—when establishing PM NAAQS that adequately protect the public health and safety. The Clean Air Act requires that the NAAQS "must protect not only average healthy individuals, but also 'sensitive citizens'—children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution."[94] "If a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard."[95] The Clean Air Act's legislative history confirms Congress's intent for EPA to set primary standards at "the maximum permissible ambient air level… which will protect the health of any [sensitive] group of the population," and that for this purpose "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group."[96]

To this point, certain analysis conducted by EPA in this reconsideration—while useful for looking at the population as a whole—does not properly account for those most exposed to $PM_{2.5}$. For example, by using area mean values, the evaluation of the impacts from $PM_{2.5}$ exposure is likely underestimating those impacts on the people who live in areas with higher concentrations. While the area mean value is a useful tool for determining health effects for the "average" population as a whole, people who live in areas with concentrations higher than the mean may experience unequal health impacts when compared to the mean. Significantly, as

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[93] *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C. Cir. 1976); *Lead Industries Ass'n* v. *EPA,* 647 F.2d 1130, 1155 (D.C. Cir. 1980) ("[R]equiring EPA to wait until it can conclusively demonstrate that a particular effect is adverse to health before it acts is inconsistent with both the [Clean Air] Act's precautionary and preventive orientation and the nature of the Administrator's statutory responsibilities.").

[94] *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998); *see also Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 524 (D.C. Cir. 2009).

[95] *Am. Lung Ass'n*, 134 F.3d at 389.

[96] S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

outlined above, those populations are disproportionately non-White and low-income communities.[97]

EPA's recent findings related to regulating Mercury and Air Toxics Standards (MATS) under the Clean Air Act section 112 are illustrative for evaluating impacts on sensitive populations.[98] There, EPA specifically noted that the resulting human health impacts were disproportionately borne across certain populations, and that some of the most exposed populations are minority and/or low income individuals.[99] EPA's risk analysis accordingly considered not just the average exposure, but those of sensitive subpopulations, including studies looking at specific low-income, female, Black subsistence fishers in the Southeast, as well as indigenous fishers active near the Great Lakes. EPA should take a similar approach here when establishing a PM NAAQS that properly accounts for specific sensitive populations disproportionately impacted by PM exposure and protects their public health within the necessary margin of safety.

C. A Primary Annual $PM_{2.5}$ Standard of 8.0 µg/m^3 Is Requisite to Protect the Public Health with an Adequate Margin of Safety.

1. Evidence demonstrates that the primary annual $PM_{2.5}$ standard must be strengthened.

The coalition commends EPA for recognizing that the current primary annual $PM_{2.5}$ standard of 12.0 µg/m^3 is not adequate to protect public health, and for proposing that the standard be strengthened.[100] As set forth in the Proposed Rule, EPA "judges that the estimated risks remaining under air quality adjusted to just meet the current suite of standards are too high to be considered requisite to protect public health with an adequate margin of safety."[101]

The coalition agrees with this assessment. As many of the coalition members pointed out in their June 29, 2020, comment letter on EPA's proposed PM NAAQS rule, there is significant evidence and information demonstrating harms to human health at concentrations lower than the current NAAQS.[102] Prevalent and widely accepted scientific literature clearly shows adverse health impacts from $PM_{2.5}$ concentrations that meet current standards. The current standard therefore does not comply with the Clean Air Act requirement for EPA to make the primary

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[97] *See* CASAC Review Letter at 8.
[98] *See* 87 Fed. Reg. 7624 (Feb. 9, 2022), 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.
[99] 87 Fed. Reg. at 7647.
[100] 88 Fed. Reg. at 5623.
[101] *Id*.
[102] *See* 2020 AG Comments at 25; *see also* Supplemental Comments of the Attorneys General of New York, California, Connecticut, Delaware, Illinois, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, and Washington filed Nov. 20, 2020, regarding Docket ID No. EPA-HQ-OAR-2015-0072/ Supplemental Comments re. Particulate Matter Studies at 1-2.

NAAQS stringent enough to "protect the public health," with such protection including "an adequate margin of safety," and must be strengthened.[103]

Recent studies bolster the conclusion that the primary annual standard must be strengthened in order to protect public health. For example, the 2022 ISA Supp. finds an even more robust correlation between exposure to $PM_{2.5}$ and cardiovascular outcomes and mortality.[104]

Based on its updated review, EPA concludes that the "number and strength" of epidemiologic studies showing that $PM_{2.5}$ concentrations well below the current annual standard of 12.0 $\mu g/m^3$ lead to adverse health effects (particularly cardiovascular effects and mortality), call into question the adequacy of the current annual standard.[105] Recent United States and Canadian cohort studies, which found consistent and positive associations between long-term $PM_{2.5}$ exposures and mortality, reported mean annual $PM_{2.5}$ concentrations ranging from 5.9 to 11.65 $\mu g/m^3$ (i.e., well below the current annual standard of 12). EPA also recognizes that additional epidemiologic studies, including those examining the 25th percentile of data, accountability studies, and restricted analyses studies, which generally examine the impacts of $PM_{2.5}$ concentrations below the current annual standard, support the need to revise the annual standard level.[106] Furthermore, EPA recognizes that toxicological studies and controlled human exposure studies support the biological plausibility of the connection between long-term PM exposure and adverse health effects.[107]

EPA's proposal to strengthen the primary annual standard was unanimously supported by CASAC.[108] In CASAC's review of the policy assessment for the Proposed Rule, all CASAC members stated their agreement that "the current level of the annual standard is not sufficiently protective of public health and should be lowered."[109] CASAC also agreed that there are "large

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[103] 42 U.S.C. § 7409(b)(1).
[104] 2022 ISA Supp. at 3-54, 3-127.
[105] 88 Fed. Reg. at 5623.
[106] *Id*.
[107] *Id*.
[108] Courts have repeatedly cited the Administrator's reliance on scientific experts, and particularly those on its scientific advisory boards like the CASAC as a basis to uphold EPA actions. *See*, *e.g.*, *City of Portland v. EPA*, 507 F.3d 706, 716 (D.C. Cir. 2007) (upholding drinking water standard based on analysis of the "best available, peer-reviewed science" using advice from the Science Advisory Board); *Ohio Valley Envtl. Coal. v. Fola Coal Co.*, 120 F. Supp. 3d 509, 523 n.16 (S.D.W.V. 2015) (upholding EPA's assignment of benchmark discharge levels and noting that "not only are there epidemiologists on the Science Advisory Board, there are some very fine epidemiologists serving in that capacity"); *United States v. Vertac Chem. Corp.*, 33 F. Supp. 2d 769, 778 (E.D. Ark. 1998), *rev'd on other grounds by United States v. Hercules, Inc.*, 247 F.3d 706 (8th Cir. 2001) (upholding EPA's cleanup level calculations at Superfund site based in part on review by Science Advisory Board).
[109] CASAC Review Letter at 2 (Sheppard cover letter).

populations at risk of $PM_{2.5}$ health effects," and that the evidence shows disparities in risk across population groups.[110]

New evidence from the States also strongly supports the conclusion that the current annual primary $PM_{2.5}$ should be strengthened:

- In Massachusetts, in 2019 alone $PM_{2.5}$ pollution—at a mean concentration of 6.3 $\mu g/m^3$—was responsible for approximately 2,780 adult deaths, including more than 1,600 from cardiovascular disease and 2,185 from lung cancer. That same year, among children $PM_{2.5}$ pollution was responsible for more than 300 low-weight births, more than 15,000 asthma cases, and a provisionally estimated loss of nearly 2 million Performance IQ points.[111]
- A recent Sierra Club report estimates that $PM_{2.5}$ from coal-fired power plants alone results in 3,800 premature deaths each year, including 234 in New York, a state that no longer has any such plants.[112]
- New York City has generally attained the annual NAAQS for $PM_{2.5}$ of 12.0 $\mu g/m^3$ since 2011 and the 24-hour standard since 2009. At these levels, the New York City Department of Health and Mental Hygiene estimates, using widely accepted health impact assessment methods, that exposure to $PM_{2.5}$ resulted in over 3,700 asthma emergency department visits to NYC hospitals and 2,000 premature deaths per year between 2015 and 2017.[113]
- A cohort study of 3.7 million adults in California demonstrated that long-term $PM_{2.5}$ exposure at 10.0 to 11.9 $\mu g/m^3$, compared with $PM_{2.5}$ exposure at below 8 $\mu g/m^3$, increased the risk of inpatient hospitalization for acute myocardial infarction by 6%, and increased the risk of ischemic heart disease mortality by 7%.[114]
- In New Jersey, the annual primary $PM_{2.5}$ concentration has decreased from 2001 to 2020 from 15.8 ug/m^3 to 9.6 ug/m^3.[115] High levels of $PM_{2.5}$ can trigger asthma in children.

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[110] *Id*.

[111] Landrigan, et al., *A replicable strategy for mapping air pollution's community-level health impacts and catalyzing prevention*, 21 ENVIRON. HEALTH 70 (July 2022), https://doi.org/10.1186/s12940-022-00879-3.

[112] Sierra Club, Out of Control: the Deadly Impact of Coal Pollution at 1 (Feb. 2023), https://coal.sierraclub.org/sites/nat-coal/files/Out%20of%20Control%20coal%20mortality%20report%20FINAL.pdf.

[113] Health impact analysis using 2015-2017 regulatory $PM_{2.5}$ data and NYC-specific baseline health data to calculate health impacts due to $PM_{2.5}$ levels in NYC. Environment and Health Data Portal, available at: Health impacts of air pollution: data for NYC | Environment & Health Data Portal.

[114] Alexeeff, et al., *Association of long-term exposure to particulate air pollution with cardiovascular events in California*, JAMA NETW. OPEN (Feb. 2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9958530/.

[115] New Jersey Department of Environmental Protection, Air Quality, Energy & Sustainability: Fine Particulate ($PM_{2.5}$) Air Concentrations (ug/m^3) in New Jersey - Highest Annual Averages, last updated March 7, 2023, https://nj.gov/dep/airmon/criteria-pollutants.html.

Children with asthma in New Jersey make up nearly 20,000 emergency department visits every year.[116]

- The District of Columbia has attained the annual NAAQS for $PM_{2.5}$ of 12 $\mu g/m^3$ since 2010 and the 24-hour standard since 2007. Despite this, data from 2018 shows that there were over 100 $PM_{2.5}$ attributable deaths in the District.[117] In that year, the District's annual $PM_{2.5}$ design value was 9 $\mu g/m^3$.

In light of this evidence, EPA is required to strengthen the primary annual standard in order to adequately protect public health.

2. Lowering the primary annual $PM_{2.5}$ standard to 8.0 $\mu g/m^3$ is necessary to protect sensitive populations and reduce existing disparities in PM exposure and health impacts.

The primary annual standard should be strengthened to 8.0 $\mu g/m^3$ to reduce the racial and ethnic disparities between PM exposure and health impacts. EPA analyzed the anticipated health impacts in 47 different study areas at the proposed primary $PM_{2.5}$ standards of 11.0 $\mu g/m^3$, 10.0 $\mu g/m^3$, 9.0 $\mu g/m^3$, and 8.0 $\mu g/m^3$. In all 47 areas, Black populations already experience the highest average $PM_{2.5}$ concentrations of all demographic groups.[118] And—across all proposed primary standards—Black populations will *still* be associated with the highest levels of $PM_{2.5}$ attributable mortality risks of all groups.[119] But lowering the primary $PM_{2.5}$ standard to 8.0 $\mu g/m^3$ will reduce the disparity in PM exposure among different ethnic groups. EPA's analysis found that both Black and other minority populations will experience proportionally the greatest reduction in PM exposure and reduction in mortality risk health in absolute terms from each successive reduction in the primary annual standard.[120] However, at 8.0 $\mu g/m^3$, the lowest alternative standard evaluated, EPA finds that, while disparities in mortality risk remain, disparities in exposure are "*virtually eliminated*."[121] By setting the primary annual $PM_{2.5}$ standard at 8.0 $\mu g/m^3$, EPA will take significant steps toward reducing the disproportionate PM burden borne by communities of color.

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[116] New Jersey Department of Health, State Health Assessment Data: *Tracking Air Quality and Asthma in New Jersey's Children*, July 2014, https://www.nj.gov/health/ceohs/documents/epht/tra_action/helping_children_breathe_easier.pdf?_gl=1*1qtu2dw*_ga*ODkxNDk3MjgyLjE2Nzk1ODMwMzg.*_ga_5PWJJG6642*MTY3OTU4MzAzNy4xLjEuMTY3OTU4Mzk3OC4wLjAuMA.

[117] Castillo, et al., *Estimating intra-urban inequities in $PM_{2.5}$-attributable health impacts: a case study for Washington, DC*, GEOHEALTH (Nov. 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8574205/.

[118] 88 Fed. Reg. at 5616; *See* 2022 Policy Assess. at 3-156-64.

[119] *Id*.

[120] 2022 Policy Assess. at 3-160.

[121] 2022 Policy Assess. at 3-162 [emphasis added].

3. The coalition encourages EPA to strengthen the primary annual $PM_{2.5}$ standard to 8.0 $\mu g/m^3$.

Although EPA's proposal to lower the primary annual $PM_{2.5}$ standard to between 9.0 $\mu g/m^3$ to 10.0 $\mu g/m^3$ is an important step, the evidence—including significant evidence introduced in this reconsideration—supports strengthening the standard to 8.0 $\mu g/m^3$ in order to protect public health with an adequate margin of safety. As EPA recognizes, the evidence consistently supports a "no-threshold relationship" and a "linear relationship" for $PM_{2.5}$ concentrations greater than 8.0 $\mu g/m^3$, meaning that one can expect a consistent decrease in negative health effects as $PM_{2.5}$ concentrations are lowered, at least until concentrations reach a level of 8.0 $\mu g/m^3$.[122] In fact, "studies have *not* identified a threshold concentration, below which associations no longer exist."[123]

Meeting a revised annual standard is estimated to reduce $PM_{2.5}$-associated health risks by about 7-9% for a level of 11.0 $\mu g/m^3$, 15-19% for a level of 10.0 $\mu g/m^3$, 22-28% for a level of 9.0 $\mu g/m^3$, and 30-37% for a level of 8.0 $\mu g/m^3$.[124] Additionally, studies reported in the Regulatory Impact Analysis estimate that lowering the annual $PM_{2.5}$ standard to 10.0 $\mu g/m^3$ would result in avoiding between 810 to 1,700 deaths per year, whereas revising the standard to 8.0 $\mu g/m^3$ would result in avoiding 4,400 to 9,200 deaths per year.[125] Strengthening the annual standard from 10.0 $\mu g/m^3$ to 8.0 $\mu g/m^3$ is also projected to avoid hundreds of hospital admissions and thousands of emergency room visits for cardiovascular and respiratory illnesses each year.[126]

Moreover, ample epidemiologic studies demonstrate a causal connection between $PM_{2.5}$ exposures at or near 8.0 $\mu g/m^3$ and mortality. For example, a U.S. study found that long-term $PM_{2.5}$ exposures were "significantly associated with all-cause mortality" among a Medicare cohort, "even when restricted to ZIP codes and times with annual exposures below 10.0 $\mu g/m^3$.[127] Notably, the study found a linear association between long-term $PM_{2.5}$ and mortality above 6.0 $\mu g/m^3$.[128] The study authors concluded that "the adverse health effects of $PM_{2.5}$ are at least retained, if not strengthened, at low levels of exposure."[129] Another study, published just this month and based on an analysis of more than 73 million Medicare enrollees, confirms that lowering $PM_{2.5}$ exposure from 12.0 $\mu g/m^3$ to 6.0 $\mu g/m^3$ is associated with an approximately linear decrease in mortality risk.[130] The study demonstrates that lower $PM_{2.5}$ levels, at 8.0 $\mu g/m^3$,

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[122] 88 Fed. Reg. at 5625.
[123] *Id*. (emphasis added).
[124] 88 Fed. Reg. at 5607 (citing 2022 Policy Assess., Table 3-17).
[125] *See* EPA, Regulatory Impact Analysis for the Proposed Reconsideration of the National Ambient Air Quality Standards for Particulate Matter, 5-34 (Dec. 2022).
[126] *Id*.
[127] Shi, et al., *Low-concentration $PM_{2.5}$ and mortality: estimating acute and chronic effects in a population-based study*, 124 ENVIRON. HEALTH PERSPECT. 4652 (2016), doi: 10.1289/ehp.1409111, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4710600/.
[128] *Id*.
[129] *Id*.
[130] Josey, et al., *supra*, at 7.

would decrease mortality risk for "all aging Americans, regardless of racial identity or socioeconomic position."[131]

Studies also demonstrate an association between long-term exposure to $PM_{2.5}$ at low concentrations, and cardiovascular disease. For example, a recent cohort study including over 30 million Medicare participants found strong associations between long-term $PM_{2.5}$ exposure and atrial fibrillation, congestive heart failure, and stroke (the fifth leading cause of death in the U.S.), at a $PM_{2.5}$ level as low as 8.0 $\mu g/m^3$.[132] Additionally, the study found "no sign of a threshold of air pollution's health effects and that there are greater marginal benefits to further reducing air pollution."[133] This study also adds to the evidence that Black populations are more susceptible to the adverse effects of air pollution, to which those populations already have higher exposure levels.[134]

In the Proposed Rule, EPA states that there is "relatively sparse data available at the lower end of the air quality distribution" and that there is a limited number of epidemiologic studies that report data from the 25th percentile (i.e., lowest quartile) of concentrations.[135] In proposing to lower the annual $PM_{2.5}$ standard to between 9.0 $\mu g/m^3$ and 10.0 $\mu g/m^3$, EPA focuses on several U.S. epidemiologic studies finding associations between $PM_{2.5}$ and negative health outcomes, and notes that the monitor-based studies reported mean concentrations ranging from 9.9-16.5 $\mu g/m^3$, and the hybrid modeling studies reported mean concentrations ranging from 9.3-12.2 $\mu g/m^3$.[136] Then, EPA states that, in a given area, the area design value is determined by the monitor reporting the highest $PM_{2.5}$ concentrations, and that $PM_{2.5}$ concentrations will generally be equal or lower at other monitors in the area.[137]

EPA finds that the annual $PM_{2.5}$ standard, which must be met by design value monitors (again, those that report the highest $PM_{2.5}$ concentrations in a given area), can be set 10-20% *higher* than the epidemiologic study-reported means for an entire area, and still "generally limit air quality exposures to levels well below" the mean values reported in the key epidemiologic studies.[138] In other words, EPA determined that setting the annual $PM_{2.5}$ standard at a level 10-20% higher than the level at which health impacts have been found would protect human health in most areas, which typically have lower PM levels than those reported by area design monitors. Because the lowest reported mean values in these key studies are approximately 9.3 $\mu g/m^3$ to 9.9

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[131] *Id*.
[132] Jin, et al.*, Associations between long-term air pollution exposure and the incidence of cardiovascular diseases among American older adults*, 170 ENVIRONMENT INTERNATIONAL 107594 (Dec. 2002), https://doi.org/10.1016/j.envint.2022.107594.
[133] *Id*.
[134] *Id*.
[135] 88 Fed. Reg. at 5623, 5625.
[136] 88 Fed. Reg. at 5626. Monitor-based studies use monitoring data from ground-based monitors to estimate $PM_{2.5}$ concentrations, while hybrid modeling studies use complex modeling to broaden the spatial coverage by expanding beyond areas with monitors and providing estimates in areas that do not have ground-based monitors. *Id.* at 5572.
[137] *Id*. at 5626.
[138] *Id*.

$\mu g/m^3$, EPA proposes that a revised standard level of 9.0 to 10.0 $\mu g/m^3$ would generally limit air quality exposures to levels well below those associated with the study-reported mean $PM_{2.5}$ concentrations in these epidemiologic studies.[139]

There are at least three problems with EPA's reasoning. First, EPA's explanation is based solely on the mean concentrations reported in the major *U.S.* studies and leaves out Canadian studies evaluating mean $PM_{2.5}$ concentrations that are significantly lower than those considered in these U.S. studies.[140] The studies based in Canada (where ambient $PM_{2.5}$ concentrations are generally much lower than in the United States), include means ranging as low as 6.9-13.3 $\mu g/m^3$ for the monitor-based studies, and 5.9-9.8 $\mu g/m^3$ for the hybrid model-based studies.[141] The majority of the CASAC pointed to the Canadian studies as supporting their recommendation to revise the annual standard level to within the range of 8.0-10.0 $\mu g/m^3$.[142] But, although EPA refers to the Canadian studies as having some value, EPA excludes the mean $PM_{2.5}$ values reported in the Canadian studies from EPA's explanation of why the primary annual standard is proposed to be set at 9.0-10.0 $\mu g/m^3$.

The Proposed Rule does not sufficiently explain its considering the U.S. reported means and excluding the Canadian means. In the 2022 Policy Assessment, EPA states that challenges are present in using information from Canadian studies to directly inform the level of the annual standard, because of the difficulty of interpreting what the Canadian study means represent relative to U.S. design values.[143] However, one of the most salient points regarding the Canadian studies is that they demonstrate that negative health outcomes exist at $PM_{2.5}$ concentrations even lower than 8.0 $\mu g/m^3$. For example, the Crouse study found a relationship between $PM_{2.5}$ at concentrations of 6.24 to 7.98 $\mu g/m^3$ and mortality; the Pinault study found a relationship between $PM_{2.5}$ at a mean concentration of 7.4 $\mu g/m^3$ and mortality and cardiovascular disease.[144] These findings, in and of themselves, can directly be translated into a $PM_{2.5}$ annual standard. As the CASAC states, the Canadian epidemiologic studies identify health associations with area averages, "and while there may be no design value in Canada, there are data that indicate what a

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[139] *Id*. at 5628.

[140] 2022 ISA Supplement at A-26-27, citing Crouse, et al., *Evaluating the sensitivity of $PM_{2.5}$-mortality associations to the spatial and temporal scale of exposure assessment*, EPIDEMIOLOGY (2020), https://pubmed.ncbi.nlm.nih.gov/31693516/ (finding a relationship between outdoor $PM_{2.5}$ and mortality at concentrations ranging from 6.24 $\mu g/m^3$ to 7.98 $\mu g/m^3$) and Pinault, et al., *Associations between fine particulate matter and mortality in the 2001 Canadian Census Health and Environment Cohort*, 159 ENVIRONMENTAL RESEARCH 406-415 (2017), https://doi.org/10.1016/j.envres.2017.08.037 (finding associations between $PM_{2.5}$ with a mean ambient concentration of 7.4 $\mu g/m^3$ and mortality and cardiovascular disease); *see also*, Zhang et al., *Long-term exposure to air pollution and mortality in a prospective cohort: The Ontario Health Study*, ENV. INT'L. 154 (2021) at 4, https://doi.org/10.1016/j.envint.2021.106570 (finding association between $PM_{2.5}$ at a mean concentration of 7.8 $\mu g/m^3$ and cardiovascular and respiratory mortality).

[141] 88 Fed. Reg. at 5627.

[142] CASAC Review Letter at 16.

[143] 2022 Policy Assess. at 3-187-88.

[144] 2022 ISA Supp. at A-26-27.

U.S. design value would be if an area average like that found in the Canadian studies were to occur in the U.S."[145] So, for example, since there is evidence that $PM_{2.5}$ at concentrations in the range of 6.24 to 7.98 $\mu g/m^3$ results in mortality, if the reported 10-20% difference between design value monitors and general area concentrations in the U.S. were applied, the U.S. primary annual $PM_{2.5}$ standard would need to be set at 8.0 $\mu g/m^3$ in order to protect general public health with an adequate margin of safety. It is not relevant that there are no Canadian design values; EPA can still apply the epidemiologic evidence to determine U.S. design values.

Second, EPA gave too much emphasis to the mean $PM_{2.5}$ concentrations reported in the key U.S. epidemiologic studies, and does not give enough weight to what the studies tell us with respect to the entire range of $PM_{2.5}$ concentrations. As the majority of the CASAC has asserted, "using mean $PM_{2.5}$ concentrations from epidemiologic studies is not the only way to estimate where any or the bulk of health effects are observed in these studies."[146] Indeed, the CASAC states that "there is an over reliance on the mean $PM_{2.5}$ concentration of a study as defining where findings are most robust. Epidemiologic studies require consideration of distribution around the mean of exposure to identify effects and thus lower levels than the mean must be considered as part of the range where the data provide higher confidence."[147] Instead, EPA could evaluate the "distribution of concentrations reported in epidemiology studies, including the median concentration and 25th percentile concentration, if available," or evaluate results from analyses excluding concentrations above the current standard.[148] As aptly put by one of the members of the CASAC, "[i]f there is enough data in lower ranges that indicate an effect there, then the fact that other study settings don't have such low levels is irrelevant."[149] While EPA does consider data representing lower concentrations in the Proposed Rule, it still gives the most weight to the mean concentrations reported in U.S. epidemiologic studies in its proposal for the primary annual standard, and not enough weight to lower concentrations where mortality and other adverse health outcomes are still found.

Third, the coalition disagrees with EPA's proposal to consider setting the $PM_{2.5}$ standard at 10-20% higher than the mean concentrations reported in epidemiologic studies. EPA bases this proposal on the consideration that design value monitors report concentrations that are higher than general area concentrations. This proposal, however, would give substantially less protection to those living near the area design value monitors where $PM_{2.5}$ levels may be highest, or to those who live in areas that do not have ground monitors but have concentrations higher than the design or mean value. Using this method to determine the primary annual standard would be especially pernicious because, as the CASAC observes, "people exposed to these higher concentrations are often disproportionately persons of color and lower-income populations. Therefore, tying standards to the area mean value [rather than to the design value monitors] is not providing adequate protection to the entire population."[150] EPA's proposed method also would be inconsistent with the requirement that the NAAQS protect sensitive

[145] CASAC Review Letter at 13-14.
[146] *Id*. at 8.
[147] *Id*. at 13.
[148] *Id*. at 8.
[149] *Id*. at A-93 (comments of Dr. Marc Weisskopf).
[150] *Id*. at 8-9.

individuals, such as those living near area design value monitors and who therefore have already had long-term exposure to the highest area $PM_{2.5}$ concentrations. These "localized" and "site-specific" health effects still represent a public health problem, and must be considered when setting $PM_{2.5}$ levels.[151]

Given that EPA's charge to establish a primary standard at a level that reduces risk sufficiently to "protect public health, including the health of sensitive groups, with an adequate margin of safety," and the compelling evidence that adverse health outcomes exist at $PM_{2.5}$ concentrations below 9.0 $\mu g/m^3$, it is legally necessary for EPA to set the primary annual standard at 8.0 $\mu g/m^3$. And—as noted above—to the extent that uncertainties exist, "the requirement to provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards that research has not yet identified."[152] In other words, where there is uncertainty, the margin-of-safety requirement mandates more protective standards to guard against "effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement."[153]

Setting the primary annual $PM_{2.5}$ standard at 8.0 $\mu g/m^3$ would appropriately take the most recent epidemiologic evidence into account, and fulfill EPA's statutory responsibility to protect public health with an adequate margin of safety.

D. The Existing 24-Hour $PM_{2.5}$ Standard Should Be Lowered to Protect Public Health with an Adequate Margin of Safety

1. Setting a stronger primary 24-hour PM NAAQS is critical to protecting disproportionately impacted communities.

Frontline communities—those communities in which sources of PM are clustered—are disproportionately exposed to acute, short-term $PM_{2.5}$ exposure measured by the 24-hour primary standard. The purpose of the 24-hour NAAQS standard is to protect populations against "peak" or acute exposure to bursts of short-term PM pollution that can occur in areas with strong contribution from local or seasonal sources.[154] Lowering the 24-hour primary NAAQS standard

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[151] *American Lung Ass'n v. EPA*, 134 F.3d 388, 392 (D.C. Cir. 1998) (EPA must explain any decision not to provide national regulations to protect the health of 41,500 exposed asthmatics in at least six community "hot spots," where repeated bursts of peak sulfur dioxide concentrations occur).

[152] 88 Fed Reg. at 5617.

[153] *Lead Industries Ass'n,* 647 F.2d at 1154; *see also Envtl. Defense Fund v. EPA*, 598 F.2d 62, 81 (D.C. Cir. 1978) (explaining the term "margin of safety" is originally an engineering term "meant to compensate for uncertainties and variabilities in design, materials workmanship, and so forth," and that Congress' borrowing of the term was meant "to take into account and compensate for uncertainties and lack of precise predictions in the area of forecasting the effects of…pollutants").

[154] *See* 2022 Policy Assess. at 3-70.

is necessary to protect these sensitive populations from serious health impacts associated with short-term $PM_{2.5}$ exposure.

Recent studies have confirmed that environmental justice communities experience more frequent acute peaks of $PM_{2.5}$ exposure the 24-hour standard is intended to protect against. In a study assessing fine-scale estimates of 48-hour average $PM_{2.5}$ concentrations across three timeframes in Salt Lake City, Utah, people of color were consistently exposed to higher short-term $PM_{2.5}$ concentrations.[155] Another study, also conducted in Salt Lake City, found that a composite measure of social disadvantage (considering racial and ethnic groups and social-economic status) was associated with more days at or above the 95 percentile of 24-hour $PM_{2.5}$ exposure.[156]

A decision not to lower the existing 24-hour standard to between 25-30 $\mu g/m^3$ fails to address these disparities. As the CASAC noted, while disparities amongst racial and ethnic groups were a significant focus of the annual standard review, the disparities and consideration of risks associated with short term $PM_{2.5}$ exposure should be given "more attention" to future PM NAAQS review.[157] Further, while EPA concludes that the risk reductions associated with lowering the 24-hour standard are smaller than those achieved through lowering the annual standard, such a demonstration is not evidence that the existing 24-hour standard adequately protects the population within an adequate margin of safety and should not be reduced to levels supported by the most recent evidence.[158]

2. Monitoring and scientific studies support strengthening the current 24-hour standard.

As the majority of the experts on the CASAC found, current evidence supports strengthening the current 24-hour standard to 25 to 30 $\mu g/m^3$ in order to adequately protect the public health within the necessary margin of safety. Frontline communities throughout the nation continue to be exposed to ambient short-term $PM_{2.5}$ concentrations that far exceed the current 24-hour standard of 35 $\mu g/m^3$. Based on the form of the standard, a three-year average of the 98^{th} percentile, the average 24-hour $PM_{2.5}$ concentration for the nation was 21.3 $\mu g/m^3$ between 2017 and 2019, an increase over the 20.9 $\mu g/m^3$ average previously analyzed between 2015 and 2017.[159] However, ambient concentrations during this period ranged from 14.0 $\mu g/m^3$ to 29.7 $\mu g/m^3$, and ambient concentrations between 2015 and 2017 ranged from 9.2 $\mu g/m^3$ up to 111 $\mu g/m^3$.[160] The parts of the country with concentrations above the current standard are located predominately in California's Central Valley and the Pacific Northwest.[161] While much of the

[155] Collins, et al., *supra*, at 2.
[156] *Id*.
[157] CASAC Review Letter at 2 (Sheppard cover letter).
[158] *See* 88 Fed. Reg. at 5615.
[159] 2022 Policy Assess. at 2-28; *see also* 2020 Policy Assessment at 2-26.
[160] *Id*.
[161] 2022 Policy Assess. at 2-29, Figure 2-15.

country has experienced significant declines in short-term exposure to ambient PM over the last 20 years, these particular areas have experienced no such changes since 2000.[162]

Both the 2019 ISA and the 2022 ISA Supp. concluded that the most recent studies conducted across the United States, Canada, Europe, and Asia all continue to provide consistent correlations between high exposure to short-term $PM_{2.5}$ and mortality.[163] Despite EPA not lowering the 24-hour standard since 2009, EPA has concluded that the evidence connecting short-term $PM_{2.5}$ exposure to health effects is substantially stronger than it was then.[164] Recent evidence has strengthened the conclusion that short-term exposure to $PM_{2.5}$ increases total mortality.[165] Recent evidence also further confirms and adds support to EPA's prior conclusion of a causal relationship between short-term $PM_{2.5}$ exposure and cardiovascular effects.[166] New studies examining the link between short-term $PM_{2.5}$ exposure and respiratory impacts, including asthma and COPD, have also strengthened the correlation between these ailments and $PM_{2.5}$. New studies also suggest there is a relationship to metabolic and nervous system effects, whereas in 2009, there was no such evidence.[167]

Critically, multiple studies have demonstrated negative health impacts below the current 35 $\mu g/m^3$ standard, warranting a lower threshold. EPA's review of the evidence shows that "positive and statistically significant associations" with mortality and short-term exposure to $PM_{2.5}$ persist at concentrations as low as 25 $\mu g/m^3$.[168] This includes multi-city studies documenting associations between mortality and average 24-hour $PM_{2.5}$ concentrations 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).[169] Lee, et al. (2015) also report that positive and statistically significant associations between short-term $PM_{2.5}$ exposures and mortality persist in analyses restricted to areas with long-term concentrations below 12.0 $\mu g/m^3$. This evidence indicates that strengthening the 24-hour standard is necessary to protect the public health of individuals that might be located in areas of attainment for the primary annual PM standard.

In line with these findings, EPA estimates that air quality meeting the current 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ would still cause 2,570 deaths annually within a subset of 11 urban study areas populated by over 11 million individuals where the 24-hour standard is currently controlling, and that lowering the standard to 30 $\mu g/m^3$ would reduce the estimated risk by 9 to 13 percent.[170]

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[162] *Id.*
[163] 2022 Policy Assess. at 3-27; 2022 ISA Supp. section 3.2.1.2; 2019 ISA section 1.4.1.5.1.
[164] 2022 Policy Assess. at 3-26-30.
[165] 2022 Policy Assess. at 3-30.
[166] *Id*.
[167] *Id*. at 3-45.
[168] *Id*. at 3-30.
[169] *Id*.
[170] 2022 Policy Assess. at 3-155.

3. Limitations on certain studies examining short-term $PM_{2.5}$ must be appropriately considered.

EPA's reliance on human clinical studies to support a decision not to strengthen the $PM_{2.5}$ 24-hour standard is misplaced. While these studies are critically important to understanding the health impacts on human from short-term $PM_{2.5}$ standards, inherent factors involved in human health studies should not be misconstrued to conclude that the current 24-hour standard is adequate to protect public health. For example, EPA recognizes that human health studies have demonstrated serious health risks when humans are exposed to short-term $PM_{2.5}$, particularly cardiovascular effects including impaired vascular functions.[171] However, EPA subsequently notes that the concentrations used in these human health studies typically do not occur in locations that meet the current standards, "thus suggesting that the current primary $PM_{2.5}$ standards provide protection against these 'peak' concentrations."[172]

Such a conclusion overstates the implication of these studies. While it is accurate that several human exposure studies include concentrations significantly higher than the current 35 $\mu g/m^3$ 24-hour standard, such studies have limitations that must be considered. First, human studies of short-term PM exposure typically include relatively short exposure durations of only 2 to 4 hours, far shorter than the 24-hour standard being evaluated to protect the public health. In light of the increased incidences of short-term peak exposures in recent years, the underlying assumption that the 24-hour standard adequately controls for short-term effects of peak exposures embedded within that timeframe is overstated. 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 PM2.5 exposures.[173] EPA must consider this adjustment when ensuring that a 24-hour standard adequately protects against shorter-term "peak" exposures.

Further, the short-term controlled-human studies relied upon exclude the types of sensitive individuals that the NAAQS must protect.[174] These studies of $PM_{2.5}$ short-term exposure rely upon subjects who are healthy, or at most have mild health issues. Children, the elderly, and other frail or sensitive individuals are purposefully excluded, meaning that these studies are not representative of the population EPA must consider in establishing NAAQS. As the majority of the CASAC agreed, for these reasons "absence of an effect at a given concentration in controlled human exposure studies should not be interpreted to represent a no-effect threshold in the 'real world.'"[175]

E. Reductions in PM Exposure Are Critical to Combating the Ongoing Impacts of the COVID-19 Pandemic.

EPA also must consider the beneficial health impacts of reducing PM exposure on managing the COVID-19 pandemic. While the nation continues to manage the COVID-19

[171] 2022 Policy Assess. at 3-205.
[172] *Id*.
[173] *Id*.
[174] See 2022 Policy Assess. at 3-64.
[175] CASAC Review Letter at 7.

pandemic and balance the risks and impacts from the respiratory illness, COVID-19 continues to dramatically impact the health of the American population. Over 170,000 people are estimated to be infected with COVID-19 each week, with 1,800 dying from the illness. For over three years, the COVID-19 pandemic has proven to contribute to significant respiratory impacts nationwide. A body of evidence has now been established that reducing exposure to PM is necessary to reduce the health impacts PM exacerbates in the on-going COVID-19 pandemic.

The 2022 ISA Supp. evaluated several studies examining the relationship between $PM_{2.5}$ exposure and COVID-19 infections and death, but found that while initial evidence points to positive associations between the two, significant uncertainties remain.[176] Evidence regarding the evolving COVID-19 pandemic continues to develop, but studies already demonstrate that exposure to high levels of PM is correlated with severe illness from COVID-19, as well as death. EPA must appropriately consider this health impact when establishing NAAQS that adequately protect the public health within the necessary margin of safety.

A recent comprehensive review of dozens of COVID-19 studies found both long-term and short-term exposure to $PM_{2.5}$ was associated with higher COVID-19 incidence and mortality.[177] In another recent study of patients impacted with the Delta variant of COVID-19, strong links were established between short-term exposure to PM and severe COVID-19 health impacts.[178] Researchers found that increases in both $PM_{2.5}$ and PM_{10} significantly increased the risk of severe COVID-19 impacts.

Another study looked at the impacts of long-term exposure to PM on COVID-19 related health impacts and found that such exposure was a more important variable than other comorbidities, including those already suffering from respiratory illness like asthma and COPD, as well as diabetes and obesity.[179] The results found that an increase of 1 $\mu g/m^3$ in long-term exposure to PM_{10} means an increase of 3.06% of patients suffering severe COVID-19, as well as an increase of 2.68% of the number of deaths.

Evidence also points to PM exposure disproportionately exacerbating the impacts from "long-COVID," an illness from which an estimated 7.5% of adults in America suffer.[180] Long

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[176] 88 Fed. Reg. at 5590-5591; *see* 2022 ISA Supp. section 3.3.2.1.
[177] Zang, et al., *Ambient air pollution and COVID-19 risk: Evidence from 35 observational studies*, 204 ENVIRONMENTAL RESEARCH 112065 (2022), https://doi.org/10.1016/j.envres.2021.112065.
[178] Li et al., *Effects of short-term ambient particulate matter exposure on the risk of severe COVID-19*, 84 JOURNAL OF INFECTION 684-691 (2002), https://doi.org/10.1016/j.jinf.2022.01.037.
[179] Marqués, et al., *Long-term exposure to PM_{10} above WHO guidelines exacerbates COVID-19 severity and mortality*, 158 ENVIRONMENT INTERNATIONAL 106930 (2002), https://doi.org/10.1016/j.envint.2021.106930.
[180] CDC/National Center for Health Statistics, Nearly One in Five American Adults Who Have Had COVID-19 Still Have "Long COVID," (2022) https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/20220622.htm; *see also*

COVID typically lasts over two months and causes a wide range of serious effects, including difficulty breathing, extreme fatigue, fever or feeling feverish, altered sense of smell and taste, headache, high resting heart rate or palpitations, cognitive impairment, gastrointestinal problems, muscle weakness, neurological symptoms, mental illness, pain and sleep disorders. While evidence continues to evolve on this serious illness, a recent study of young adults found positive association between PM exposure and long COVID impacts.[181]

These studies show that reducing PM exposure is critical to protecting the population from severe COVID-19 illness. Yet EPA's analysis fails to adequately account for the additional COVID-19 related health impacts due to continued PM exposure or the public health benefits of reducing the PM NAAQS on the severity of COVID-19 cases.

F. EPA Must Properly Evaluate Strengthening the Primary PM_{10} Standard to Adequately Protect the Public Health

EPA's Proposed Rule will not strengthen the PM_{10} standard, leaving it at the threshold of 150 $\mu g/m^3$ with a 24-hour averaging time, the standard EPA established to protect the public health in 2006. EPA chose not to reevaluate the body of evidence on which the prior Administrator decided not to lower the PM_{10} standard, deciding not to update the 2019 ISA for PM_{10} in the 2022 ISA Supp.[182] Accordingly, EPA's decision that the current PM_{10} standards protect the public health and safety within an adequate margin of safety is based on evidence published through January 2018, not considering studies conducted within the last five years.[183] EPA reasons that because the 2019 ISA on which this record was based failed to conclude a causal relationship for $PM_{10-2.5}$ for any exposure durations or health effects categories, it need not update the prior review.[184]

EPA's conclusion not to lower the primary PM_{10} standards is based on a determination that the current standard adequately protects the public health within an adequate standard of review.[185] The primary PM_{10} standard is intended to provide public health protection from particles between PM_{10} and $PM_{2.5}$. As the CASAC noted, while uncertainties may remain, there is a "clear progression" in the evidence proving causality between $PM_{10-2.5}$ and a variety of health impacts, including increased mortality, cardiovascular effects, and cancer.[186] And despite EPA's decision not to evaluate the most recent evidence, new studies have demonstrated links between

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CDC/National Center for Health Statistics, Long COVID: Household Pulse Survey: https://www.cdc.gov/nchs/covid19/pulse/long-covid.htm.

[181] Yu, et al., *Ambient air pollution exposure linked to long COVID among young adults: a nested survey in a population-based cohort in Sweden*, THE LANCET REGIONAL HEALTH - EUROPE, 100608 (2023), https://doi.org/10.1016/j.lanepe.2023.100608.

[182] 88 Fed. Reg. at 5629.

[183] *Id*.

[184] *Id.* at 5630.

[185] 88 Fed. Reg. at 5629-30.

[186] CASAC Review Letter at 18.

exposure to $PM_{10-2.5}$ and respiratory impacts,[187] impacts to the nervous system,[188] and reproductive and developmental effects.[189] We urge EPA to properly consider the most recent scientific evidence in its decision to set NAAQS standards for PM_{10}.

IV. CONCLUSION

After years of advocating that EPA establish PM NAAQS that adequately protect the public health within the statutorily required margin of safety for sensitive populations, this coalition urges EPA to follow the most recent scientific evidence and promulgate a Final Rule for primary $PM_{2.5}$ standards that are the most protective under consideration—an annual $PM_{2.5}$ standard of 8.0 $\mu g/m^3$ and a 24-hour $PM_{2.5}$ standard of 25-30 $\mu g/m^3$.

Sincerely,

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[187] Kollath, et al., *PM_{10} and other climatic variables are important predictors of seasonal variability of coccidioidomycosis in Arizona,* MICROBIOLOGY SPECTRUM 10(2) (2022), https://doi.org/10.1128/spectrum.01483-21.
[188] Herrera-Molina, et al., *Associations between dust exposure and hospitalizations in El Paso, Texas, USA*, 12(11) ATMOSPHERE 1413 (2021), https://doi.org/10.3390/atmos12111413.
[189] Enders et al., *Exposure to coarse particulate matter during gestation and term low birthweight in California: Variation in exposure and risk across region and socioeconomic subgroup*, 653 SCI. TOTAL ENVIRON. 1435-44 (2018), https://doi.org/10.1016/j.scitotenv.2018.10.323.

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