



December 11, 2018

The Honorable Andrew Wheeler, Acting Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Sent via Regulations.gov

RE: Comments on the first External Review Draft of the Integrated Science Assessment for Particulate Matter—EPA/600/R-18/179

Dear Acting Administrator Wheeler:

We public health and medical organizations offer these joint comments on the Draft Integrated Science Assessment for Particulate Matter (ISA) for your consideration and for the consideration of the Clean Air Scientific Advisory Committee (CASAC).

Our organizations consider the review of the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) to be a top priority concern for the protection of public health, a position reinforced by the escalating evidence of its widespread harm. Particulate matter air pollution poses risks of serious health effects, including premature death, and the evidence compiled in this ISA documents greater risks than had previously been recognized. The evidence in the last review indicated that adverse health effects ranging from respiratory problems to early death persisted at levels below both primary standards set in 2006 and 2012. Newly available evidence reinforces this concern.

The U.S. Environmental Protection Agency has provided extensive analysis in the format, coverage of issues, criteria, and consistent framework for decision-making. We believe that extensive new evidence that has emerged since the last review strengthens the case for setting stringent short- and long-term standards for particulate matter.

### Protection of public health is primary

The Clean Air Act demands precautionary action to protect public health in setting the NAAQS and explicitly recognizes the need to maintain an adequate margin of safety. In keeping with that requirement, EPA should set air quality standards that provide broad protection against effects that are not limited to those where a causal relationship is established or where there is likely to be a causal relationship. EPA should provide protection against effects found to be “suggestive of a causal relationship.”

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. As the D.C. Circuit held in reviewing the NAAQS revisions, “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 Assoc. v. EPA*, 283 F.3d 355, 369 (D.C. Cir. 2002) (quoting Particulate Matter NAAQS, 62 Fed. Reg. 38653); *id.* (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”)).<sup>1</sup>

In the seminal case on the NAAQS, the court held 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.”<sup>2</sup> NAAQS must be set at levels that are not only adequate to protect the average member of the population, but also guard against adverse effects in vulnerable subpopulations, such as children, the elderly, and people with heart and lung disease.

The Clean Air Act explicitly recognizes the uncertainty in scientific research in its requirements to periodically review the air pollution criteria and to err on the side of protection. This precautionary principle requires that EPA set air quality standards to protect against effects suggestive of causality.

### EPA must reinstate the PM advisory panel

Our organizations call on EPA to reinstate the expert review panel for PM that had been serving since shortly after the initiation of this review in December 2015. Such expert advisors have historically assisted the CASAC in the complex review of these studies and data. EPA’s unexplained decision to dismiss the panel severely weakens the review. No seven CASAC members could adequately address the vast array of issues that this review requires, including the clinical, epidemiological and toxicological studies; the research into the chemistry and exposures; and the estimates of the risk to human health at multiple concentrations and durations of exposure. The panel’s absence will deprive EPA scientists and CASAC of essential expertise and valuable perspectives on these issues. EPA must reinstate that panel.

In reinstating that panel, EPA must not exclude current recipients of EPA grants. EPA grants are core research funding sources that have helped to provide new and expanded insights into the complexity of the impact of air pollution on human health. EPA grants fund research conducted by some of the most experienced scientists in these questions. Preventing them from serving on this panel would continue to restrict the expert assistance the CASAC needs to perform its responsibility to EPA. Our organizations

note that, in the memo and directive from former Administrator Pruitt declaring that no appointees to the Federal Advisory Committees could currently be recipients of EPA grants or funding, EPA included no discussion of even potential conflicts of interest by recipients of funding from industrial or corporate sources.<sup>3</sup> The assumption that potential conflicts would only occur with EPA funding is seriously flawed.

#### EPA needs to allow sufficient time for a thorough review

Our organizations urge EPA to recognize that a second draft ISA is often needed to review how EPA addresses and incorporate the comments CASAC and the PM panel provided. With the proposed schedule, not only does EPA miss the opportunity to get feedback on its revised science assessment, EPA must begin the development of the next round of documents that depend on that assessment without a completed ISA.

#### Particulate matter has proven health harms that call for a stronger standard to protect health

The draft ISA provides ample evidence of the risks to life and health from particulate matter. Below are summary comments on the major findings by health effects category of this draft ISA from our organizations. Please note that, while EPA has concluded that PM<sub>2.5</sub> (and in one case, ultrafines) causes or likely causes the health effects summarized in the ISA, the findings should apply to PM<sub>10</sub> as well, since PM<sub>10</sub> includes all particles that would comprise the PM<sub>2.5</sub> and ultrafine sizes.

**Mortality.** Our organizations agree with EPA's conclusion of a causal determination for premature deaths from both short-term and long-term exposure to particulate matter. EPA recognizes the abundant evidence from major repeated US and international studies that demonstrates beyond question that PM shortens life. From evidence from the 1952 London Fog through the American Cancer Society studies and the Six Cities studies to the newer Medicare studies and others, the multiple repeated, well-researched and intensely reviewed studies show clearly and without question that exposure to PM shortens life.

**Respiratory effects.** Our organizations support a causal determination for both short-term and long-term exposures on respiratory effects. The evidence of increased emergency department visits and hospital admissions, particularly for asthma exacerbations, biologically plausible pathways, and controlled human exposure studies all support the causal impact of short-term exposures on respiratory health. Growing epidemiological and toxicological evidence shows consistent, causal impacts on increased risk of asthma onset as well as respiratory mortality in people with chronic obstructive pulmonary disease from long-term exposure.

**Cardiovascular effects.** Our organizations agree with EPA's conclusion of a causal determination for both short-term and long-term exposures on cardiovascular harm, including increased risk of emergency department visits and hospital admissions for Ischemic Heart Disease and Heart Failure, as well as premature deaths from cardiovascular causes.

**Cancer.** Our organizations support a causal determination for the long-term exposure on lung cancer, in keeping with the findings of the International Association for Research on Cancer.

**Nervous System effects.** Our organizations agree with EPA's conclusion of a likely to be causal determination from long-term exposure on the impacts to the nervous system, including increased risk of neurodegeneration.

**Reproductive and Development effects.** Our organizations agree with EPA's conclusion that the evidence suggests harm from long-term exposure for reproductive and developmental effects, including increased risk of low birthweight and premature births.

**Metabolic effects.** Our organizations agree with EPA's conclusion that the evidence suggests harm from long-term exposure, including associations with increased risk of development of diabetes and increased risk of premature death from diabetes.

Some of our organizations will provide additional comments on these and other findings in separate comments.

#### No threshold exists for harm from particulate matter.

Our organizations support EPA's finding that no threshold exists for the harm from PM, a finding reached in the prior reviews in the 2004 and 2009 science assessments. This is especially important in the evidence from the long-term exposure to PM<sub>2.5</sub>, where studies show harm as low as 5-8 µg/m<sup>3</sup>, as EPA acknowledges.

#### Many populations face increased risk from particulate matter.

As EPA notes in the ISA, millions of Americans are at risk from PM. Our organizations are pleased to see EPA's acknowledgement that where people live impacts their exposure and increases their risk. Too often, people with low socioeconomic status and communities of color who often live or work near major sources of PM, such as heavily-traveled highways, have not been recognized as being at risk from air pollution. For that reason, we support the recognition that nonwhite groups and people with low socioeconomic status face increased risk from particulate matter. Our groups also affirm the newer research showing that people who are obese and people with certain genetic variants face greater risk.

However, our organizations urge EPA to restore the previous recognition that older adults face increased risk from particulate matter. In prior reviews, EPA had identified older adults as at higher risk, primarily based on the many changes in physiological processes from aging as well as the higher prevalence of preexisting conditions including both cardiovascular and respiratory. In this review, EPA acknowledges that evidence shows that older adults likely receive higher doses of PM because of the decreased clearance of lungs due to aging. Yet EPA argues that older adults are less likely to live where high levels of PM exist, a factor that should come as a serious surprise to the 2.44 million people over age 65 who live in metropolitan Los Angeles, or the more than 500,000 people over age 65 who live in the greater Pittsburgh area—two of the metropolitan areas where PM<sub>2.5</sub> levels violate the current annual PM<sub>2.5</sub> standard.<sup>4</sup> Being more exposed is not the sole determinant; the conclusion that the air may be less polluted where *most* older people live does not alter the reality that high risks exist where *millions* of older people live.

Protection of public health with an adequate margin of safety must be EPA's priority with this review. Protecting public health must be maintained as the primary priority for the standards, as it is for our patients and our communities. Our organizations urge EPA to strengthen the standard to protect our patients and our communities from this dangerous air pollutant.

Sincerely,

**Alliance of Nurses for Healthy Environments**

**Association of Schools and Programs of Public Health**

**Asthma and Allergy Foundation of America**

**Center for Climate Change and Health**

**American Heart Association**

**Children's Environmental Health Network**

**American Lung Association**

**National Association of County and City Health Officials**

**American Public Health Association**

**National Environmental Health Association**

**American Thoracic Society**

**Physicians for Social Responsibility**

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<sup>1</sup> Limited data are not an excuse for failing to establish the level at which there is an absence of adverse effect. To the contrary, as the D.C. Circuit has explained, "Congress' directive to the Administrator to allow an 'adequate margin of safety' alone plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful." *Lead Indus. Ass'n*, 647 F.2d at 1154-55

<sup>2</sup> *Lead Industries Assn. v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980)

<sup>3</sup> Pruitt, E. Scott. Memorandum to Assistant Administrators, Regional Administrators, Office of General Counsel, October 31, 2017. Strengthening and Improving Membership on EPA Federal Advisory Committees. Accessed at <https://www.epa.gov/faca/strengthening-and-improving-membership-epa-federal-advisory-committees>.

<sup>4</sup> American Lung Association. "State of the Air 2018" report. Data from the U.S. Census Bureau for 2016.