November 12, 2019

Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington D.C. 20460

Sent via Regulations.gov.

Re: Comments on Docket ID No. EPA-HQ-OAR-2015-0072

Dear Administrator Wheeler:

The American Lung Association appreciates the opportunity to provide comments on the Policy Assessment for Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft, September 2019 (Draft PA).

EPA's revised review process undermines the protection of public health

The Lung Association continues to express our objections to the changes to the process that EPA has adopted in this review. EPA's changes restrict the full discussion and review of the information, undermining the core purpose of this process: to set standards that "protect health with an adequate margin of safety." While the Lung Association has long supported and, indeed, taken legal action to ensure the completion of the reviews in a timely manner, the Lung Association opposes the current process because it undermines the ability of CASAC and EPA to arrive at appropriate and adequate decisions on these standards. The revised process threatens that the decisions you make as Administrator would not be based on a thorough review of the evidence.

The review process adopted in 2006 followed an open, deliberative discussion led by CASAC of the changes needed to improve the process. Based on the desire to provide an informed and robust assessment of the information, EPA established a protocol that included separate reviews of two separate drafts of critical documents, including a separate Risk and Exposure Assessment (REA). That process ensured that EPA would have reached conclusions on the scientific evidence about health and welfare impacts before beginning work on the policy implications. CASAC had agreed to such a plan for the review of the PM NAAQS in 2016, at the

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beginning of this process. EPA upended that agreement and reversed the long-established process with no public or CASAC review of the proposed changes.

EPA has set up an unprecedented, flawed process to truncate the review of the particulate matter and the ozone NAAQS. With these changes, critical information that forms the basis of the decisions is absent or unresolved. The Draft PA for particulate matter should have been fully informed by the Integrated Science Assessment (ISA). EPA should not have released the Draft PA until EPA finalized the ISA. Until the ISA is final, no final, reliable determination of the air quality criteria exists; that is, there is no full conclusion on the information which "accurately reflect[s] 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 presence to such pollutant in the ambient air." 42 U.S.C 7408(a)(2).

Without first finalizing the ISA, EPA impairs the determination of the relevant policy decisions in accessing the Draft PA. EPA's process unacceptably handicaps the review.

Further, EPA dismissed the established independent advisory panel for particulate matter, a step that cost the CASAC and EPA essential expertise in the complex avenues that the documents explore. Such panels had served multiple CASAC reviews for decades. EPA offered flawed arguments for eliminating the in-place, working panel: that under the Clean Air Act, only CASAC can advise EPA, and that such elimination would expedite the review. Both arguments are specious. The independent panels have always provided expert assistance only to CASAC, which CASAC then used to advise EPA. The panels have worked closely with CASAC to assist in an accurate and thorough scientific review following the adopted schedule.

Not until CASAC itself acknowledged its limitations and requested assistance in a letter to you did EPA take limited steps to provide additional assistance.[1] EPA appointed a new pool of advisors who lacked experience in the NAAQS review process and PM, and then mangled the process again by limiting advisory actions to one single panelist's opinion, by letter, in response to written questions. This restricted process eliminated the traditional approach that provided a more complete and open discussion with multiple, experienced panelists who contributed independent perspectives and deliberated their consensus recommendations on topics throughout the reviews of each document.

The shining light in this damaged process is the diligence and thoroughness of the EPA staff in preparing this assessment. In general, there is much to support in their assessment. They have attempted to provide a full, extensive review, albeit based on the draft ISA, which should provide added evidence to EPA that more protective standards are needed for particulate matter.

The Lung Association strongly urges EPA to issue a second draft PA, reappoint the independent CASAC advisory panel and restore the process that the Agency had previously followed to complete this review to protect public health. The Lung Association also urges that EPA publish the final ISA before releasing a second draft PA.

Millions of Americans face increased risk from particulate matter

The Lung Association agrees with the finding in the draft PA, that "a substantial portion of the U.S. population" face increased risk from breathing particulate matter. The Lung Association supports recognition of these groups as at risk, as mentioned in the draft PA: children and teenagers; older adults; people with chronic lung diseases or cardiovascular diseases; people who are overweight

or obese; people with specific genetic variants; Hispanics; non-Hispanic blacks; and people who have low incomes. Evidence also indicates that healthy adults who work and exercise outdoors also face higher risk. The Lung Association particularly calls attention to the new evidence showing that African Americans face a three-time higher risk from PM than the entire population.[2] This adds to the evidence that African Americans, Hispanics and low-income communities face higher risk because social and environmental disparities.

The Lung Association is acutely concerned about the impacts to millions of people with lung diseases. In 2017, estimates show that 15.3 million adults had chronic obstructive pulmonary disease (COPD) and 25.2 million Americans had asthma, including 6.2 million children.[3] In 2019, more than 228,000 Americans will be diagnosed with lung cancer.[4]

All Americans deserve to have their health protected by stronger PM standards.

The current fine particulate standards fail to protect public health

One of the key findings in this Draft PA is overwhelming evidence that the current annual fine particulate ($PM_{2.5}$) standard fails to protect public health. The Lung Association strongly supports that conclusion, as discussed below. However, strong evidence exists that the 24-hour $PM_{2.5}$ standard also fails to provide that required protection to public health. The Lung Association urges EPA to strengthen both the annual and the 24-hour $PM_{2.5}$ standards.

Today, more robust evidence than ever before supports the increased risk of premature death from levels below the current standards. No evidence exists of a threshold to that risk, as EPA has acknowledged. Recent U.S. studies that restrict the analysis to long-term exposures below 10 $\mu g/m^3$ [5] and Canadian studies that find evidence down to and below 8 $\mu g/m^3$ [6] all found premature deaths at those lower levels. A large study looking at short-term exposures also added evidence of harm below the current annual standard.[7] These studies offer new information that answered questions in previous reviews. The Canadian studies, in particular, offer data on low levels of exposures over long periods.

The Draft PA estimates that the current standards allow "a substantial number" of deaths from $PM_{2.5}$ exposure in the U.S. today. The analysis in Table 3-5 estimates that, using 2015 air quality data adjusted to just meet the 2015 annual standard, the median estimated annual mortality ranges from 13,500 to 52,100 premature deaths.[8] The evidence extends to the 24-hour standard, where even with the current standard, the median estimated mortality from short-term exposures ranges from 1,200 to 3,870 premature deaths annually.[9] These studies show consistent evidence that the current standards allow significant and unacceptable increased risk to health, unquestionably failing to provide the legally required protection. In addition, EPA's estimates do not explore the evidence of harm from multiple other health effects of PM exposure, including COPD and asthma exacerbations. The Draft PA therefore does not consider the full impact of these inadequate standards.

The vast evidence that $PM_{2.5}$ shortens lives remains consistent as it has from the landmark studies in the 1990s. The follow-up studies that further tracked those cohorts mirror the findings in newer studies looking at lower levels of pollution[10] including some with one of the largest data sets in history, the 61 million people in the Medicare cohort.[11] The research included studies that examined the evidence using different ways of accessing exposure,[12] diverse regions of the country and diverse populations,[13] and different statistical models.[14]

We strongly disagree with the specious arguments provided in the Draft PA to create some justification for retaining the current standard. The powerful evidence from these epidemiological studies alone undercut these rationalizations of uncertainty. The evidence from the toxicological studies and clinical trials support these conclusions. The lack of studies examining exposures down to zero create no valid uncertainty over whether reducing PM levels further would add to the health benefits. We urge EPA to remove those arguments and that option from consideration.

We also disagree with EPA's evaluation that the 24-hour $PM_{2.5}$ standard provides sufficient protection for public health. EPA argues that its primary use is to supplement the annual standard. Even with that role, that combination fails to provide protection for many communities across the nation where the annual level is quite low. For communities in Alaska, parts of the Northwest and parts of New England, shorter-term exposures pose the primary risk because of the emissions from woodstoves and other sources that create elevated levels of $PM_{2.5}$. Nearly all these areas have year-round concentrations that are well under the annual standard. The risk assessment in the Draft PA did not include areas in these parts of the nation, limiting the assessment of exposures to these sources.

Further, while wildfires do pose a significant source of the 24-hour exposures at high levels, they should not be dismissed as not caused by human action. Droughts exacerbated by climate change and fires from flawed electrical infrastructure as seen in California this year provide two examples of the human actions that contribute to the expanding burden of wildfires in the United States. Research supports this. In a study examining wildfires nationwide, researchers estimated that human activities caused 84 percent of wildfires between 2009 and 2012.[15]

The Lung Association continues to support changes to the form of the short-term standard, recommending at 99th percentile rather than at the 98th. The Draft PA continues to argue that the 98th percentile offers more stability to the standard than would at 99th percentile standard. While that is true, stability fails public health protection when the 98th percentile allows as many as 21 days to be exempted before meeting the standard.

Further, the Lung Association urges the consideration of a rolling 24-hour standard, rather than one that covers the 24 hours of a single calendar day. As one of the main sources of 24-hour PM spikes, woodstove smoke often peaks during shorter, overnight periods that may not be appropriately captured in the split that occurs at midnight. The Lung Association also urges EPA to require $PM_{2.5}$ monitoring to be a continuous monitoring network. The continued use of monitoring limited to data capture only every three or six days adds to the gaps in protection that Americans deserve from this deadly pollutant.

The coarse particulate standard should be strengthened

The PM_{10} standard has stood in place, unaltered, since its adoption in 1987. That comes despite the long recognition that, while intended to provide protection against the coarse particles ($PM_{10-2.5}$), inadequate monitoring and research limit the standard's ability to protect health from these particles. In 2010, CASAC advised EPA to consider a stronger PM_{10} standard with a different form (98th percentile) and a more protective level, down to 65 µg/m^3.[16] This Draft PA did not examine that recommendation.

EPA should reconsider the CASAC 2010 recommendation on PM_{10} in a second Draft PA. The Lung Association supports strengthening the standard, based on a more complete review of the 2010 CASAC recommendations. In addition, EPA should expand the monitoring data for the coarse

fraction ($PM_{10-2.5}$), to provide sufficient information to assess exposure and health risks that may be different from those solely of the fine particle fraction.

Recommendations for proposed $PM_{2.5}$ standards

Real world studies demonstrate that the current standards fail to protect health. EPA must adopt stronger standards based on the best available evidence that would protect health with an adequate margin of safety

Based on the information in the Draft ISA and Draft PA, the Lung Association urges EPA to strengthen the annual $PM_{2.5}$ standard to 8 $\mu g/m^3$ and the 24-hour standard to 25 $\mu g/m^3$. The Draft PA considers annual standard levels down to 8 $\mu g/m^3$ based on the current evidence. These studies—including the Medicare cohort study[17] that found mortality associated with levels as low as 7 $\mu g/m^3$—provide sufficient, robust evidence that the standard should be no higher than 8 $\mu g/m^3$ to protect public health with an adequate margin of safety.

The Lung Association recommends adopting a stronger standard of 25 $\mu g/m^3$ for the 24-hour standard, as well as changing the form of the standard to the 99th percentile.

EPA should support additional research

Research forms the basis of our understanding of the complex sources, composition, size, transmission, and health risks from particulate matter. The Lung Association urges EPA to increase research on particulate matter health impacts, including improved monitoring and health effect research on ultrafines, $PM_{10-2.5}$ and speciation, especially on respiratory health.

EPA should return to the previous review process with an experienced CASAC and independent advisory panel

The flawed process imposed on this review by EPA poses serious limits to the Agency's ability to fulfill its requirements under the Clean Air Act to protect human health. The inadequate review is now accompanied by an even more egregiously reduced review of the ozone NAAQS in an even shorter time. These reviews create an overwhelmingly impossible task for CASAC and EPA to complete in any reasonably appropriate way.

The Lung Association strongly urges EPA to restore the review process previously adopted and to restore the prior CASAC members and the prior independent panel. Only by returning to the full process that EPA abandoned will EPA be able to fulfill its duties required under the Clean Air Act.

Sincerely,

Deborah P Brown

Deborah Brown
Chief Mission Officer

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[2] Di Q. Wang Y, Zanobetti A, Wang Y, Koutrakis P, Choirat C, Dominici F and Schwartz JD. 2017. Air pollution mortality in the Medicare population. *NEJM*. 376(26): 2513-2522.

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

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[7] Di Q, Dai L, Wang Y, Zanobetti A, Choirat C, Schwartz JD and Dominici F. 2017. Association of short-term exposure to air pollution with mortality in older adults. *JAMA* 318(24): 2446-2456.

[8] U.S. EPA, Policy Assessment for Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft, September 2019, Table 3-5; Thurston GD, Ahn J, Cromar KR, et al. 2016. Ambient particulate matter air pollution exposure and mortality in the NOH-AARP Diet and Health Cohort. *Environmental Health Perspectives* 124(4): 484-490; Pope CA, Turner MC, Burnett R, et al. 2015.. Relationships between fine particulate air pollution, cardiometabolic disorders and cardiovascular mortality. *Circulation Research* 116(1): 108-U258.

[9] Ito K, Ross Z, Zhou J, Nádas A, Lippmann M and Thurston GD. 2013. National Particle Component Toxicity (NPACT) initiative: Study 3. Time-series analysis of mortality, hospitalizations, and ambient PM2.5 and its components. Boston, MA, Health Effects Institute**:** 95-125; Zanobetti A, Dominici F, Wang, Y and Schwartz, JD. 2014. A national case-crossover analysis of the short-term effect of PM2.5 on hospitalizations and mortality in subjects with diabetes and neurological disorders. *Environmental Health: A Global Access Science Source* 13(1): 38.

[10] U.S. EPA. Draft Integrated Science Assessment for Particulate Matter. 2018 sections 11.2.2.2, 11.2.5

[11] Di Q et al., 2017.

[12] EPA 2018, section 11.2.5.1

[13] EPA 2018, section 11.2.5.3

[14] EPA 2018, section 11.2.5.2

[15] Balch JK, Bradley BA, Abatzoglou JT, Nagy RC, Fusco EJ, and Mahood AL. 2017.Human-started wildfires expand the fire niche across the United States. *Proceedings of the National Academy of Sciences.* 114, 2946-2951.

[16] Samet J. CASAC Letter to the Administrator in Review of the Policy Assessment for the Review of the PM NAAQS – Second External Review Draft (June 2010). EPA – CASAC-10-015. September 10, 2010.

[17]Di Q et al. 2017.