October 10, 2023

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20004

**Re: Comment on EPA's Proposed Rule in the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (Docket #EPA–HQ–OAR–2015–0072; RIN 2060–AV52)**[1]

Dear Administrator Regan:

The undersigned health, medical, and nursing organizations offer the following comments on EPA's Proposed Rule in the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (PM NAAQS). We call on EPA to follow the science and the law and finalize a primary annual standard of 8 $\mu g/m^3$ and a primary 24-hour standard of 25 $\mu g/m^3$. We further call on EPA to update the form of the 24-hour standard to the 99$^{th}$ percentile. These updates are all critical for providing an adequate margin of safety to protect public health, especially of at-risk groups.

Our organizations have submitted several detailed written and oral comments in support of a primary annual fine particulate matter ($PM_{2.5}$) standard of 8 $\mu g/m^3$ and primary 24-hour standard of 25 $\mu g/m^3$. We have engaged throughout this entire PM NAAQS review process, including the

[1] Environmental Protection Agency (Jan 27, 2023). Reconsideration of the National Ambient Air Quality Standards for Particulate Matter. [EPA–HQ–OAR–2015–0072; FRL–8635–01– OAR]; Federal Register Vol. 88, No. 18

Clean Air Scientific Advisory Committee (CASAC) deliberations on the Integrated Science Assessment (ISA) and the Policy Assessment (PA), which started in 2021. These levels are not only supported by current science but are also within the recommended ranges of the large majority of the PM CASAC panel.

While the need to update the standards is clear, EPA's proposal falls short. In this rule, EPA acknowledges the inadequacy of current standards in protecting public health, but only to the extent of the annual standard. The agency proposes to revise the level of current annual standard from 12 $\mu g/m^3$ to within the range of 9-10 $\mu g/m^3$ calculated as an annual mean averaged over 3 years, but to retain the current level and form of the 24-hour standard of 35 $\mu g/m^3$ calculated at the 98$^{th}$ percentile averaged over 3 years. The proposed levels do not follow the science, do not meet the statutory requirement of the Clean Air Act to protect public health, and do not include an adequate margin of safety to protect vulnerable groups.

Here we provide additional details and rationale in support of our ask - that EPA issue a final rule that sets the primary annual standard at 8 $\mu g/m^3$ and a primary 24-hour standard of 25 $\mu g/m^3$. We further call on EPA to update the form of the 24-hour standard to the 99$^{th}$ percentile. Finally, we urge EPA to finalize this rule by August 2023.

**Submitted by:**

Allergy & Asthma Network
Alliance of Nurses for Healthy Environments
American Academy of Pediatrics
American Cancer Society
American Cancer Society Cancer Action Network
American College of Physicians
American Heart Association
American Lung Association
American Medical Association
American Public Health Association
Asthma and Allergy Foundation of America
Children's Environmental Health Network
Climate Psychiatry Alliance
Health Care Without Harm
Medical Society Consortium on Climate and Health
National Association of Pediatric Nurse Practitioners
National League for Nursing
Public Health Institute
The Michael J. Fox Foundation for Parkinson's Research

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## 1. Clean Air Act Requirements: Margin of Safety and Standard-Setting vs. Implementation

The Clean Air Act requires that the primary NAAQS be set at a level "requisite to protect the public health" with "an adequate margin of safety." 42 U.S.C. § 7409(b)(1). EPA must select a primary standard that is based on air quality criteria reflecting "the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air…" 42 U.S.C. § 7408(a)(2). In short, this means that EPA's standards must (1) protect public health and (2) provide an adequate margin of safety" in order to "3) prevent any known or anticipated health-related effects from polluted air.

In exercising their judgement, the EPA Administrator must err on the side of protecting public health and may not consider cost or feasibility. The U.S. Court of Appeals for the D.C. Circuit summed up EPA's mandate:

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

*American Lung Ass'n v. EPA,* 134 F.3d 388, 389 (D.C. Circ. 1998); see also *Whitman v. Am. Trucking Ass'ns,* 531 U.S. 457, 464-71 (2001).

EPA must err on the side of protecting public health when there is scientific uncertainty. Courts have properly characterized the NAAQS as "preventative in nature." *Ethyl Corp. v. EPA,* 541 F.2d1, 15 (D.C. Cir. 1976). The Act's mandate requires that in considering uncertainty, EPA must err on the side of caution in terms of protecting human health and welfare. The D.C. Circuit has held, "The Act requires EPA to promulgate protective primary NAAQS even where … the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree." *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 359 (D.C. Cir. 2002).

In keeping with the precautionary and preventative nature of the NAAQS, EPA must set a standard that protects against potential health effects – not just those impacts that have been well established by science. See *Am. Trucking Ass'ns,* 283 F.3d at 369 (citing Ozone NAAQS, 62 Fed. Reg. 38857 (section 109(b)(1)'s "margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information … as well as to provide a reasonable degree of protection against hazards that research has not yet identified"); see also *API v. EPA,* 684 F.3d 1342, 1352 (D.C. Cir. 2012.)

In a seminal NAAQS case, the D.C. Circuit found that Congress "specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." *Lead Indus. Ass'n v. EPA,* 647 F.2d 1130, 1154. Limited data are not an excuse for failing to establish the level at which there is an absence of adverse effect. To the contrary, "Congress' directive to the Administrator to allow an 'adequate margin of safety' alone plainly refutes any suggestion that the Administrator is only authorized to set the primary air quality standards which are designed to protect against health effects that are known to be clearly harmful." *Id.* at 1154-55.

The Clean Air Act's requirements also mean that implementation concerns, including costs and technical feasibility, have no place in the primary standard setting-process. The Supreme Court universally held that EPA may not consider implementation costs in setting the NAAQS. *Whitman v. Am. Trucking Ass'ns,* 531 U.S. 457, 464-71 (2001). The opinion cites an earlier Supreme Court case that held that "the most important forum for consideration of claims of economic and technological infeasibility is before the state agency formulating the implementation plan," *Union Elec. Co. v. EPA*, 427 U. S., at 266. Our organizations recognize that the implementation of the NAAQS will have important implications for all communities, including those seeking to mitigate the harm of catastrophic wildfire risk with the use of prescribed fire. We welcome EPA's work outside of the standard-setting process to further clarify how implementation of stronger PM NAAQS can work compatibly with the responsible use of prescribed fire as a tool to mitigate uncontrolled burns. However, EPA must not allow these or any other implementation issues to factor into the level of the NAAQS. To do so would violate the clear requirements of the Clean Air Act.

As we discuss below, to meet the Clean Air Act's requirements, EPA must finalize a primary annual standard of 8 $\mu g/m^3$ and a primary 24-hour standard of 25 $\mu g/m^3$ set at the 99$^{th}$ percentile.

## 2. Level of Primary Annual $PM_{2.5}$ NAAQS

EPA is proposing a primary annual $PM_{2.5}$ NAAQS of 9-10 $\mu g/m^3$ while taking comment on alternative annual standard levels down to 8.0 $\mu g/m^3$. Here we offer our analyses and rationale in support of this 8.0 $\mu g/m^3$ annual standard.

EPA's current reconsideration of the $PM_{2.5}$ NAAQS is a response to numerous petitions for review and for reconsideration of its decision on the 2020 review to retain the standards. In its own words, "(t)he EPA is reconsidering the December 2020 decision because the available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act. The EPA noted that the 2020 PA concluded that the scientific evidence and information called into question the adequacy of the primary $PM_{2.5}$ standards and supported consideration of revising the level of the primary annual $PM_{2.5}$ standard to below the current level of 12.0 $\mu g/m^3$ while retaining the primary 24-hour $PM_{2.5}$ standard (U.S. EPA, 2020a)."[2]

EPA's 2019 Integrated Science Assessment (ISA) concluded that breathing $PM_{2.5}$ causes premature death, cardiovascular harm, likely causes respiratory harm, likely causes cancer, likely causes nervous system harm and may cause reproductive and developmental harm.[3]

The 2019 CASAC panel had noted that the Integrated Science Assessment (ISA), which underlies the 2019 Draft PA, "does not provide a sufficiently comprehensive, systematic assessment of the available science relevant to understanding the health impacts of exposure to PM, due largely to a lack of a comprehensive, systematic review of relevant scientific literature; inadequate evidence and rationale for altered causal determinations; and a need for clearer discussion of causality and causal biological mechanisms and pathways."[4] Even with

[2] U.S. EPA, Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 10

[3] U.S. EPA, *Integrated Science Assessment (ISA) for Particulate Matter* (Final Report, 2019). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-19/188, 2019. Available at https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=347534

[4] Clean Air Scientific Advisory Committee (CASAC). (Dec 16, 2019). Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019); Report #: EPA-CASAC-20-001; page 1

these limitations, the 2019 CASAC panel concluded that the current annual standard set in 2012 was inadequate to protect public health.

Further, in 2020 an Independent Particulate Matter Review Panel composed of experts previously appointed to the CASAC review panel determined that the current standards are not protective of health. Relying on studies published since 2012 that show exposure to $PM_{2.5}$ causes premature death at concentrations below current standards, the panel concluded:

> US multicity epidemiological studies, supported by consistent results from Canadian multicity epidemiologic studies, consistent results from accountability studies, and coherent results from animal toxicological and controlled human exposure studies, provide clear and compelling scientific evidence that the current $PM_{2.5}$ standards are not adequate to protect human health. The epidemiological evidence is based on different locations, study designs, and statistical approaches, which enhances its robustness.[5]

In comments to EPA in 2020, national health and medical organizations noted that in addition to the clear evidence demonstrating the inadequacy of the current standards, no evidence exists of a threshold for harm from PM. We identified U.S. studies that restricted the analysis to long-term exposures below 10 $\mu g/m^3$ and Canadian studies that find evidence down to and below 8 $\mu g/m^3$; all found premature deaths at those lower levels.[6,7] A Medicare cohort study found mortality associated with levels as low as 7 $\mu g/m^3$.[8]

As noted in the 2021 petition for reconsideration filed by several health and environmental organizations, numerous additional studies that conducted after EPA's cutoff for inclusion in the ISA for the 2020 standards further underscore the importance down to 8 $\mu g/m^3$. For example, one study found that "estimated mean age at death for a population with an annual average $PM_{2.5}$ exposure of 12 $\mu g/m^3$ was 0.89 years less … than estimated for a counterfactual $PM_{2.5}$ exposure of 7.5 $\mu g/m^3$."[9] Another found for each 5 $\mu g/m^3$ increase in annual $PM_{2.5}$ concentrations, the hazard ratio was 1.13 for first hospital admission for Parkinson's disease

[5] Frey HC, Adams P, Adgate JL, et al. Advice from the Independent Particulate Matter Review Panel (formerly EPA CASAC Particulate Matter Review Panel) on EPA's policy assessment for the review of the National Ambient Air Quality Standards for particulate matter (external review draft — September 2019), submitted to Hon. Andrew Wheeler, Administrator, docket ID no. EPA–HQ–OAR–2015–0072, and Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency. Washington, DC: October 22, 2019 Accessed at https://yosemite.epa.gov/sab/sabproduct.nsf/81DF85B5460CC14F8525849B0043144B/%24File/Independent+Particulate+Matter+Review+Panel+Letter+on+Draft+PA.pdf

[6] Shi I., et al. 2016. Low Concentration PM2.5 and mortality; estimating acute and chronic effects in population-based study. *Environmental Health Perspectives*, 124(1)46-52.

[7] Szyszkowicz M. 2009. Air pollution and ED visits for chest pain, *American Journal of Emergency Medicine*. 27(2): 165-168; Steib DM, et al. 2009 Air pollution and emergency department visits for cardiac and respiratory conditions: A Multi-city time series analysis. *Environmental Health: A Global Science Access Source.* 8(25):25; Weichenthal S. et al. 2016; Ambient PM2.5 and risk of emergency room visits from myocardial infarction: Impact of regional PM2.5 oxidative potential: a case-crossover study. *Environmental Health*. 15:46.; Weichenthal et al., 2016.; PM 2.5 and emergency room visits for respiratory illness: effect modification by oxidative potential." *AJRCCM*. 194(5): 577-586.

[8] Di Q, Dai L, Wang Y, Zanobetti A, Choirat C, Schwartz JD, Dominici F. Association of Short-Term Exposure to Air Pollution with Mortality in Older Adults. JAMA. 2017;318:2446-2456.

[9] Schwartz et al., 2018. Estimating The Effects Of PM2.5 On Life Expectancy Using Causal Modeling Methods. Environ Health Perspect 126:127002. https://ehp.niehs.nih.gov/doi/10.1289/EHP3130

and for Alzheimer's disease and related dementias. The mean $PM_{2.5}$ concentration for the whole cohort was 9.7 μg/m$^3$.[10]

A 2020 paper found that each 1 μg/m$^3$ increase in long- and short-term $PM_{2.5}$ levels was associated with increased excess deaths at an average level of 9.0 μg/m$^3$ long-term PM.[11] And a 2019 study found that exposure to levels of $PM_{2.5}$ between 8 and 10 μg/m$^3$ increased all-cause mortality compared to levels below 8 μg/m$^3$.[12]

In support of our ask, we offer for EPA's consideration this science-policy summation from the large majority of the current PM CASAC panel: based on EPA's 2019 ISA, 2022 ISA supplement and revised 2021 PA, the majority recommended that the annual standard be lowered to a range down to 8 μg/m$^3$, which is "supported by placing more weight on: epidemiologic studies in the United States that show positive associations between $PM_{2.5}$ exposure and mortality with precision among populations with mean concentrations likely at or below 10 μg/m$^3$; epidemiologic studies in the United States showing such associations at concentrations below 10 μg/m$^3$ and below 8 μg/m$^3$; Canadian studies, some of which show such associations at concentrations below 10 μg/m$^3$ and below 8 μg/m$^3$; a meta-analysis of 53 studies, 14 of which report such associations at concentrations below 10 μg/m$^3$ down to 5 μg/m$^3$; protection of at-risk demographic groups; evidence consistent with no threshold and a possible supra-linear concentration-response function at lower levels; recognition that the use of the mean to define where the data provide the most evidence is conservative since robust data clearly indicate effects below the mean in concentration-response functions; and consideration that people are not randomly distributed over space such that populations in neighborhoods near design value monitors are exposed to the levels indicated at those monitors and likely to be more at risk."[13]

We further note that while the current body of evidence outlined in the ISA and ISA supplement is sufficient to show that an annual standard of 8 μg/m$^3$ and a 24-hour standard of 25 μg/m$^3$ are required to protect health with an adequate margin of safety, those reviews fail to fully take into account the current evidence.

In the 2019 ISA, which underlies the PA on which EPA's proposed rule is based, EPA restricted its analyses to only those studies that fulfilled four criteria, including "(1) the studies examined exposures consisting of $PM_{2.5}$ from U.S. airsheds or those representative of the U.S. (e.g., Europe, Canada)" and these "criteria applied to both experimental and epidemiologic studies".[14] We point out that Canada, with its airsheds and air zones similar to those of US as EPA deems, has adopted much stricter standards than the US with a 24-hour standard of 27 μg/m$^3$ and an annual standard of 8.8 μg/m$^3$ annual average of the daily 24-hour average concentrations.[15]

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[10] Shi, Liuhua, Xiao Wu, Mahdieh Danesh Yazdi, Danielle Braun, Yara Abu Awad, Yaguang Wei, Pengfei Liu, et al. "Long-Term Effects of PM2.5 on Neurological Disorders in the American Medicare Population: A Longitudinal Cohort Study." The Lancet Planetary Health 4, no. 12 (December 2020): e557–65. https://doi.org/10.1016/S2542-5196(20)30227-8

[11] Wei, Yaguang, Yan Wang, Xiao Wu, Qian Di, Liuhua Shi, Petros Koutrakis, Antonella Zanobetti, Francesca Dominici, and Joel Schwartz. "Causal Effects of Air Pollution on Mortality in Massachusetts." *American Journal of Epidemiology*, June 19, 2020. https://doi.org/10.1093/aje/kwaa098.

[12] Wu et al., 2019. Causal Inference In The Context Of An Error Prone Exposure: Air Pollution And Mortality. Ann Appl Stat 13(1):520-547. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6812524

[13] Clean Air Scientific Advisory Committee (CASAC). (Mar 18, 2022). Review of the EPA's Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – October 2021); Report #: EPA-CASAC-22-002; page 3

[14] EPA. (Dec, 2019). Integrated Science Assessment for Particulate Matter, EPA/600/R-19/188; page 104 (P-15)

[15] Canada's Air (Accessed Mar, 2023). Canadian Ambient Air Quality Standards (CAAQS).

We appreciate that in the draft Policy Assessment, EPA included an examination of the relationship between $PM_{2.5}$ exposure and health outcomes with both a *causal* and *likely to be causal* relationship. However, we believe that the fact that the supplement to the 2019 ISA does not include more recent findings about respiratory health, cancer and nervous system effects may have limited the assessment in ways that will hamper the ability to fully evaluate the policy implications of the evidence.

The failure to take a full accounting of morbidity outcomes results in a disproportionately limited view of the effect of particle pollution on communities of color. People of color are more likely than white people to be living with one or more chronic conditions that make them more vulnerable to the health impacts of air pollution, including asthma, diabetes and heart disease. Recent scientific literature about these health outcomes would be useful in assessing the nature of health disparities.

Restricting the evidence review in the supplement to the 2019 ISA to cardiovascular outcomes and mortality also almost completely excludes children from this reconsideration. We have strong evidence of the deleterious effect of $PM_{2.5}$ exposure on the developing lungs in children, putting them at increased risk of a lifetime of compromised health. They deserve to be taken into consideration when determining the adequacy of the standards that will affect their future.

A primary annual standard of 8 $\mu g/m^3$ would ensure that public health is better protected from long-term particle pollution, with an adequate margin of safety to protect at-risk vulnerable subpopulations including those of racial and ethnic groups, of lower socio-economic position, at different life stage (e.g. elderly, children, pregnant people), those with pre-existing conditions or predisposed to morbidities, outdoor workers, and others. Finalizing a level that is any higher than this most stringent value recommended by the expert scientists on the CASAC panel and strongly supported by the public fails to follow the science and the law.

### 3. Level of Primary 24-hour $PM_{2.5}$ NAAQS

EPA is proposing "to retain the current primary 24-hour $PM_{2.5}$ standard (at a level of 35 $\mu g/m^3$) while taking comment on revising the level as low as 25 $\mu g/m^3$".[16] Here we offer our rationale to revise the level of the current primary 24-hour standard to 25 $\mu g/m^3$ to adequately protect public health from acute short term exposures to particle pollution.

Our ask is supported by science. A large majority of the current PM CASAC panel recommended that the level of the 24-hour standard be lowered to a range down to 25 $\mu g/m^3$ to be adequately protective of public health. In making this recommendation, they explained: "Regarding the 24-hour $PM_{2.5}$ standard, the majority of CASAC members find that the available evidence calls into question the adequacy of the current 24-hour standard…conditional on retaining the current form, the majority of CASAC members favor lowering the 24-hour standard. There is substantial epidemiologic evidence from both morbidity and mortality studies that the current standard is not adequately protective. This includes three U.S. air pollution studies with analyses restricted to 24-hour concentrations below 25 $\mu g/m^3$. The majority of CASAC members also note that controlled human exposure studies are not the best evidence to use for justifying retaining the 24-hour standard without revision. These studies preferentially recruit less susceptible individuals and have a typical exposure duration much shorter than 24 hours. Thus, the evidence of effects from controlled human exposure studies with exposures close to the current 24-hour standard supports epidemiological evidence for lowering the standard. Overall, this places greater weight on the scientific evidence than on the values estimated by the risk

[16] EPA Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 3 (5560)

assessment. The risk assessment may not adequately capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective. There is also less confidence that the annual standard could adequately protect against health effects of short-term exposures."[17]

Multiple examples exist from the prior review of calls for a strengthening of the 24-hour standards. In comments to EPA in 2020, seventeen national health organizations noted, "Even at levels that meet current NAAQS, exposure to short-term $PM_{2.5}$ can be deadly. A 2016 study found that people aged 65 and older in New England faced a higher risk of premature death from particle pollution, even in places that met current standards for short-term particle pollution.[18] Another study in 2017 looked more closely at Boston and found a similar higher risk of premature death from particle pollution in a city that meets current limits on short-term particle pollution.[19] Looking nationwide in a 2017 study, researchers found more evidence that older adults faced a higher risk of premature death even when levels of short-term particle pollution remained well below the current national standards. This was consistent whether the older adults lived in cities, suburbs or rural areas.[20]

EPA's proposal, however, seems to follow the opinion of a minority of CASAC members, by evidently placing a greater weight on controlled human exposure studies and on risk assessment in deciding to retain the current 24-hour standard. In doing so it also subscribes to the minority of CASAC's contention that the "annual standard is the controlling standard across most of the urban study areas" and "revising the level of the 24-hour standard is estimated to have minimal impact on the $PM_{2.5}$-associated risks. Therefore, the annual standard can be used to limit both long- and short-term $PM_{2.5}$ concentrations."[21] EPA's data shows that there are areas that will attain an annual standard as low at 8 $\mu g/m^3$ and still exceed a daily standard as high as 35 $\mu g/m^3$. Demonstrating that the annual standard alone does not protect against high daily exposures. The proposal, like a minority of the CASAC panel, deemed "the annual standard was most effective in controlling ''typical'' $PM_{2.5}$ concentrations near the middle of the air quality distribution... but also provided some control over short-term peak $PM_{2.5}$ concentrations. On the other hand, the 24-hour standard, with its $98^{th}$ percentile form, was most effective at limiting peak 24-hour $PM_{2.5}$ concentrations, but in doing so also had an effect on annual average $PM_{2.5}$ concentrations. Thus, while either standard could be viewed as providing some measure of protection against both average exposures and peak exposures, the 24-hour and annual standards were not expected to be equally effective at limiting both types of exposures."[22]

Despite this recognition, and against the recommendation of the majority of CASAC experts, the "Administrator concluded that an annual standard (as the arithmetic mean, averaged over three years) remained appropriate for targeting protection against the annual and daily $PM_{2.5}$ exposures around the middle portion of the $PM_{2.5}$ air quality distribution. Further, recognizing

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[17] 2022 CASAC Review of the EPA's Policy Assessment for the Reconsideration of the NAAQS for PM; pages 3-4

[18] Shi L, Zanobetti A, Kloog I, et. al. Low-concentration PM2.5 and mortality: estimating acute and chronic effects in a population-based study. Environ Health Perspect. 2016; 124:46-52. http://dx.doi.org/10.1289/ehp.1409111

[19] Schwartz J, Bind MA, Koutrakis P. Estimating causal effects of local air pollution on daily deaths: Effect of low levels. Environ Health Perspect. 2017; 125:23-29. http://dx.doi.org/10.1289/EHP232.

[20] Di Q, Dai L, Wang Y, Zanobetti A, Choirat C, Schwartz JD, Dominici F. Association of Short-Term Exposure to Air Pollution with Mortality in Older Adults. JAMA. 2017;318:2446-2456.

[21] 2022 CASAC Review of the EPA's Policy Assessment for the Reconsideration of the NAAQS for PM; pages 3-4

[22] EPA 's Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 20 (5577)

that the 24-hour standard (with its 98th percentile form) was more directly tied to short-term peak $PM_{2.5}$ concentrations, and more likely to appropriately limit exposures to such concentrations, the Administrator concluded that the current 24-hour standard (with its 98th percentile form, averaged over three years) remained appropriate to provide a balance between limiting the occurrence of peak 24-hour $PM_{2.5}$."[23]

Looking at the history of the Clean Air Act and the primary $PM_{2.5}$ NAAQS, it is evident that two - a short-term 24-hour and a long-term annual – standards were established because neither one alone was deemed controlling of or sufficient to protect human health from particle pollution throughout the year.

EPA needs to revise the level of current 24-hour $PM_{2.5}$ primary NAAQS to 25 $\mu g/m^3$ to adequately protect the public from acute short-term exposures, as warranted by science.

### 4. Form of Primary 24-hour $PM_{2.5}$ NAAQS

The current 24-hour standard is calculated as the 3-year average of annual 98th percentile 24-hour average concentrations of $PM_{2.5}$ calculated (averaged from hourly measurements) or measured from midnight to midnight at each monitoring site (24-hour standard design value). This form of the standard excludes 7.3 days (24-hour periods) of highest $PM_{2.5}$ levels per year (~22 days over the 3-year averaging period) from standard attainment consideration. Additionally, days of poor air quality may be exempted from regulatory consideration due to unusual or naturally occurring exceptional events such as "wildfires, high wind dust events, prescribed fires, stratospheric ozone intrusions, and volcanic and seismic activities."[24] A recent study showed that "the frequency of exceptional event reporting for $PM_{2.5}$…had increased since 2007" and that "wildland fires and windblown dust drive many exceptional events in several EPA regions." [25] The authors "note the importance of growth in the number of exceptional event days due to wildfire smoke in the future due to climate change and point to possible changes to the NAAQS and implementations."[26]

Climate change has "health and welfare consequences beyond air quality and other effects from combinations of climate and air quality."[27] The ozone CASAC panel had noted the measurable penalty that climate change impacts impose on ambient air pollution, and the PM CASAC panel noted the "weather penalty" which is the result of "weather-associated changes in $PM_{2.5}$ composition, termed as due to increased temperature in the industrial Midwest and Northwest during the warm and cold seasons, and in the upper Midwest and West during the cold season, along with increased relative humidity and decreased wind speeds."[28] Both these penalties will only increase as the impacts of anthropogenic climate change become more frequent and intense.

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[23] EPA Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 20 (5577)

[24] "Exceptional Events are unusual or naturally occurring events that can affect air quality but are not reasonably controllable using techniques that tribal, state or local air agencies may implement in order to attain and maintain the National Ambient Air Quality Standards." Treatment of Air Quality Data Influenced by Exceptional Events (Homepage for Exceptional Events) | US EPA

[25] David, L. M. *et al*. (2021). Could the exception become the rule? 'Uncontrollable' air pollution events in the US due to wildland fires. *Environ. Res. Lett.* 16, 034029.

[26] David, L. M. *et al*. (2021). Could the exception become the rule? 'Uncontrollable' air pollution events in the US due to wildland fires. *Environ. Res. Lett.* 16, 034029.

[27] National Academies of Sciences, Engineering, and Medicine. (Oct, 2022). Advancing the Framework for Assessing Causality of Health and Welfare Effects to Inform National Ambient Air Quality Standard Reviews. ISBN: 978-0-309-69011-9; Sponsor: EPA, page 105.

[28] CASAC review of PM PA. (Nov 22, 2022), page 71 (A-35)

Areas experiencing the effects of an exceptional event may not need to claim an exemption if they are in attainment, but their citizens are exposed to poor air quality nonetheless. For example, smoke from western US and southern Canada wildfires moved into the eastern U.S. on July 21, 2021 resulting in poor air quality in several major cities from the Mid-Atlantic to the Northeast, including Philadelphia, New York City and Boston, with Washington DC and Baltimore issuing code orange air-quality alerts for that day.[29]

The PM CASAC panel noted that for the 24-hour standard, "the level is conditional on the form, and all of the CASAC members conclude that the Draft PA does not provide sufficient information to adequately consider alternative form and level combinations…The CASAC recommends that in future reviews, the EPA provide a more comprehensive assessment of the 24-hour standard that includes the form as well as the level. The CASAC recognizes that they have insufficient information with which to evaluate alternative forms of the 24-hour standard and the CASAC recommends that the form be revisited in future reviews."[30]

Given the increasingly severe and frequent threats to air quality from anthropogenic climate change and considering the long timeline between NAAQS reviews and also in the full implementation of revised standards, there is an urgent need to address the form now to protect the health of vulnerable at-risk populations. We ask that the form of the primary 24-hour $PM_{2.5}$ standard be set at the 99$^{th}$ percentile to reduce by half the number of currently allowed exceedances and to account for climate change impacts on air pollution, to protect the health of vulnerable at-risk populations with a margin of safety.

### 5. Air Quality Index

EPA proposes the following changes to the $PM_{2.5}$ sub-index of the *daily* AQI to align with any changes to the primary $PM_{2.5}$ standards that are being considered in this review:

1. Revise the lower AQI breakpoint of 50 (code Yellow; level of concern Moderate) within the range of 9.0 and 10.0 µg/m$^3$ and retain the AQI values of 100 (code Orange; level of concern Unhealthy for Sensitive Groups) and 150 (code Red; level of concern Unhealthy) at 35.4 µg/m$^3$ and 55.4 µg/m$^3$, respectively.

2. Revise the upper AQI breakpoints of 200 (code Purple; level of concern Very Unhealthy), 300 (code Maroon; level of concern Hazardous) and 500 to 125.4 µg/m$^3$, 225.4 µg/m$^3$, and 325.4 µg/m$^3$, respectively, replacing the current "linear-relationship approach" with one "that more fully considers the $PM_{2.5}$ health effects evidence from controlled human exposure and epidemiologic studies that has become available in the last 20 years", and

3. Revise the daily reporting requirement from 5 days per week to 7 days per week.

In the Lung Association's 2021 comments to CASAC on the draft PA, we noted that the inadequate 24-hour standard is the basis for EPA's Air Quality Index (AQI) that is used to communicate daily air pollution levels to the public. Using EPA's AirNow tool or similar communications from state and local air pollution agencies, the public is informed about air quality forecasts and pollutant levels in their community. The Air Quality Index suggests that only exposures of more than 35.5 µg/m$^3$ are unhealthy for sensitive groups and designated code orange. Days with $PM_{2.5}$ levels from 12.1 µg/m$^3$ to as high as 35.4 µg/m$^3$ are labeled "moderate" or code yellow days. This provides an inaccurate picture of the health risks of daily

[29] Samenow, J. (Jul 20, 2021). Wildfire smoke pouring into Mid-Atlantic prompts air-quality alert for D.C. and Baltimore. The Washington Post.
[30] CASAC review of PM PA. (Nov 22, 2022), page 2

exposure to $PM_{2.5}$.

EPA's official caution for a code yellow moderate day for $PM_{2.5}$ is,

> "Who Needs to be Concerned? Some people who may be unusually sensitive to particle pollution.
> What Should I Do? Unusually sensitive people: Consider reducing prolonged or heavy exertion. Watch for symptoms such as coughing or shortness of breath. These are signs to take it easier. Everyone else: It's a good day to be active outside."[31]

Further, in order for the warning level to be elevated to code red or "unhealthy", meaning that everyone needs to take precautions, the daily $PM_{2.5}$ levels must exceed 55.5 $\mu g/m^3$. Setting a more protective 24-hour standard will not only drive pollution cleanup, but also provide more accurate information so individuals, teachers, coaches and others can make decisions to reduce or prevent exposures to $PM_{2.5}$ at levels that threaten health.

The AQI is primarily a communication tool "to inform the public when air quality is poor and thus when they should consider taking actions to reduce their exposures."[32] Unlike the short-term pollutant standards to which it is tied, the AQI is not a regulatory tool to reduce air pollution and the "EPA does not provide guidance on the use of the AQI for such purposes."[33]

We note that EPA cites "new controlled human exposure and epidemiologic studies published since the completion of the 2009 ISA" and "considers it appropriate to consider scientific evidence for these purposes beyond the scope of the ISA" -- all of which in the Agency's view warrant updating the AQI-PM framework (revising the breakpoints for its color-coded $PM_{2.5}$ levels) but evidently do not warrant revising the primary 24-hour $PM_{2.5}$ standard.[34] In doing so, EPA is shifting its responsibility to protect citizens from acute or peak $PM_{2.5}$ exposures by setting stringent $PM_{2.5}$ standards to the citizens themselves.

We support revising the breakpoints for upper air quality indices of 200, 300, and 500 to fully reflect current science on the adverse health impacts daily exposures to high levels of fine $PM_{2.5}$. This adherence to current science needs to be reflected not only in revising AQI breakpoints but in setting the PM2.5 NAAQS themselves.

Changing the AQI reporting requirement to cover all seven days of the week is a good start. But to make the AQI a more useful and informational tool, EPA needs to go further and address other elements of the AQI:[35]

i. Daily reporting is currently required only of Metropolitan Statistical Areas (MSAs) with a population of more than 350,000 based on the latest available census population (which is updated on a decadal basis)
ii. Required reporting for the AQI is backward-looking – citizens are informed of yesterday's air quality: "It takes a full 24 hours to obtain an AQI value (that's 24 hourly values for PM or the max 1-hour or 8-hour value in a 24-hour period for other pollutants), so you are in

[31] Air quality Guide for Particle Pollution, August 2015, EPA-456/F-15-005 (airnow.gov)
[32] EPA Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 81 (5638)
[33] EPA Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 81 (5638)
[34] EPA Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 81 (5638)
[35] Environmental Protection Agency. (Sep, 2018). Technical Assistance Document for the Reporting of Daily Air Quality – the Air Quality Index (AQI). EPA 454/B-18-007; page 1

effect required to report yesterday's AQI"
iii. Reporting on current AQI values as well as air quality forecasts, which are both useful and relevant, is voluntary
iv. Reporting on health effects of and cautionary statements for poor air quality is voluntary
v. Reporting on the AQI for sub-areas of the reporting area or less densely populated areas is voluntary
vi. Reporting on the causes for unusual AQI values is voluntary
vii. Reporting on actual pollutant concentrations is voluntary
viii. Reporting on "AQI for other pollutants or on statements that "blend" health effects and cautionary information for more than one pollutant" is voluntary.

To ensure that the *daily* AQI is of practical and immediate value to the public in protecting themselves, EPA needs to make mandatory the voluntary reporting elements listed above. Only then will the AQI be a useful and educational tool that helps citizens take action on days of poor air quality. The *daily* AQI works as a public health advisory tool as it is intended to be only if the 24-hour standard is strengthened. To truly protect citizens from harmful $PM_{2.5}$ pollution every day and all through the year, EPA needs to strengthen the annual standard to 8 and 24-hour standards to 25 $\mu g/m^3$ to fully reflect, in EPA's own words, "$PM_{2.5}$ health effects evidence from controlled human exposure and epidemiologic studies that has become available in the last 20 years".

## 6. Environmental and Social Injustice of $PM_{2.5}$ Pollution

Concentrations of criteria air pollutants have declined in recent decades in the U.S., but the improvements in air quality are not equitably distributed across various populations. A recent study showed that "despite declines in pollutant concentrations, over time, disparities in exposure increased for racially and educationally isolated communities."[36] A given area with "racial isolation was associated with higher $PM_{2.5}$ but not with the rate of decline in $PM_{2.5}$." The study authors suspect that "an overall improvement in air quality could, in fact, mask widening disparities based on geographic, social, or demographic factors."[37]

A recent study has shown that "most emission source types - representing ~75% of exposure to $PM_{2.5}$ in the United States - disproportionately affect racial-ethnic minorities. This phenomenon is systemic, holding for nearly all major sectors, as well as across states and urban and rural areas, income levels, and exposure levels. Industry, light-duty gasoline vehicles, construction, and heavy-duty diesel vehicles are often among the largest sources of disparity."[38] The disparity in exposure to air pollution and associated adverse health impacts is clearly seen with both chronic long-term (annual mean) as well as with acute short-term (daily peak) $PM_{2.5}$ exposures as discussed below.

A 2019 study of a very large cohort of more than 4.5 million U.S. veterans found the attributable burden of death (from nine causes) associated with exposures to annual mean $PM_{2.5}$ levels was "disproportionally borne by (B)lack individuals and socioeconomically disadvantaged communities; 99% of the burden was associated with $PM_{2.5}$ levels below (annual) standard set

[36] Bravo, M. A., et al. (2022). Where Is Air Quality Improving, and Who Benefits? A Study of PM2.5 and Ozone Over 15 Years. Am J Epidemiol, 191(7):1258-1269.
[37] Bravo, et al. Where Is Air Quality Improving, and Who Benefits? A Study of PM2.5 and Ozone Over 15 Years.
[38] Tessum, C. W. *et al*. (2021). $PM_{2.5}$ polluters disproportionately and systemically affect people of color in the United States. *Science Advances*, 7(18).

by EPA.[39] A very recent "national study of short-term air pollution exposure disparities revealed an environmentally unjust pattern for POC (people of color)."[40] The study found that between 2012–2016, people of color across the nation experienced 23, 6.4, and 1.7 more days overall with respective $PM_{2.5}$ concentrations of ≥15, 25, and 35 μg/m$^3$ than non-Hispanic white people. "Disparities appear larger for short-term vs. long-term $PM_{2.5}$ exposures nationwide. Although prior estimates of disparities in long-term $PM_{2.5}$ exposures (<10 μg/m$^3$) between the most and least exposed racial/ethnic groups were respectively 13% - 14% (absolute) and 1.1 (relative), we found worsening disparities as the short-term $PM_{2.5}$ threshold increased from 15 to 25 to 35 μg/m$^3$ (absolute: 25% to 69% to 109%; relative: 1.3 to 1.8 to 2.7). This suggests that tightening/lowering the $PM_{2.5}$ NAAQS toward WHO (World Health Organization) benchmarks might attenuate racial/ethnic exposure disparities."[41]

These studies make compelling arguments for strengthening both the annual and 24-hour $PM_{2.5}$ standards to reduce the disproportionate impacts of $PM_{2.5}$ exposure across all demographics and to ensure equitable distribution of the benefits of clean healthy air from implementing those standards. EPA's own Regulatory Impact Analysis (RIA)[42] bears out this understanding. EPA found in the RIA for this proposal that all populations would experience greater health benefits at 8 μg/m$^3$, and that only the tighter end of the standards analyzed would reduce racial disparities in air pollution exposure.

Figure 6-1 in the RIA shows Hispanic, Asian, and Black people (compared to White people) experience higher-than-national-average annual $PM_{2.5}$ levels under the current standard and this disparity is projected to persist at the same relative levels if the annual standard alone were lowered. However, lowering the annual standard to 8 μg/m$^3$, even while retaining the current 24-hour standard, shows significantly more reductions in exposure levels nationally for Asian (5.5%) and Hispanic people (4.8%) compared to proposed annual standards, (Figures 6-5 & 6-9, RIA).

Nationwide, Black people would experience the most reductions in total mortality rates per 100K by adopting 8/35 μg/m$^3$ compared to the current 12/35 μg/m$^3$ NAAQS, (Figure 6-11, RIA). Adopting an annual standard of 8 μg/m$^3$ translates to an average annual mortality rate reduction (per 100k) of >7.5 ~2.2x among Black people, ~2.7x, ~1.7x for Hispanic people, and 2.5x, ~1.6x for Asian people relative to adopting the proposed 10 μg/m$^3$, 9 μg/m$^3$ standards respectively, (Figure 6-15, RIA). A similar trend is seen in the national average percent mortality rate reductions (per 100k People) among these demographics (Figure 6-19, RIA).

Implementing an annual standard of 8 μg/m$^3$ saves 9,200 adults from premature death in 2032 (year of full implementation of new standards) alone, compared to 1,700 and 4,200 with an annual standard of 10 and 9 μg/m$^3$ respectively, (Table ES-6, RIA). This translates to 5.4x, ~2.5x more avoided PM-related premature mortalities among adults. This trend is also seen with infant mortality: ~6.9x, 6.1x reduction for 8 μg/m$^3$ vs a 10, 9 μg/m$^3$ standard as proposed in the rule, (Table ES-6, RIA). The overall estimated monetized benefits as well as those from avoided mortalities & morbidities among adults are also similarly >5x, >2x greater for 8/35 μg/m$^3$ relative to 10/35, 9/35 μg/m$^3$ (Tables ES-7 and ES-10, RIA).

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[39] Bowe, B., Xie, Y., Yan, Y., & Al-Aly, Z. (2019). Burden of Cause-Specific Mortality Associated With PM2.5 Air Pollution in the United States. *JAMA Network Open*; 2(11): e1915834.
[40] Collins, T. W. & Grineski, S. E. (Aug 19, 2022). Racial/Ethnic Disparities in Short-Term PM2.5 Air Pollution Exposures in the United States. *Environmental Health Perspectives*, 130(8)
[41] Ibid 24
[42] EPA. (Dec, 2022). Regulatory Impact Analysis for the Proposed Reconsideration of the National Ambient Air Quality Standards for Particulate Matter, EPA-452/P-22-001; page 24 (ES-2)

We are unable to assess or understand the projected additional net benefits of implementing our asks of annual/24-hour standard levels of 8/25 $\mu g/m^3$ because the RIA does not provide any data on this alternative standards suite although EPA is soliciting comment on both those levels.

The benefits of strengthening the annual standard to 8 $\mu g/m^3$ alone yield numerous net benefits as seen from EPA's own regulatory impact analyses. By setting truly protective primary annual/24-hour $PM_{2.5}$ NAAQS of 8/25 $\mu g/m^3$, EPA would be able to save more lives and reduce $PM_{2.5}$-related illnesses, address environmental justice for vulnerable communities by reducing disparities in exposures and associated health impacts, ensure a more equitable distribution of clean air benefits, gain economic and monetary benefits, act on current science and meet the requirements of the Clean Air Act.

## 7. Conclusion

The current $PM_{2.5}$ NAAQS reconsideration is a unique opportunity for the EPA to set meaningful and effective standards to truly protect public health with an adequate margin of safety from deadly particle pollution. Setting health protective standards is required by the Clean Air Act. We request that EPA follow the science and the law, and no later than August 2023 finalize the rule for a primary annual $PM_{2.5}$ standard of 8 $\mu g/m^3$ and a primary 24-hour $PM_{2.5}$ standard of 25 $\mu g/m^3$ set at the $99^{th}$ percentile.