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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:

The American Lung Association offers these 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).

The review of the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) is 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

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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”)).¹

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.” (*Lead Industries Assn*, 1980). 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

The Lung Association calls 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.

¹ 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

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. Notably, 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. The assumption that potential conflicts would only occur with EPA funding is seriously flawed.

EPA needs to allow sufficient time for a thorough review

The Lung Association urges EPA to provide CASAC a second draft ISA before the final ISA is concluded. EPA needs CASAC to review how EPA addresses and incorporates the comments CASAC and the PM panel provided and to include studies published in 2018 and early 2019. With the proposed schedule, not only does EPA miss the opportunity to incorporate major new studies and 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.

EPA should continue to follow the current approach for determining causality for health effects

The Lung Association supports the long-established and well-vetted approach that EPA has used for the past decade to determine the causal relationships between exposures to specific pollutants and human health effects. EPA based this approach on those used by other federal and scientific community activities, particularly including recommendations in the document published in 2008 by the National Academy of Sciences Institute of Medicine (now the National Academy of Medicine), *Improving the Presumptive Disability Decision-Making Process for Veterans* (Samet and Bodurow, 2008). CASAC members and panels have reviewed and supported the use of this process multiple times in reviewing the ISAs between 2008 and 2015. This process is also similar to those used by the National Academy of Science (Samet and Bodurow, 2008), the Centers for Disease Control and Prevention (CDC, 2004), and the International Agency for Research on Cancer (IARC, 2006, updated 2015).

This process follows a weight of evidence approach, examining the available research from human exposure, toxicological, controlled human exposure and epidemiological studies. EPA examines specific considerations for each category of research to integrate and assess the findings and to recognize the uncertainties in each approach.

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. Please note that, while EPA has concluded that PM_{2.5} (and in one case, ultrafines) causes or likely causes the health effects summarized in the ISA, the findings should apply to PM₁₀ as well, since PM₁₀ includes all particles that would comprise the PM_{2.5} and ultrafine sizes. EPA's assessments of the impacts of the coarse fragment of PM₁₀—that is, PM_{10-2.5}—revealed important considerations

that add weight to the need to strengthen the NAAQS to address those concerns across the total size range.

Mortality

The Lung Association agrees 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.

At least two additional studies published in 2018 add to the weight of evidence and should be included in a second draft ISA for incorporation into the review: Schwartz et al., 2018 and Schulz et al., 2018. Both studies found evidence of premature deaths at levels well below the current standards.

Respiratory effects

The Lung Association supports 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 (Keet et al., 2018; Kravitz-Wirtz et al., 2018) as well as respiratory mortality in people with chronic obstructive pulmonary disease from short-term and long-term exposure (DeVries et al. 2017; Pinault et al., 2018).

Cancer

The Lung Association supports a causal determination for the long-term exposure on lung cancer. Considering the IARC determination that PM causes lung cancer, EPA's less strong conclusion of "likely causal" is surprising. Even under EPA's ongoing conservative approach to these findings, these elements showed that the evidence was strong:

- Evidence showed the biological plausibility that PM causes cancer (Section 10.2.1).
- Evidence showed multiple ways that PM can damage genes (Sections 10.2.2.5 and 10.2.3.4) to appear to be plausible mechanisms for carcinogenic impact.
- Toxicological studies showed the potential for carcinogenesis. (Section 10.2.4).

Additional studies published in 2018 should be helpful, including a review (Wang et al., 2018) and a meta-analysis of cohort studies (Kim et al., 2018).

No threshold exists for harm from particulate matter.

The Lung Association fully supports 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_{2.5}, where multiple studies show harm as low as 5-8 µg/m³, as EPA acknowledges. In addition to those cited in the draft ISA, two additional studies published in 2018 (Schwartz et al., 2018 and Schulz et al., 2018) show harm from short-term and long-term exposures at levels well below the current NAAQS.

Many populations face increased risk from particulate matter.

As EPA concludes in the ISA, "both the general population as well as specific populations and lifestages are at risk for PM_{2.5}-related health risks." (ISA, p. 12-1). EPA's analysis examines in depth whether PM_{2.5} places specific groups at increased risk compared to the risks faced by the general population.

The Lung Association agrees with 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. We also affirm the newer research showing that people who are obese and people with certain genetic variants face greater risk.

The Lung Association urges EPA to reexamine its conclusion that the evidence merely suggests that people with respiratory diseases are among the groups that face an increased risk from PM_{2.5}, compared to the population at large. As noted in two recent reviews (Fan et al., 2015 and Zheng et al., 2015), growing evidence continues to show that adults and children with asthma face increased risk of hospitalization and emergency department visits. That continues with several studies published in 2018 as well as new evidence of impacts to people with allergic respiratory disease and COPD (Szyszkowicz et al., 2018; Wu et al., 2018; Zieliński et al. 2018).

EPA should 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_{2.5} levels violate the current annual PM_{2.5} standard (American Lung Association, 2018). Being more likely to be

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.

EPA should also reconsider its conclusion to not include diabetics as a group at increased risk. At least one large new study in Canada (Pinault L et al., 2018) demonstrated that diabetes increased the risk of cardiovascular mortality from PM2.5, even among people with diabetes who were managing their diabetes with insulin or medication.

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 EPA noted, the public faces great risks from particulate matter. The American Lung Association urges EPA to strengthen the standard to protect the health of the nation from this dangerous air pollutant.

Sincerely,



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