March 28, 2023

EPA's Proposed Rule in the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter[1]

Docket #: EPA–HQ–OAR–2015–0072; RIN 2060–AV52

Comment from the American Lung Association

CONTENTS

[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.

I. Introduction

In the proposed rule on the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM), EPA acknowledges the inadequacy of one of the current standards in protecting public health and proposes to:

1. revise the level of current $PM_{2.5}$ annual standard from 12 µg/m^3 to within the range of 9-10 µg/m^3 calculated as an annual mean averaged over 3 years,
2. retain the current level and form of the 24-hour $PM_{2.5}$ standard of 35 µg/m^3 calculated at the 98th percentile averaged over 3 years,
3. revise some aspects of the Air Quality Index (AQI), and
4. revise some aspects of PM NAAQS monitoring requirements.

In proposing to retain the 24-hour standard and to revise the annual standard within a very weak range, EPA is ignoring science and the recommendations of the scientific experts, does not fulfill the statutory requirement of the Clean Air Act (CAA) to protect public health, does not include an adequate margin of safety to protect vulnerable groups, and is therefore entirely unacceptable.

In our previous comments at different stages in this NAAQS reconsideration process, we have pointed to scientific research that supports strengthening both the primary standards, which was also recommended by the PM panel of the Clean Air Scientific Advisory Committee (CASAC). Here we provide additional details and rationale supporting our ask that EPA strictly follow the science and the requirements of the CAA to expeditiously finalize the rule on PM NAAQS with a primary annual $PM_{2.5}$ standard of 8 µg/m^3 and a primary $PM_{2.5}$ 24-hour standard of 25 µg/m^3 set at the 99th percentile. These standards, supported by science, would provide an adequate margin of safety to protect human health, especially of at-risk groups, and would also address environmental justice by reducing exposure disparities and related health burdens borne by socioeconomic and racial/ethnic subpopulations.

We further recommend changes to the Air Quality Index (AQI) beyond what EPA proposes in this rule to truly reflect health risks from daily PM and provide the guidance the public needs to protect itself from acute short-term exposures. We also suggest improving the siting of monitors to more effectively address exposure disparities.

II. Clean Air Act Requirement

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

> 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).

The NAAQS are "preventative in nature." *Ethyl Corp. v. EPA,* 541 F.2d1, 15 (D.C. Cir. 1976). 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). See further *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.)

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.

III. The Previous Review was Fundamentally Flawed

EPA last updated the annual PM standard in 2012, revising the $PM_{2.5}$ standard to the current 12 $\mu g/m^3$ (micrograms per cubic meter), and retaining the 24-hour $PM_{2.5}$ standard at 35 $\mu g/m^3$ set in 2006. Prior to 2012, the Agency last updated the annual $PM_{2.5}$ standard in 1997.

The 2020 review resulting in the affirmation of the current, inadequate standard was fundamentally flawed. In 2018, then-EPA Administrator Pruitt announced a "back to basics" policy for the NAAQS that truncated scientific review processes and stacked review boards with industry appointees.[2,3] He further dismissed the expert PM review panel that had been convened.

The Trump administration followed this approach in the PM review and proposed to maintain the 2012 standards in April 2020. The agency finalized the standards on December 7, making the rule effective immediately on publication in the Federal Register. "Review of the National Ambient Air Quality Standards for Particulate Matter," 85 Fed. Reg. 24,094 (Apr. 30, 2020) (Proposed Rule); "National Ambient Air Quality Standards for Particulate Matter," 85 Fed. Reg. 82,684 *et seq.* (Dec. 18, 2020) (Final Rule).

That process relied on deeply flawed assessments of the science, including the former Administrator's arbitrary dismissal of the epidemiologic studies that relied on hybrid modeling approaches. *See* 85 Fed. Reg. at 82,711/1-3 (citing purported remaining uncertainties and imperfections in hybrid modeling approach when throwing out such studies).

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[2] Scott Pruitt, EPA Administrator (May, 2020). Back-to-Basics Process for Reviewing National Ambient Air Quality Standards. Memorandum to assistant administrators.

[3] Harvard Law School's Environmental and Energy Law Program. (10/24/2018). Limiting Expertise in EPA's Review of the Air Quality Standards.

Many of the scientists and physicians with expertise in multiple disciplines of air pollution and who served on the 2015 PM CASAC panel were dismissed from the 2018 PM CASAC panel. These experts formed an independent review panel through which they articulated the need for stringent $PM_{2.5}$ NAAQS based on the extensive scientific evidence currently available.[4]. The Panel praised the hybrid modeling approach's performance as "quite good" and explained that the approach's "substantial improvements" marked a "substantial advancement" that "enables epidemiologic studies of large cohorts not served by the ambient monitoring network," with the resulting new studies (which the Administrator dismissed without notice) being "groundbreaking" and "highly compelling."[5]

EPA also determined in the 2020 final rule that EPA provisionally considered new studies but determined that they did not change the broad conclusions regarding the health and welfare effects of PM, and therefore they did not need to reopen the review. EPA established a cutoff date for studies to be included in the first draft of the ISA of about January 2018, and unlike in previous reviews, did not give CASAC the opportunity to review and add important new studies for consideration. *85 Fed. Reg. at 82,691*.

The Lung Association, along with other health and environmental organizations and represented by Earthjustice, filed a petition for review in 2021 after EPA finalized its 2020 rule to retain the inadequate existing PM standards. EPA then announced its plans to reconsider the rule.

IV. Particulate Matter Causes Severe Harm to Human Health

Scientific evidence to date shows the breadth of harm $PM_{2.5}$ poses to public health. More than fifteen years ago, Rom and Samet (2006), in their editorial, noted the evidence that showed "Small Particles Have Big Effects":

> PM has now been linked to a broad range of adverse health effects, both respiratory and cardiovascular, in epidemiologic and toxicologic research. The diversity of effects may reflect the complexity of airborne PM, which is made up of a rich mixture of primary and secondary particles. [6]

In the 2009 ISA, EPA noted increasing evidence that strengthened the association with $PM_{2.5}$ and hospital admission and emergency department visits for asthma, COPD and respiratory infection[7] which also confirmed the need for greater prevention of pediatric pulmonary harm from PM exposure. Evidence had also been increasing on $PM_{2.5}$ causation of lung cancer mortality. The extended follow-up to the Harvard Six Cities Study by Laden *et al*. (2006)[8] and two follow-up studies of the American Cancer Society cohort study by Jerrett *et al*. (2005)[9] and Krewski *et al*. (2009)[10] showed positive association of $PM_{2.5}$ exposure with lung cancer mortality. Given the long latency period for cancer, these findings are significant in the assessment of

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[4] Frey, C. H., Adams, P. J., Adgate, J. L., Allen, G. A., Balmes, J., Boyle, K., Chow, J. C., Dockery, D. W., Felton, H. D., Gordon, T., Harkema, J. R., Kinney, P., Kleinman, M. T., McConnell, R., Poirot, R. L., Sarnat, J. A., Sheppard,L., Turpin, B., & Wyzga, R. (Aug, 2020). The Need for a Tighter Particulate-Matter Air-Quality Standard. *N Engl J Med*., 383, 680-683.

[5] *Advice from the Independent Particulate Matter Review Panel,* EPA-HQ-OAR-2015-0072-0037 at B-7 to -8, B-14 to -15.

[6] Rom WN & Samet JM. (2006). Small Particles with Big Effects. *American Journal of Respiratory and Critical Care Medicine*,173, 365-369.

[7] EPA. (2009). Integrated Science Assessment for Particulate Matter (Final Report). EPA/600/R-08/139F;6-150.

[8] Laden F, *et al*. (2006). Reduction in fine particulate air pollution and morality: extended follow-up of the Harvard Six Cities study. *American Journal of Respiratory and Critical Care Medicine*,173, 667-643.

[9] Jerrett M, *et al*. (2005). Spatial analysis of air pollution and mortality in Los Angeles. *Epidemiology*, 16, 727-736.

[10] Krewski D, *et al*. (2009). Reanalysis of the Harvard Six Cities study and the American Cancer Society study of particulate air pollution and mortality: a special report of the Institute's Particle Epidemiology Reanalysis Project. Health Effects Institute.

long-term health effects that can be prevented by tighter $PM_{2.5}$ standards. Pope, Ezzati, and Dockery (2009)[11] studied the impact of $PM_{2.5}$ in 211 counties in 51 metropolitan areas in the U.S. and found that a decrease of 10 $\mu g/m^3$ was associated with added life expectancy of five months on average.

Since that review, evidence has continued to mount showing extensive health harms, with specific impacts outlined below. A systematic review from 2020 found that $PM_{2.5}$ was associated with increased mortality even below exposure levels of 10 $\mu g/m^3$.[12] A 2023 analysis looked at the full contiguous United States to estimate the 2015 burden of $PM_{2.5}$ exposure to total 120,000 premature adult deaths, 75,000 respiratory emergency room visits, 110,000 non-fatal heart attacks, 27,000 cases of Alzheimer's disease and 24,000 childhood asthma emergency room visits. The authors note that up to 70% of these impacts were not captured in EPA's analysis in the most recent Policy Assessment.[13]

1. Cardiovascular Effects

In May 2010, the American Heart Association (AHA) updated its Scientific Statement[14] to reflect growing evidence based on scientific research from 2004 through March 2009 reviewed by an independent team of scientists, which concluded:

> Exposure to PM <2.5 µm in diameter ($PM_{2.5}$) over a few hours to weeks can trigger cardiovascular disease–related mortality and nonfatal events; longer term exposure (e.g. a few years) increases the risk for cardiovascular mortality to an even greater extent than exposures over a few days and reduces life expectancy within more highly exposed segments of the population by several months to a few years; reductions in PM levels are associated with decreases in cardiovascular mortality within a time frame as short as a few years; and many credible pathological mechanisms have been elucidated that lend biological plausibility to these findings. It is the opinion of the writing group that the overall evidence is consistent with a causal relationship between $PM_{2.5}$ exposure and cardiovascular morbidity and mortality.

In 2020, the Heart Association issued additional scientific statements on personal protection and policy recommendations to reduce cardiovascular disease (CVD) from PM exposure, noting that since the 2010 statement, "unequivocal evidence of the causal role of fine particulate matter air pollution … in cardiovascular disease has emerged"[15], and new evidence had accumulated that confirms that exposures to $PM_{2.5}$ lead to adverse acute and chronic cardiovascular effects.

[11] Pope CA, Ezzati M, & Dockery DW. (2009). Fine Particulate Air Pollution and Life Expectancy in the United States. *New England Journal of Medicine*, 360, 376-86.

[12] Chen J, & Hoek G. (2020). Long-term exposure to PM and all-cause and cause-specific mortality: A systematic review and meta-analysis. *Env Int* 143,105974.

[13] Industrial Economics. (Mar. 21, 2023). *Analysis of $PM_{2.5}$-Related Health Burdens Under Current and Alternative NAAQS: Updated Final Report*.

[14] Brook RD, *et al*. (2010). on behalf of the American Heart Association Council on Epidemiology and Prevention, Council on the Kidney in Cardiovascular Disease, and Council on Nutrition, Physical Activity and Metabolism. Particulate matter air pollution and cardiovascular disease: an update to the scientific statement from the American Heart Association. *Circulation*, 121, 2331-2378.

[15] Rajagopalan S, *et al*. (2020). American Heart Association Council on Lifestyle and Cardiometabolic Health; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Clinical Cardiology; Council on Cardiovascular and Stroke Nursing; and Stroke Council. Personal-Level Protective Actions Against Particulate Matter Air Pollution Exposure: A Scientific Statement from the American Heart Association. *Circulation*. 142(23) .

In their literature review to inform AHA's "Guidance to Reduce the Cardiovascular Burden of Ambient Air Pollutants", Kaufman *et al*. (2020)[16] showed that short-term (hours to days) acute exposures to $PM_{2.5}$ can trigger cardiovascular events, hospitalization episodes, and mortality and long-term (months to years) chronic exposures to $PM_{2.5}$ can increase the risk of major adverse cardiovascular events and also lead to observable acceleration of underlying morbidities such as atherosclerosis.[17] This study also revealed that exposure to $PM_{2.5}$ could reduce life expectancy. The authors noted the accumulating experimental studies which have identified "key mechanisms through which $PM_{2.5}$ exposures contribute to cardiovascular events through inflammatory, metabolic, and autonomic nervous system pathways."[18] They cited growing scientific evidence on the effects of air pollution on CVD and its contributing causes, including atherogenesis, hypertension and metabolic disease.

Their review suggested that these effects, which are more pronounced for patients with heart failure, are observed even below a long-term average of 12 μg/m^3 of $PM_{2.5}$[19,20] and a short-term average of <25 μg/m^3 of $PM_{2.5}$[21] which are the levels at or below the current standards. "The authors note that $PM_{2.5}$ -associated cardiovascular mortality across the world has been increasing especially in rapidly industrializing countries[22] and "consistent associations between CVD mortality and short-term increases in $PM_{2.5}$ levels have been reported from >600 cities around the world."[23]

Further, the ELAPSE study (Effects of Low-Level Air Pollution: A Study in Europe) found in 2021 that long-term exposure to low-level ambient air pollution increased incidence of stroke and coronary heart disease,[24] and that long-term-exposure to $PM_{2.5}$ (and NO_2) lower than the current EPA annual limits was associated with cardiovascular mortality, as well as non-malignant respiratory and lung cancer mortality in Europe.[25]

2. Pediatric, Prenatal, and Neonatal Effects

The American Academy of Pediatrics (AAP) issued an updated policy statement in June 2021 highlighting the health hazards to children from ambient air pollution.[26] The statement cited EPA's 2019 report on "America's children and the environment (ACE): ACE environments and

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[16] Kaufman JD, *et al*. (2020). American Heart Association Advocacy Coordinating Committee. Guidance to Reduce the Cardiovascular Burden of Ambient Air Pollutants: A Policy Statement from the American Heart Association. *Circulation*,142(23).
[17] Samet JM, *et al*. (2000). The National Morbidity, Mortality, and Air Pollution Study. Part II: morbidity and mortality from air pollution in the United States. *Res Rep Health Eff Inst*., 94pt 25–70.
[18] Kaufman *et al*. (2020). AHA Policy Statement.
[19] Di Q, *et al*. (2017). Air pollution and mortality in the Medicare population. *N Engl J Med.,* 376, 2513–2522.
[20] Pinault L, *et al*. (2016). Risk estimates of mortality attributed to low concentrations of ambient fine particulate matter in the Canadian community health survey cohort. *Environ Health*,15:18.
[21] Di Q, *et al*. (2017). Association of short-term exposure to air pollution with mortality in older adults. *JAMA*, 318, 2446–2456.
[22] Li T, *et al*. (2018). All-cause mortality risk associated with long-term exposure to ambient $PM_{2·5}$ in China: a cohort study. *Lancet Public Health*, 3:e470–e477; Yin P, *et al*. (2017). Long-term fine particulate matter exposure and nonaccidental and cause-specific mortality in a large national cohort of Chinese men. *Environ Health Perspect*.,125:117002.
[23] Liu C, *et al*. (2019). Ambient particulate air pollution and daily mortality in 652 cities. *N Engl J Med*., 381,705–715.
[24] Wolf, K., *et al*. (2021). Long-term exposure to low-level ambient air pollution and incidence of stroke and coronary heart disease: a pooled analysis of six European cohorts within the ELAPSE project. *The Lancet Planetary health*, *5*(9), e620–e632.
[25] Stafoggia, M., *et al*. (2022). Long-term exposure to low ambient air pollution concentrations and mortality among 28 million people:results from seven large European cohorts within the ELAPSE project. *The Lancet Planetary health*, *6*(1), e9–e18.
[26] Brumberg HL. *et al*. (2021). COUNCIL ON ENVIRONMENTAL HEALTH, Ambient Air Pollution: Health Hazards to Children. *Pediatrics*, 147 (6).

contaminants"[27] in stating that Asian American or Pacific Islander, Black non-Hispanic, and Hispanic individuals were more likely to live in counties unable to meet $PM_{2.5}$ (and ozone) standards compared to non-Hispanic white individuals. A systematic review and meta-analysis of relevant literature[28] on health impacts of pollutants showed that exposure to higher representative concentrations of multiple pollutants included $PM_{2.5}$ were associated with birth weight decrements of about 10 to 30 g with odds ratios of 1.05 to 1.10 for low birth weight and of 1.04 to 1.06 for preterm birth. Another study translated this effect in the context of environmental tobacco smoke and showed that the risk of low birth weight associated with a 10 $\mu g/m^3$ increase in $PM_{2.5}$ was equivalent to the effect of maternal passive smoking of 3.8 ± 2.3 cigarettes.[29]

The public health impact is significant, not only in human suffering terms but also economic terms: "across the 48 states, 3.32% of all preterm births in 2010 were attributable to $PM_{2.5}$ (15,808; sensitivity analysis using ORs of 1.07 and 1.16: range, 7,532–29,968)" which "cost $760 million in medical care (sensitivity analysis: $362 million–1.44 billion), and $4.33 billion (sensitivity analysis: $2.06–8.22 billion) in lost economic productivity…(based on estimated reductions in IQ and estimated consequences for productivity over a lifetime)".[30] This estimate is corroborated by EPA's own simulations.[31] Using a recent meta-analysis and county-level air quality, and $PM_{2.5}$ pollution-related preterm birth (PTB) data, they found "a 10% decrease from 2008 $PM_{2.5}$ levels resulted in a reduction of 5,016 PTBs and savings of at least $339 million, potentially reaching over one billion dollars when considering later-life effects of PTB."

There is increasing evidence to suggest that early-life (including *in utero*) exposures to pollutants can lead to reduced lung function and the development of asthma and allergic disease in childhood. Not surprisingly, the respiratory system is developing from early in embryonic life, starting as early as 3 weeks and continuing after parturition into adolescence.[32] During this prolonged period of pre- and post-neonatal development, the lungs and other developing organs and systems may face higher risk in their immaturity stemming from cell development and metabolic changes.[33] A Southern California Children's Health study[34] examined the long-term effects of particle pollution on 1,759 children between ages 10 and 18, and found that those who grew up in more polluted areas faced an increased risk of having underdeveloped lungs. The lung function was found to be on average 20% below what could be expected for the child's age and similar to the impact of growing up in a home with parents who smoked. Because underdeveloped lungs may never grow or recover to their full capacity, this finding indicates potentially permanent damage with long-term risks of air pollutant exposure.

There is increasing evidence of association between maternal air pollution exposure and hypertensive disorders in pregnancy[35] which "provides a mechanistic link to intrauterine growth

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27 https://www.epa.gov/americaschildrenenvironment

28 Stieb DM, Chen L, Eshoul M, & Judek S. (2012). Ambient air pollution, birth weight and preterm birth: a systematic review and meta-analysis. *Environ Res*.,117, 100–11.

29 van der Zee SC, Fischer PH, & Hoek G. (2016). Air pollution in perspective: health risks of air pollution expressed in equivalent numbers of passively smoked cigarettes. *Environ Res*.,148, 475–483.

30 Trasande, L. Malecha,P. & Attina, T. M. (2016). Particulate Matter Exposure and Preterm Birth: Estimates of U.S. Attributable Burden and Economic Costs. *Env. Health Perspectives*, 124(12).

31 Jina J. Kim, J. J., Daniel A. Axelrad, D. A., & Dockins, C. (2018). Preterm Birth and Economic Benefits of Reduced Maternal Exposure to Fine Particulate Matter. National Center for Environmental Economics (NCEE) Working Paper.

32 Josi S & Kotecha S. (2007). Lung Growth and Development. *Early Human Development,* 83, 789-794.

33 Šrám RJ, Bincová B, Demjmek, & Bobak M. (2005). Ambient Air Pollution and Pregnancy Outcomes: A Review of the Literature. *Environmental Health Perspectives,* 113(4), 375-382.

34 Gauderman WJ, *et al*. (2004). The effect of air pollution on lung development from 10 to 18 years of age. *New England Journal of Medicine*, 351,1057-1067.

35 Pedersen M, *et al*. (2014). Ambient air pollution and pregnancy-induced hypertensive disorders: a systematic review and meta-analysis. *Hypertension*, 64(3), 494–500.

restriction, perinatal and neonatal mortality, preterm birth, and associated prematurity-related neonatal diseases, all highly associated with maternal hypertensive disorders. In addition, several studies report associations between airborne particulate exposures and increased risk of postneonatal death from respiratory causes."[36]

Several large cohort studies from Europe and North America have shown consistent associations of early-life exposure to PM (at home and at school in proximity to roads with high traffic density) and other pollutants with increased risk of development and exacerbation of asthma[37] and with lung function impairment in children.[38] Studies of pediatric cohorts both with and without asthma show strong support for adverse effects on lung function growth in childhood and adolescence[39] and improvements in lung function growth when children were relocated to less polluted areas or to areas with secular trends in air quality improvement, highlighting the potential public health benefit of stronger standards to improve air quality.[40]

Children with asthma are particularly vulnerable to the adverse respiratory effects of air pollutants. PM and other air pollutants have been consistently associated with reduced asthma control as shown by increased symptoms including wheezing, rescue medication use, decreased lung function, and increased use of medical services accompanied by school absences.[41] Bronchiolitis and otitis media, two of the most common infectious diseases of early childhood, have been linked to ambient air pollution.[42]

Patel, *et al*. (2009)[43] found that in predominantly Dominican and African American neighborhoods of New York City, children up to 2 years of age suffered coughing and wheezing associated with several $PM_{2.5}$ components in the mix. This association with nickel and vanadium and (in some seasons) elemental carbon held up even after accounting for potential confounders such as smoking in the home. These components were recognized as common pollutants from urban heating oil combustion and traffic pollution.

Islam *et al*., (2007) found that children in the California Children's Health Study who were more likely to have developed asthma were those who lived in areas with higher $PM_{2.5}$ where their lung function was lowered.[44] Morgenstern *et al*. (2008) found German six-year olds had an increased risk for asthmatic bronchitis or asthma diagnosis with each 1.0 $\mu g/m^3$ increase in $PM_{2.5}$.[45] Gehrig *et al*. (2010) also found a positive association of $PM_{2.5}$ with a significant increase in the incidence and prevalence of asthma and its symptoms in a follow up of their study of a cohort of children at age 8 in the Netherlands which also showed that children who lived in the

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[36] Brumberg *et al*. (2021). Ambient Air Pollution: Health Hazards to Children. AAP Policy Statement.
[37] Guarnieri M, and Balmes JR. (2014). Outdoor air pollution and asthma. *Lancet*, 383(9928),1581–1592.
[38] Rice MB, *et al*. (2016). Lifetime exposure to ambient pollution and lung function in children. *Am J Respir Crit Care Med*.,193(8), 881–888.
[39] Götschi T, Heinrich J, Sunyer J, and Künzli N. (2008). Long-term effects of ambient air pollution on lung function: a review. *Epidemiology*,19(5), 690–701.
[40] Gauderman WJ, *et al*. (2015). Association of improved air quality with lung development in children. *N Engl J Med*., 372(10), 905–913.
[41] Gilliland FD. (2009). Outdoor air pollution, genetic susceptibility, and asthma management: opportunities for intervention to reduce the burden of asthma. *Pediatrics*,123(suppl 3):S168–S173.
[42] Karr CJ, *et al*. (2009). Influence of ambient air pollutant sources on clinical encounters for infant bronchiolitis. *Am J Respir Crit Care Med*.,180(10), 995–1001; MacIntyre EA, *et al*. (2011). Residential air pollution and otitis media during the first two years of life. *Epidemiology*, 22(1), 81–89.
[43] Patel M, *et al*. (2009). Ambient Metals, Elemental Carbon, and Wheeze and Cough in New York City Children through 24 Months of Age. *American Journal of Respiratory and Critical Care Medicine*, 180,1107-1113.
[44] Islam T, *et al*. (2007). The Relationship Between Air Pollution, Lung Function and Asthma in Adolescents. *Thorax,* 62, 957-963.
[45] Morgenstern V, *et al.* (2008). Atopic Diseases, Allergic Sensitization, and Exposure to Traffic–related Air Pollution in Children. *American Journal of Respiratory and Critical Care Medicine*, 177, 1331-1337.

same place their entire lives had an even stronger likelihood of asthma.[46] Monitoring 182 elementary school children for 28 days in urban Windsor, Ontario, Dales *et al*. (2009) found that their lung function declined during the day, even though the daily mean was 7.8 µg/m^3, well below both the current $PM_{2.5}$ NAAQS, and adjusted for potential confounders.[47] Strickland *et al*. (2010)[48] examined data of over 10 million Atlanta emergency department visits and found that even at "relatively low levels" a strong association between pediatric emergency department visits for asthma and mean 24-hour $PM_{2.5}$ level of 16.4 µg/m^3. This finding of low level $PM_{2.5}$ exposure reinforces "the need for the continued evaluation" of the NAAQS to "ensure that the standards are sufficient to protect susceptible individuals."

3. Respiratory Effects

In addition to respiratory effects on children mentioned above, numerous studies have identified major respiratory health risks to older Americans from $PM_{2.5}$ exposure at levels below the current $PM_{2.5}$ NAAQS.[49] These risks are especially concerning as the previous decline in exposures to $PM_{2.5}$ appears to have levelled off, in part due to the increasing burden of wildfire smoke. There is substantial evidence of $PM_{2.5}$-related mortality and cardiovascular effects in older adults and in people with pre-existing cardiovascular disease.[50] There is also strong evidence of PM-related respiratory effects in people with pre-existing respiratory disease, particularly asthma.[51] Liu *et al*. (2017) found short-term exposure to wildfire-specific $PM_{2.5}$ was associated with heightened risk of respiratory diseases in the elderly population in the Western United States.[52]

4. Other Health Effects

Data from large well-designed cohort studies and systematic reviews of multiple epidemiological studies support the association of Traffic Related Air Pollution (TRAP) with adverse impacts on developing central nervous system, with strongest evidence currently for $PM_{2.5}$-associated increase in the risk of autism spectrum disorder.[53] Air pollution may adversely affect individuals with cystic fibrosis by increasing their risk of pulmonary exacerbations and related antibiotic use as well as by increasing the risk of lung function decline.[54]

In addition to asthma, other atopic conditions (eczema, allergic rhinitis) have been associated with exposure to TRAP.[55] Epidemiological studies, experimental data from animals studies, *in vitro* systems, and human exposure experiments provide evidence of diesel exhaust particle

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[46] Gehring U, *et al*. (2010). Traffic-related Air Pollution and the Development of Asthma and Allergies during the First 8 Years of Life. *American Journal of Respiratory and Critical Care Medicine*,181, 596-603.

[47] Dales R, Chen L, Frescura AM, Liu L, and Villeneuve PJ. (2009). Acute effects of outdoor air pollution on forced expiratory volume in 1 s: a panel study of schoolchildren with asthma. *European Respiratory Journal*, 34, 316-323.

[48] Strickland MJ, *et al*. (2010). Short-term Associations between ambient Air Pollutants and Pediatric Asthma Emergency Department Visits. *American Journal of Respiratory and Critical Care Medicine*,182, 307-316.

[49] DeFlorio-Barker, *et al*. (2019). Cardiopulmonary Effects of Fine Particulate Matter Exposure among Older Adults, during Wildfire and Non-Wildfire Periods, in the United States 2008–2010. *Environmental Health Perspectives* 127 (3), 037006.

[50] Pope, C. *et al*. (2019). Mortality Risk and Fine Particulate Air Pollution in a Large, Representative Cohort of U.S. Adults. *Environmental Health Perspectives*, 127(7), 077007.

[51] EPA. (Dec, 2019). Integrated Science Assessment for Particulate Matter, EPA/600/R-19/188; section 5.1

[52] Liu, J. C., *et al*. (2017). Wildfire-Specific Fine Particulate Matter and Risk of Hospital Admissions in Urban and Rural Counties. *Epidemiology*, 28(1), 77–85.

[53] Flores-Pajot MC, *et al*. (2016). Childhood autism spectrum disorders and exposure to nitrogen dioxide, and particulate matter air pollution: a review and meta-analysis. *Environ Res*.,151, 763–776.

[54] Goss CH, *et al*. (2004). Effect of ambient air pollution on pulmonary exacerbations and lung function in cystic fibrosis. Am J Respir Crit Care Med.,169(7), 816–821; Goeminne PC, Kiciński M, Vermeulen F, *et al*. (2013). Impact of air pollution on cystic fibrosis pulmonary exacerbations: a case-crossover analysis. *Chest*,143(4), 946–954.

[55] Brandt EB, *et al*. (2015). Air pollution and allergic diseases. *Curr Opin Pediatr*., 27(6), 724–735.

induction of airway inflammatory reaction and enhancement of immunologic response to allergens.[56] Meta-analysis of studies on TRAP-related health impacts revealed PM to be associated with sensitization to outdoor allergens, such as pollen and grass.[57]

V. Both Standards Need to Be Strengthened

Scientific data assessed during the last review clearly showed that the annual average standard needed to be much more protective than the current $PM_{2.5}$ annual standard of 12 µg/m^3 that was set in 2012. Multiple, multi-city studies over long periods of time have since given clear evidence of premature death, cardiovascular and respiratory harm as well as reproductive and developmental harm at $PM_{2.5}$ concentrations far below the level of the current standard.

In their analysis of the scientific data, the aforementioned independent particulate matter review panel[58] gave more weight to the evidence-based approach, supported by data from the risk-based approach, in concluding unequivocally and unanimously that the current $PM_{2.5}$ standards do not adequately protect public health. The scientific "evidence is consistent within each discipline and coherent among the multiple disciplines in supporting a causal, biologically plausible relationship between ambient concentrations well below the current $PM_{2.5}$ standards and adverse health effects, including premature death… We found no evidence for an ambient concentration threshold for health effects at the lowest observed levels, either for annual or for 24-hour exposure periods."

The panel continued, "The EPA risk assessment focused on all-cause mortality, mortality due to ischemic heart disease, and mortality due to lung cancer. Exposure to current levels of $PM_{2.5}$ is also causally linked to numerous other adverse health outcomes, including long- and short-term cardiovascular events, respiratory illnesses, death from cancers other than lung cancer, and nervous system diseases (e.g., cognitive decrements and dementia). Additional health concerns, such as adverse pregnancy and birth outcomes, are associated with particulate air pollution." This panel recommended an annual standard between 10 µg/m^3 and 8 µg/m^3 to protect the general public, noting that the margin of safety to protect vulnerable groups increases as the level of the standard is lowered within this range. Based on scientific evidence, and with the knowledge that the continuum of adverse effects decrease as the level of the standard is tightened, the panel recommended setting the 24-hour standard within a range of 30 - 25 µg/m^3.[59]

Extended analyses of the cohorts in the landmark American Cancer Society study[60] and the Harvard Six Cities study[61] have confirmed that particulate matter causes premature death. Laden *et al*. (2006)[62] and Krewski *et al*. (2009)[63] not only confirmed the findings of the original major studies, but added to the evidence. Laden *et al*. found statistically significant evidence that during this extended period, as the air quality improved, premature mortality dropped as well. A further follow-up extended the Six Cities study by 11 additional years, during which air

[56] Riedl MA. (2008). The effect of air pollution on asthma and allergy. *Curr Allergy Asthma Rep*., 8(2),139–146.
[57] Bowatte G, *et al*. (2015). The influence of childhood traffic-related air pollution exposure on asthma, allergy and sensitization: a systematic review and a meta-analysis of birth cohort studies. *Allergy*, 70(3), 245–256.
[58] Frey *et al*. (2020). The Need for a Tighter Particulate-Matter Air-Quality Standard.
[59] Frey *et al*. (2020). The Need for a Tighter Particulate-Matter Air-Quality Standard.
[60] Pope CA III, *et al*. (1995). Particulate air pollution as a predictor of mortality in a prospective study of US adults. American Journal of Respiratory and Critical Care Medicine, 151, 669-674.
[61] Dockery DW, *et al*. (1993). An association between air pollution and mortality in six US cities. *New England Journal of Medicine*, 329, 1753-1759.
[62] Laden F, *et al*. (2006). Reduction in fine particulate air pollution and morality: extended follow-up of the Harvard Six Cities study. *American Journal of Respiratory and Critical Care Medicine*, 173, 667-643.
[63] Krewski D, *et al*. (2009). Extended follow-up and spatial analysis of the American Cancer Society study linking particulate air pollution and mortality. Health Effects Institute, Report No. 140.

quality was well below the level of the current annual average standard.[64] Investigators reported an association between $PM_{2.5}$ and increased risk of premature all-cause, cardiovascular, and lung cancer deaths. The concentration- response relationship was linear down to 8 μg/m^3, with no evidence of a threshold. These findings were consistent with a large Canadian cohort study that reported that long-term exposure to $PM_{2.5}$ (mean, 8.7 μg/m^3; interquartile range, 6.2 μg/m^3) was associated with increased risk of cardiovascular mortality in adults.[65]

Newer large, long-term studies also added to the evidence of premature death from $PM_{2.5}$ at levels well below the current annual standard. The Women's Health Initiative studied over 65,800 women who had no history of cardiovascular disease in 36 U.S. cities.[66] Each increase of $PM_{2.5}$ of 10 μg/m^3 was associated with a 76% increase in premature deaths from cardiovascular causes.

Evidence from multiple studies that examined short-term exposures found harm at levels well below the current annual standard. PM exposure-associated health effects found in these studies range across those found in the ISA to be causal and likely causal. Below are just a few of the studies that looked at short-term exposures and had mean annual $PM_{2.5}$ concentrations well below 12 μg/m^3.

Dominici *et al*. (2006)[67] examined hospital admissions for 11.5 million Medicare enrollees and found that hospital admissions for cardiovascular and respiratory causes increased significantly with every 10 μg/m^3. There were clear regional differences, but the researchers concluded the $PM_{2.5}$ levels indicated "an ongoing threat to the health of the elderly population from airborne particles" and strong evidence that the NAAQS should be "as protective of their health as possible." Bell *et al*. (2008)[68] followed up on these Medicare enrollees in 202 counties looking at regional and seasonal differences. This analysis found continued strong associations with increased hospital admissions for both cardiovascular and respiratory harm, particularly in the Northeast, for increases of 10 μg/m^3.

Multiple epidemiological studies have found significant evidence of harm with strong confidence well below the current annual standard of 12 μg/m^3 including the Women's Health Initiative study and the Medicare study by Bell *et al*. (2008) discussed earlier. Bell *et al*. (2007)[69] showed that low birth weights were associated with long-term mean concentrations below 12 μg/m^3.

A 2023 study found that children experienced instances of asthma exacerbations and decreases in pulmonary function at levels well below the 24-hour standard in the days immediately preceding their illness.[70]

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[64] Lepeule J, *et al*. (2012). Chronic Exposure to Fine Particles and Mortality: An Extended Follow-Up of the Harvard Six Cities Study from 1974 to 2009. *Environmental Health Perspectives*, 120, 708-714.
[65] Crouse DL, *et al*. (2012). Risk of Nonaccidental and Cardiovascular Mortality in Relation to Long-term Exposure to Low Concentrations of Fine Particulate Matter: A Canadian National-Level Cohort Study. *Environmental Health Perspectives*, 120, 708-714.
[66] Miller KA, *et al*. (2007). Long-term exposure to air pollution and incidence of cardiovascular events in women. New England Journal of Medicine; 356, 447-458.
[67] Dominici F, *et al*. (2006). Fine Particulate Air Pollution and Hospital Admission for Cardiovascular and Respiratory Diseases. *Journal of the American Medical Association*, 295(10), 1127-1134.
[68] Bell ML, *et al*. (2008). Seasonal and Regional Short-term Effects of Fine particles on Hospital Admission in 202 US Counties, 1999-2005. American Journal of Epidemiology,168, 1301-1310.
[69] Bell ML, Ebisu K, & Belanger K. (2007). Ambient Air Pollution and Low Birth Weight in Connecticut and Massachusetts. *Environmental Health Perspectives*, 115 (7), 1118-1125.
[70] Altman MC, *et al*. (2023). Associations between outdoor air pollutants and non-viral asthma exacerbations and airway inflammatory responses in children and adolescents living in urban areas in the USA: a retrospective secondary analysis. *Lancet Planet Health*, 7:e33–e44.

In the journal *Risk Analysis*, EPA staff published another analysis that estimates the annual toll from $PM_{2.5}$ at 130,000 premature deaths each year, based on 2005 air quality levels.[71] The study estimated a staggering 1.1 million life-years lost among people over age 65, accounting for 7% of life- years lost in 2005 in this population of elderly Americans. This translates into an average shortened lifespan of 8.5 months per individual affected. Further, the authors estimate 1,800 deaths among babies and infants attributable to PM air pollution. This same analysis gauged the annual morbidity impacts of $PM_{2.5}$ pollution at tens of thousands of hospital and emergency department visits for cardiac and respiratory causes and millions of asthma exacerbations, bronchitis, and other respiratory symptoms in children.

These are preventable deaths. These are avoidable sicknesses and suffering. We have the means to control manmade air pollution to end this unnecessary toll on human life. Air pollution control efforts driven by more protective air quality standards for $PM_{2.5}$ can give us the relief so sorely needed.

5. Level of Primary Annual $PM_{2.5}$ NAAQS

In its rule, EPA is proposing a primary annual $PM_{2.5}$ NAAQS of 9-10 μg/m^3 while taking comment on alternative annual standard levels down to 8.0 μg/m^3. Here we offer our analyses and rationale in support of this 8.0 μg/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, "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 μg/m^3 while retaining the primary 24-hour $PM_{2.5}$ standard (U.S. EPA, 2020a)."[72]

We ask EPA to review this science-policy summation by the large majority of the current PM CASAC panel, who recommended that the annual standard be lowered in 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."[73]

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[71] Fann N, *et al*. (2012). Estimating the National Public Health Burden Associated with Exposure to Ambient $PM_{2.5}$ and Ozone. *Risk Analysis*, 32, 81-95.
[72] EPA Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 10.
[73] 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.

In the 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".[74]

We would like to 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 U.S. with a 24-hour standard of 27 $\mu g/m^3$ and an annual standard of 8.8 $\mu g/m^3$ annual average of the daily 24-hour average concentrations.[75]

EPA's own Regulatory Impact Analysis on this proposal identifies that an annual standard of 8 $\mu g/m^3$ would result in thousands more premature deaths prevented than levels of 9 or 10 $\mu g/m^3$, with a central estimate of 9,200 adult premature deaths avoided at 8 $\mu g/m^3$ versus 4,200 at 9 and 1,700 at 10 $\mu g/m^3$.[76]

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 groups. Finalizing a level that is higher than this most stringent value recommended by the expert scientists on the CASAC panel and strongly supported by the public would fall short of EPA's legal obligation to establish an annual primary standard that protects health with an adequate margin of safety and would represent a major missed opportunity to improve public health and advance environmental justice.

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

In its proposed rule, 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 $\mu g/m^3$".[77] While EPA's logic in not including levels of the standards in the proposed rule on which it is soliciting public comment is unclear, 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. Based on the 2019 ISA and additional research data that has become available since the ISA, and the PA, a large majority of the 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

[74] EPA. (Dec, 2019). Integrated Science Assessment for Particulate Matter, EPA/600/R-19/188; page 104 (P-15).
[75] Canada's Air (Accessed Mar, 2023). Canadian Ambient Air Quality Standards (CAAQS).
[76] EPA (2023). Regulatory Impact Analysis for the Proposed Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page ES-17.
[77] EPA Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 3 (5560).

> 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 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. [*Emphasis added.]*[78]

EPA placed a greater weight on controlled human exposure studies and on risk assessment in deciding to retain the current 24-hour standard with the belief that the "annual standard is the controlling standard across most of the urban study areas" as asserted by a small minority of the CASAC panel, and hence "the annual standard can be used to limit both long- and short-term $PM_{2.5}$ concentrations."

EPA acknowledges that "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." Despite this recognition, and contrary to 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 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 $PM_{2.5}$."[79]

The way the annual $PM_{2.5}$ standard is calculated means that it cannot be the controlling standard and must not be used to limit short-term daily peak $PM_{2.5}$ levels. The annual standard by design reflects the *long-term chronic average daily exposure.* For this purpose, the $PM_{2.5}$ annual standard design value is calculated as an average of averages of averages - it is "(t)he 3-year average of annual means for a single monitoring site or a group of monitoring sites" where the "(a)nnual mean refers to a weighted arithmetic mean based on quarterly means".[80] This successive averaging of daily observations is designed to preclude the influences of daily meteorological conditions, or variations in air quality brought about by unusual social or environmental conditions (e.g. COVID-related transient improvement in air quality, brief deterioration of air quality due to chemical accidents or to wildfires, etc.), or inter-annual variations, to yield a steady-state average level of $PM_{2.5}$ that the public is exposed to daily over the course of a year. The averaging function flattens daily peak $PM_{2.5}$ levels observed over the three years and therefore does NOT capture the daily high values/ peak $PM_{2.5}$ concentrations experienced by local communities.

EPA's own Regulatory Impact Analysis identifies the potential health benefits of strengthening the 24-hour standard to 30 µg/m^3. The central estimate points to avoided premature deaths, hospital admissions and ED visits, stroke, lost work days and more due to even this inadequately stronger level.[81]

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[78] 2022 CASAC Review of the EPA's Policy Assessment for the Reconsideration of the NAAQS for PM; pages 3-4.
[79] EPA Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 20 (5577).
[80] Environmental Protection Agency. APPENDIX N TO PART 50—INTERPRETATION OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR $PM_{2.5}$; page 127.
[81] EPA (2023). Regulatory Impact Analysis for the Proposed Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page ES-17.

The fact that two $PM_{2.5}$ standards – a short-term 24-hour and a long-term annual – were established attests to their separate need in reducing acute peak exposures as well as chronic continued exposures. Because neither standard alone is deemed controlling of or sufficient stringency to protect human health from particle pollution throughout the year, we reiterate our ask that EPA revise the level of current 24-hour $PM_{2.5}$ primary NAAQS to 25 µg/m^3 as warranted by current science and as recommended by the majority of the CASAC panel.

7. 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".[82] A recent study[83] 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". 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."

The ozone CASAC panel 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."[84] Both these penalties will only increase as the impacts of anthropogenic climate change become more frequent and intense. Climate change has "health and welfare consequences beyond air quality and other effects from combinations of climate and air quality."[85]

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.[86]

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[82] "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.

[83] 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.

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

[85] 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.

[86] Samenow, J. (Jul 20, 2021). Wildfire smoke pouring into Mid-Atlantic prompts air-quality alert for D.C. and Baltimore. The Washington Post.

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."

Given the increased severe 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 99th percentile to reduce by half the number of currently allowed exceedances and to account for the increasing impacts of climate change on air pollution, to protect the health of vulnerable at-risk populations with a margin of safety.

VI. Air Quality Index and Enhanced $PM_{2.5}$ Monitoring

The Air Quality Index (AQI) is a communication tool "to inform the public when air quality is poor and thus when they should consider taking actions to reduce their exposures."[87] The AQI is not a regulatory tool to control air pollution and "EPA does not provide guidance on the use of the AQI for such purposes,"[88] but it is tied to short-term standards of PM and other pollutants. EPA is proposing to update the AQI-PM framework while retaining the 24-hour standard. EPA is proposing to revise:

i. 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.
ii. 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
iii. the daily reporting requirement from 5 days per week to 7 days per week.

In our earlier comment on the draft PA,[89] we noted that the 24-hour $PM_{2.5}$ standard is the basis for AQI-PM that is used to communicate daily air pollution levels to the public. The AQI suggests that only exposures of more than 35.5 µg/m^3 are unhealthy for sensitive groups on code orange days. 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, which does not convey the health risks of $PM_{2.5}$ exposure accurately. 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 µg/m^3. Setting a more protective 24-hour standard will not only drive pollution reduction, but also provide more accurate information so that citizens can make decisions to reduce or prevent exposures on days of high $PM_{2.5}$ levels that threaten health.

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

[87] EPA Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 81 (5638).
[88] EPA Reconsideration of the National Ambient Air Quality Standards for Particulate Matter; page 81 (5638).
[89] https://www.lung.org/getmedia/3e468cd0-0579-4cfe-a6d1-faf7da7a3218/American-Lung-Association-Comments-Docket-EPA-HQ-OAR-2015-0072.pdf.

$PM_{2.5}$. This adherence to current science needs to be reflected not only in revising AQI breakpoints but in setting the $PM_{2.5}$ NAAQS themselves.

Further, 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:[90]

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 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.

Metropolitan statistical areas (MSAs) are defined as geographic locations having at least one urbanized area of ≥50,000 inhabitants.[91] The current AQI reporting requirement does not reflect this definition (bullet #1 above). We ask that the reporting requirement be revised to say Micropolitan Statistical Areas ("which must have at least one urban cluster of at least 10,000 but less than 50,000 population").[92] To ensure that the *daily* AQI is of practical and immediate value to the public in protecting themselves, and to truly protect people from harmful $PM_{2.5}$ pollution every day and all through the year, we urge EPA to make mandatory the voluntary reporting elements listed above, and to strengthen the annual standard to 8 $\mu g/m^3$ and the 24-hour standard to 25 $\mu g/m^3$. The AQI will help all people nationwide take action on days of poor air quality only if it provides accurate and timely data, and is based on a stringent 24-hour standard that fully reflects current science.

We support EPA's proposed monitor network design requirement to specifically locate $PM_{2.5}$ monitoring stations in at-risk communities to improve the assessment of exposures in such communities. The proposed enhancement of monitor network should not be restricted just to areas with major stationary or mobile emission sources or to just urban MSAs with populations of over 50,000. At-risk communities are disproportionately affected by poor air quality. These communities are multiple and include children, elderly, racial and ethnic minorities, groups of lower socioeconomic status, and people with preexisting morbidities. Just as they are made up of diverse groups they are also diverse in their location. At-risk communities exist outside of MSAs throughout the country and may be exposed to higher $PM_{2.5}$ levels, but without ground monitors, exposure assessment is extremely difficult. Absence of monitored data does not mean absence of adverse impacts or presence of cleaner air. As such, we ask EPA to extend the proposed monitoring network to Micropolitan Statistical Areas with populations of 10,000 - 50,000, and to rural areas. Funding from the Inflation Reduction Act to "Address Air Pollution"

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[90] 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.

[91] https://www.census.gov/programs-surveys/metro-micro/about.html.

[92] https://www3.epa.gov/ttnamti1/files/ambient/pm25/qa/vol2sec06.pdf.

(which we commented on[93]) could be used for this purpose. Additionally, EPA must synchronize the AQI reporting requirements (see above) to these extended monitored areas. We also ask that these sites employ federal equivalent methods (FEMs) which can provide continuous monitoring that will be useful in determining NAAQS compliance as well as in issuing AQI advisories. Measured data on real-time $PM_{2.5}$ levels on all days of the year is essential for both regulatory action and for individuals to take action on poor air quality days.

VII. Benefits of Stronger Standards for Environmental and Social Justice

President Biden's Executive Order 14008 shone a spotlight on the priority and opportunity of addressing environmental injustices, directing, "Agencies shall make achieving environmental justice part of their missions by developing programs, policies, and activities to address the disproportionately high and adverse human health, environmental, climate-related and other cumulative impacts on disadvantaged communities…It is therefore the policy of my Administration to secure environmental justice."[94]

EPA's Regulatory Impact Analysis for this proposed rule partially illustrates the health equity opportunity of strengthening both standards. EPA found 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. 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. Black people would experience the most reductions in total mortality rates, 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).[95]

The scientific literature further illustrates that setting the PM NAAQS at the most protective levels of 8 μg/m^3 for the annual standard and 25 μg/m^3 for the 24-hour standard is critical to achieving President Biden's environmental justice goal. With regard to the annual standard, a March 2023 study using Medicare data found that "lower $PM_{2.5}$ exposure was associated with lower mortality in the full population, but marginalized subpopulations appeared to benefit more as $PM_{2.5}$ decreased." Decreasing $PM_{2.5}$ levels from 12 μg/m^3 to 8 μg/m^3 had outsized benefits for marginalized groups. The hazard ratio associated with this decrease was 0.963 for higher-income white populations but 0.931 for higher-income Black populations, 0.940 for lower-income white populations and 0.939 for lower-income Black populations, indicating that the latter three groups may benefit more from lower $PM_{2.5}$ levels.[96]

The authors note that EPA's Regulatory Impact Analysis in this proposed rule may underestimate the health benefits of stronger NAAQS, and concluded, "The EPA public health

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[93] Comment from the American Lung Association (2023). Docket #: EPA-HQ-OAR-2022-0876, available at https://www.regulations.gov/comment/EPA-HQ-OAR-2022-0876-0021.

[94] Executive Order 14008, available at: https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/executive-order-on-tackling-the-climate-crisis-at-home-and-abroad/.

[95] 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).

[96] Josey, K., Delaney, S. W., Wu, X., Nethery, R. C., DeSouza, P., Braun, D., & Dominici, F. (Mar, 2023). Air Pollution and Mortality at the Intersection of Race and Social Class. *New England Journal of Medicine*.

and environmental justice–seeking mandates may require considerably stronger NAAQS for annual $PM_{2.5}$ (e.g. ≤8 µg per cubic meter)."[97]

With regard to the 24-hour standard, the American Thoracic Society noted that "improvements in air pollutant concentrations measured at regulatory monitoring locations do not always result in the same level of improvement in 'hot-spot' locations…this problem is exacerbated when the relationship between monitored pollutant concentrations and exposure levels at nearby hot-spot locations is not considered when determining the controlling standards for revised NAAQS levels." The authors note that EPA can help address this issue by strengthening the 24-hour standard to account for these environmental justice concerns.[98]

These studies and comments build on decades of environmental justice research that show the disproportionate burden of fine PM on communities of color.

A 2021 study found that "racial-ethnic minorities in the United States are exposed to disproportionately high levels of ambient fine particulate air pollution ($PM_{2.5}$), the largest environmental cause of human mortality." The authors identified emissions source types by state and city, identifying industry, light-duty gasoline vehicles, construction and heavy-duty diesel vehicles as among the largest sources of disparity. Most source types, representing approximately 75% of fine PM exposure in the U.S., disproportionately affected racial-ethnic minorities – across states, urban vs rural areas, income levels and exposure levels.[99]

In a 2019 cohort study of more than 4.5 million US veterans, nine causes of death were associated with exposures to annual mean $PM_{2.5}$ levels: cardiovascular disease, cerebrovascular disease, chronic kidney disease, chronic obstructive pulmonary disease, dementia, type 2 diabetes, hypertension, lung cancer and pneumonia. Authors found that the attributable burden of death associated with $PM_{2.5}$ was disproportionally borne by Black individuals and socioeconomically disadvantaged communities, and that 99% of the burden was associated with $PM_{2.5}$ levels below standards set by EPA.[100]

A 2018 study found that racial and ethnic minorities were exposed to significantly higher levels of air pollution compared to whites, and that the difference was most pronounced in metropolitan areas with high levels of residential segregation.[101]

A 2018 study found that people in poverty had 1.35 times higher burden of $PM_{2.5}$; non-whites had 1.28 times higher burden; and Blacks specifically had 1.54 times higher burden than did the overall population.[102] The seminal Di *et al.* Medicare chronic mortality study showed three times higher relative risk (hazard ratio) for Black populations compared to the general population (a hazard ratio of 1.21 per 10 µg/m^3 increase in $PM_{2.5}$).[103] A study by Thind *et al.* (2019) identified

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97 *Ibid.*
98 Cromar, Kevin, Alison Lee, Jack Harkema, Isabella Annesi-Maesano (2022). Science-based Policy Recommendations for Fine Particulate Matter in the United States. *American Journal of Respiratory and Critical Care Medicine*, 206(9).
99 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).
100 Bowe, B., Xie, Y., Yan, Y., & Al-Aly, Z. (2019). Burden of Cause-Specific Mortality Associated With $PM_{2.5}$ Air Pollution in the United States. *JAMA Network Open*; 2(11): e1915834.
101 Woo, B. *et al*. (2019). Residential Segregation and Racial/Ethnic Disparities in Ambient Air Pollution. *Race and Social Problems*, 11(1), 60–67
102 Mikati, I. *et al*. (2018). Disparities in Distribution of Particulate Matter Emission Sources by Race and Poverty Status. *American Journal of Public Health*, 108(4), 480–85.
103 Di Q, et al. (2017). Air pollution and mortality in the Medicare population. N Engl J Med., 376, 2513–2522.

high air pollution exposures among African Americans from electricity generation.[104] In that study, disparities by race/ethnicity were observed for each income category, indicating that the racial/ethnic differences hold even after accounting for differences in income.[105]

EPA's own ISA from the 2020 review noted that analyses that directly compare PM-related health effects across groups indicated that minority populations have higher $PM_{2.5}$ exposures than white populations, contributing to adverse health risk in non-white populations.[106]

VIII. Implementation Concerns Have No Place in Standard-Setting

As noted above, implementation concerns, including costs and technical feasibility, have no place in the primary standard setting-process. *Whitman v. Am. Trucking Ass'ns* 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.

The Lung Association notes that among the implementation concerns that have been raised as EPA developed this proposal is the issue of prescribed fire. The Lung Association issued a research review that found that in some circumstances, prescribed fire can an important tool for reducing overall smoke-related health impacts by helping prevent catastrophic wildfires.[107] The robust practices involved in planning and completing prescribed burns, including methods to reduce smoke distribution and allow the public to take protective measures, are critical.

However, concerns about the implications of stronger PM NAAQS for prescribed fire practitioners have no bearing on the levels of the standards themselves. Implementation issues, such as prescribed fire, are irrelevant to the standards setting process. We encourage EPA to work outside of this rule to address improvements in NAAQS implementation that could ensure the use of responsible prescribed fire for the express purpose of catastrophic wildfire mitigation that prescribed burn practitioners and other experts call for. The Clean Air Act requires that these concerns have no bearing on the level of the standards, and if EPA were to finalize NAAQS that allowed for more pollution in an attempt to make prescribed burns simpler to plan or complete, it would be a clear violation of the law.

IX. The Public and the Health Community Support Much Stronger Standards

The health and medical community is largely united behind our asks of 8 $\mu g/m^3$ for the annual standard, 25 $\mu g/m^3$ for the 24-hour standard, and updating the form of the 24-hour standard to the 99th percentile. A 2022 letter to Administrator Regan calling for these asks was signed by fifteen leading national health and medical organizations. In fact, the only instances we are aware of in which health organizations are supporting a different level for the primary standards is that some may call for an even more protective annual standard of 5 $\mu g/m^3$. Given the lack of threshold for health harms from PM, many medical professionals have stated support for the most protective level possible.

A March 2023 public opinion poll commissioned by the Lung Association found that voters overwhelmingly view the Clean Air Act (65% favorable/14% unfavorable) and EPA (65%/20%) favorably. An overwhelming 72% of voters support EPA updating standards with stricter limits on air pollution generally, with majority support across party lines. Specifically, voters support

[104] Thind, M. *et al*. (2019). Fine Particulate Air Pollution from Electricity Generation in the US: Health Impacts by Race, Income, and Geography. *Environmental Science & Technology*, 53(23), 14010–19.
[105] EPA. (Dec, 2019). Integrated Science Assessment for Particulate Matter, EPA/600/R-19/188; section 11.
[106] EPA. (Dec, 2019). Integrated Science Assessment for Particulate Matter, EPA/600/R-19/188; section 12.5.4.
[107] Hill, L., Jaeger, J., & Smith, A (2022). Can Prescribed Fires Mitigate Health Harm?

EPA updating both the annual and daily PM standards, with 74% supporting stricter standards for fine particles on both an annual and daily basis.

Further, when the survey informed voters that EPA had decided to set new limits that are stricter than the current standards but not as strict as the most protective standards recommended by its scientific advisors, a strong 65% majority agree that EPA should "reconsider its decision and place stricter standards that align with the strong standards that were recommended by the scientific advisors." Voters also overwhelmingly believed that stricter limits on fine particles would have positive impacts on the quality of the air they breathe and the health of families like theirs.[108]

X. Conclusion

The new EPA standards must follow the requirements of the Clean Air Act and be set at levels that will protect the public with an adequate margin of safety, including children, the elderly, people with respiratory or cardiovascular disease or diabetes and people already disproportionately burdened.

We urge EPA to strictly follow the science and the requirements of the CAA to expeditiously finalize the rule on PM NAAQS with a primary annual $PM_{2.5}$ standard of 8 $\mu g/m^3$ and a primary $PM_{2.5}$ 24-hour standard of 25 $\mu g/m^3$ set at the 99th percentile.

[108] Global Strategy Group. (2023). New nationwide data reveals strong support for the EPA implementing stricter daily and annual soot standards. Available at https://action.lung.org/site/DocServer/ALA_Particulate_Matter_Nationwide_Memo.pdf?_ga=2.244900166.2143757269.1679881912-1290029384.1651002209&_gl=1*14gfn9c*_ga*MTI5MDAyOTM4NC4xNjUxMDAyMjA5*_ga_P13PC1PGW8*MTY3OTkwNzgwMC45NjEuMS4xNjc5OTEwMjkwLjYwLjAuMA.