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

Submitted via Regulations.gov

RE: Comments on the draft Integrated Review Plan for the Ozone National Ambient Air Quality Standards, Docket ID No.: EPA-HQ-OAR-2018-0279.

Dear Acting Administrator Wheeler:

The American Lung Association appreciates the opportunity to submit comments on the draft Integrated Review Plan for the Ozone National Ambient Air Quality Standards. Many of these comments were shared at the hearing on this review before the Clean Air Scientific Advisory Committee. This letter includes those, as well as additional comments and citations.

[EPA Must Protect the Health of the Public, including Sensitive Populations](#)

The Clean Air Act establishes the primary National Ambient Air Quality Standard to protect public health from the nation's most widespread air pollutants. The Clean Air Act directs the Administrator to set standards that are "requisite to protect public health" with "an adequate margin of safety" (42 U.S.C. § 7409 (b) (1)).

Millions of Americans face health risks from demonstrated harm from ozone pollution. In the most recent review, many populations were recognized as facing higher vulnerability because of their age, their existing health, and their socioeconomic status. Children, people with asthma and other lung diseases, seniors, people with low incomes were all recognized as facing increased risk from ozone. In addition to these groups, growing research has added evidence of increased risk to women, to newborns, to cardiovascular harm and to cognitive function (Gatto et al., 2014; Mendola et al., 2017; Yang et al., 2014; Bell et al., 2014). Others at risk include some healthy adults, as the previous Integrated Science Assessment acknowledged,

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including outdoor workers and some with specific genetic variations, and people who have low socioeconomic status (EPA ISA, 2013). Health-based standards must be set at levels that will protect all people, but particularly these sensitive groups.

[Ozone poses a grave threat to public health at levels well below the current standard](#)

The current standard of 70 ppb fails to meet the requirements of the Clean Air Act. Clinical and epidemiological studies have repeatedly shown that breathing ozone can threaten life and health at concentrations far lower than the 70 ppb 8-hour average standard. Growing research is providing significant additional evidence that the standard must be strengthened (Holm et al., 2018). In previous reviews, CASAC has repeatedly recommended to EPA that the ozone standard be set as low as 60 ppb.

In each of the three comment letters the CASAC wrote to EPA Administrator Stephen L. Johnson, the independent experts charged with advising EPA unanimously recommending selection of an 8-hour average ozone NAAQS within the range of 60 to 70 ppb (Henderson 2006; Henderson 2007; Henderson 2008).

During the reconsideration of the 2008 Ozone NAAQS, CASAC reaffirmed its support for the selection of an 8-hour average ozone NAAQS within the 60 – 70 ppb range (Samet, 2010). Again, that recommendation came based solely on the studies that had been available during the prior review, a period that closed in 2006.

The most recent prior CASAC summarized extensive scientific evidence in their recommendations to EPA for a range from 70 to 60 ppb. The CASAC concluded that the new evidence showed that even that range was too broad, noting that “based on the scientific evidence, a level of 70 ppb provides little margin of safety for the protection of public health particularly for sensitive subpopulations” (Frey, 2014).

“At 70 ppb, there is substantial scientific evidence of adverse effects as detailed in the charge question responses, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation. Although a level of 70 ppb is more protective of public health than the current standard, it may not meet the statutory requirement to protect public health with an adequate margin of safety” (Frey, 2014).

CASAC concluded the evidence showed that a level of 60 ppb would “certainly provide more public health protection than a standard of 65 or 70 ppb and would provide an adequate margin of safety” (Frey, 2014).

Although in the prior review, EPA failed to follow CASAC recommendations for a much stronger standard, EPA did at least strengthen the standard. In this shortened review, the Lung Association repeats the prior recommendation for EPA to consider the growing evidence of harm well below the current standard of 70 ppb.

[The proposed process has serious limitations that EPA should rectify](#)

Last summer, two and one-half years after the adoption of the 2015 standard, EPA finally initiated the long-overdue next review for ozone. In the IRP, EPA stated its intention to complete the review by late 2020, which could meet the Clean Air Act-requirement that these reviews be

completed every five years. However, the delayed start means that the abbreviated timeline would curtail the much-needed thorough review and discussion.

The Lung Association has long worked to ensure that these reviews are completed in a timely manner, including taking legal action to secure a deadline when reviews had been delayed for too many years. The American public has the right to be protected from the harms from ozone, particulate matter, and the other criteria pollutants. Without these thorough and timely reviews of the ever-growing evidence, the basis of their protection—the NAAQS—would reflect increasingly outdated science. These timely reviews can literally save lives with up-to-date research by setting standards that “protect public health with an adequate margin of safety.”

However, the Lung Association is deeply troubled by changes in the process and by the curtailed review proposed in this IRP that would be required to meet that deadline.

The Lung Association urges EPA to restore the ozone advisory panel that assists the CASAC in the review of the evidence. These twenty-plus independent experts have provided essential analysis and perspectives in these reviews in the past. EPA’s decision to not provide 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; as well as the estimates of the risk to human health at multiple concentrations and durations of exposure. The last ozone Integrated Science Assessment (ISA) alone ran more than 1,200 pages. Their absence will deprive EPA scientists and CASAC of essential expertise and valuable perspectives on these issues. EPA needs to appoint that panel.

The Lung Association recommends EPA follow the current format that incorporates the in-depth analysis of the health effects into the review of the ISA. EPA’s proposal to shift these discussions into Appendices risks minimizing the vital discussions that they contain.

The Lung Association urges EPA to recognize that a second draft ISA is often needed to review how EPA addresses and incorporates the comments CASAC and the ozone 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.

The Lung Association opposes the proposal to combine Risk and Exposure Assessment (REA) with the Policy Assessment (PA). Eliminating the separate review of the REA would be an unwise decision. Combining the two means that the CASAC and EPA will be forced to review conclusions reached using unreviewed risk and exposure analyses. As exposures vary in many parts of the country and even in metro areas, that assessment needs to provide as much appropriate, validated information for CASAC and EPA decision makers as possible.

The Lung Association opposes the addition of the final two questions from the May 2018 memo by former EPA Administrator Pruitt to the list of charges for CASAC’s and EPA’s review (Pruitt, 2018). We are pleased that the IRP at least recognizes that these “may elicit info that is not relevant.” In fact, both have serious flaws. The last two charge questions are clearly outside the appropriate considerations under the NAAQS decision. Given the challenging timeline, we urge EPA to disregard these questions that are not relevant to the NAAQS.

The question on background ozone inappropriately encourages placing it as a factor in the setting of the standard itself. Background ozone cannot be measured directly because ozone is ozone—no chemical differences distinguish the sources (unlike particulate matter, for example). Ozone’s impact on human health is also irrespective of the sources: your lungs cannot tell where the ozone comes from. Therefore, as the Lung Association has reminded EPA repeatedly: The Clean Air Act requires that the standard must be set where it protects human health with an adequate margin of safety, regardless of the source of the ozone. Dealing with all sources that contribute to ozone must be left to the implementation of the rule, not setting the standards.

The final question seeking information on any adverse economic effects of the NAAQS flies in the face of the unanimous Supreme Court decision in 2001 that concluded costs of implementation could not be considered in setting the standards. Estimated or projected costs cannot and must not be considered. Other impacts of meeting the standards, including public health and welfare, are typically considered in the ISA, the REA and the PA.

[EPA’s review must follow the requirements to protect public health in the Clean Air Act](#)

The process must be founded in the strongest requirement of the Clean Air Act: that the NAAQS protect public health with an adequate margin of safety. In the last three reviews, ending the 2008 review, the 2010 reconsideration, and the 2015 review, the Lung Association recommended strongly that the primary 8-hour standard should be 60 ppb based on the available evidence. Despite the strong evidence of increased morbidity and mortality from ozone down to 60 ppb with no discernable threshold, EPA has failed to provide that protection required under the law.

The American Lung Association urges EPA to recognize the powerful evidence of harm and to provide the protection to public health required by the Clean Air Act.

Sincerely,



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