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December 16, 2019

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

Sent via Regulations.gov.

Re: Comments on the Policy Assessment (PA) for the Ozone National Ambient Air Quality Standards (External Review Draft)—EPA-452/P-19-002; Docket ID No. EPA-HQ-OAR-2018-0279

Dear Administrator Wheeler:

The American Lung Association appreciates the opportunity to provide comments on the Policy Assessment (PA) for the Ozone National Ambient Air Quality Standards (External Review Draft)—EPA-452/P-19-002.

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 of the ozone national ambient air quality standards (NAAQS). EPA's changes restrict the full discussion and review of the available scientific evidence, 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 means that the decisions you make as Administrator on these standards could 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

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two separate drafts of the Integrated Science Assessment (ISA) and Policy Assessment (PA), 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.

EPA has set up an unprecedented, flawed process to truncate the review of the particulate matter NAAQS and the ozone NAAQS. With these changes, critical information that forms the basis of the decisions is absent or unresolved.

Time is extraordinarily limited for this ozone NAAQS review. EPA chose to wait to initiate this review until only two years were left in the five-year review cycle stipulated under the Clean Air Act. EPA's ability to make appropriate decisions about multiple complex questions for this review are limited as well because of the overlapping deliberation on key documents for the review of the particulate matter NAAQS. This overlap is particularly egregious because of the multiple, heterogeneous issues involved in each review.

EPA issued this draft PA even before completion of the ISA. Without first finalizing the ISA, EPA impairs the determination of the relevant policy decisions in accessing the Draft PA. EPA should not have released the Draft PA until the agency finalized the ISA. EPA's current process unacceptably handicaps the review.

EPA further restricts the review by allowing only 45 days for the review of this 926-page document.

Until the ISA is finalized, no reliable determination of what ambient ozone concentrations will protect public health exists; that is, there is no full conclusion on the evidence 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).

Further, EPA failed to appoint an independent scientific panel for the ozone review, 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 ending the practice: that under the Clean Air Act, only the statutory CASAC can advise EPA, and that having no additional independent advisory panel 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 ozone, 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.

Despite this damaged process, we commend EPA staff's efforts to prepare this assessment. In general, there is much to support in their assessment. They have attempted to provide a full, extensive review, despite the all-too-abbreviated timeline. But absent a final ISA, the PA is fundamentally and fatally flawed.

The Lung Association recommends that EPA withdraw the PA until the final ISA is completed. The Lung Association strongly urges EPA to issue a second draft ISA, appoint an independent CASAC advisory panel and restore the process that the Agency had previously followed successfully for decades to complete this review to protect public health.

The Lung Association provides the remainder of these comments in case the EPA continues this flawed process with the limited available information.

The evidence shows that the ozone NAAQS must be strengthened

The American Lung Association does not agree with the finding in the draft PA that the current standard meets the requirement of the Clean Air Act; that is, that it would "protect public health with an adequate margin of safety."

During the last complete review of the ozone NAAQS, CASAC in 2014, found strong evidence for setting the standard well below the current 70 ppb.

"The CASAC advises 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. In this regard, our advice differs from that offered by EPA staff in the Second Draft PA. 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."²

Evidence they cited including the controlled human exposure studies that documented evidence of risk at levels well below the current standard. They demonstrate that healthy adults exposed to 60 ppb ozone experience measurable reduction in lung function, even when only exposed for 6.6 hours.³ Since these studies only included healthy adults as subjects, the impact on the health at that level would likely be much greater for children, people with chronic lung diseases and others at risk, whose lungs would not so easily recover. As the 2014 CASAC review noted as well,

"if subjects had been exposed to ozone using the 8- hour averaging period used in the standard, adverse effects could have occurred at lower concentration. Further, in our judgment, the level at which adverse effects might be observed would likely be lower for more sensitive subgroups, such as those with asthma."⁴

EPA also acknowledges that these studies do provide warnings that the impacts to these more sensitive groups could be even greater than to these healthy adult subjects.

"[W]e recognize some uncertainty, reflecting limitations in the evidence base, with regard to the exposure levels eliciting effects in some population groups not included in the

available controlled human exposure studies, such as children and individuals with asthma, as well as the severity of the effects.”⁵

These controlled human exposure studies continue to document the need for a more protective standard as the prior CASAC determined.

As during the last review, real-world evidence shows harm to sensitive populations at levels well below the current standard of 70 ppb. Two studies of Canadian cities found evidence of harm where the ozone levels remained below 70 ppb for 10 years. Even in these cities, where the air quality would have met the current standards, epidemiologists found ozone exposures associated with increased risk of emergency department visits for lower respiratory diseases⁶ and for childhood asthma.⁷ Each of these studies controlled for the impact of other pollutants as well.

EPA’s own assessment showed the substantial risk to children with asthma even among the cities in the U.S. that just meet the current standard of 70 ppb. In this assessment, approximately 11 percent of children with asthma would be exposed to one or more days when levels reach 60 ppb or higher.⁸

Retaining the current primary standard fails to protect millions of Americans.

In a final summary analysis, EPA estimated that the worst case would mean just over three percent of children with asthma, on average, would experience two or more days of ozone above 60 ppb, if that were the official standard. However, the draft PA dismisses that as a small number, basically not worth protecting.⁹ The American Lung Association strongly disagrees with this unlawful conclusion. Even at three percent, that means more than 186,000 children with asthma would fail to get the protection the Clean Air Act requires. EPA did not estimate the impact to adults with asthma, even though 19 million adults also have this disease. Certainly, leaving so many vulnerable people at risk to ozone exposures that threatens their health fails to meet the statutory requirements of “requisite to protect the public health.”

Nor did EPA evaluate the impact to the more than 71 million outdoor workers who will be exposed during vigorous exertion to unhealthy air when ambient ozone is at the level of the current NAAQS.¹⁰ That at-risk population also deserves protection from the polluted air they breathe, especially since millions of them likely suffer from asthma or other lung diseases.¹¹

One critical impact to health is the risk of premature death from ozone. Unlike in the previous PA, EPA did not assess the risk to premature death at various design values. EPA’s lack of assessment of this may stem from EPA’s flawed conclusion in the draft ISA that ozone should no longer be considered as “likely causal” for premature death, despite strong evidence of respiratory-caused deaths.¹² As mentioned earlier, the lack of a final ISA limits the evidence that EPA has available to consider in this review of the PA, and significantly weakens the conclusions.

The evidence supports a standard no higher than 60 ppb.

In 2014, after reviewing even less available data, the previous CASAC recommended that EPA “set the level of the standard lower than 70 ppb with a range down to 60 ppb.”¹³ If EPA continues the current abbreviated process, we at the Lung Association urge this CASAC to review and reconsider the advice of the prior CASAC on this decision.



Given the available information, the Lung Association recommends a standard no greater than 55 ppb to 60 ppb to protect public health.

EPA needs to reject this flawed process

Finally, as we have shared in previous comments, the Lung Association firmly opposes EPA's changes that have undermined and weakened the NAAQS review process. Especially in this time-constricted ozone review, EPA cannot effectively assess potential new standards that truly protect public health.

Sincerely,



Deborah Brown
Chief Mission Officer



Albert Rizzo, MD, FACS
Chief Medical Officer



¹ Cox L.A. 2019. Clean Air Scientific Advisory Committee Letter to A. Wheeler, U.S. Environmental Protection Agency. CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018). EPA-CASAC-19-002, April 11, 2019.

² Letter from H. Christopher Frey, CASAC Chair, to Gina McCarthy, EPA Administrator, dated June 26, 2014, p. ii, <https://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/%24File/EPA-CASAC-14-004+unsigned.pdf>.

³ Adams, WC (2002). Comparison of chamber and face-mask 6.6-hour exposures to ozone on pulmonary function and symptoms responses. *Inhalation Toxicology* 14(7): 745-764; Adams, WC (2003). Comparison of chamber and face mask 6.6-hour exposure to 0.08 ppm ozone via square-wave and triangular profiles on pulmonary responses. *Inhalation Toxicology* 15(3): 265-281; Adams, WC (2006). Comparison of chamber 6.6-h exposures to 0.04-0.08 PPM ozone via square-wave and triangular profiles on pulmonary responses. *Inhalation Toxicology* 18(2): 127-136.

⁴ Letter from Frey to McCarthy.

⁵ U.S. Environmental Protection Agency. 2019. Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, External Review Draft, p.3-82

⁶ Kousha, T and Rowe, BH (2014). Ambient ozone and emergency department visits due to lower respiratory condition. *Int J Occup Med Environ Health* 27(1): 50-59.

⁷ Villeneuve, PJ, Chen, L, Rowe, BH and Coates, F (2007). Outdoor air pollution and emergency department visits for asthma among children and adults: A case-crossover study in northern Alberta, Canada. *Environmental Health: A Global Access Science Source* 6: 40.

⁸ U.S. EPA, draft PA. pp 3-77 to 3-78.

⁹ U.S. EPA, draft PA. p.3-85.

¹⁰ Based on the BLS estimates, roughly 71.2 million adults work outdoors. U.S. Department of Labor Bureau of Labor Statistics (BLS). "Over 90 percent of protective service and construction and extraction jobs require work outdoors. January 06, 2017. TED: The Economics Daily. Accessed 11/19/19 at <https://www.bls.gov/opub/ted/2017/over-90-percent-of-protective-service-and-construction-and-extraction-jobs-require-work-outdoors.htm>; BLS, Labor Force Statistics from the Current Population Survey. Household Data Annual Averages. 1. Employment status of the civilian noninstitutional population, 1948 to date. Accessed on 11/19/2019 at <https://www.bls.gov/cps/cpsaat01.htm>.

¹¹ Among adults 18 and over 5.4% of males and 9.8% of women have asthma. Even with an all-male outdoor workforce, that could mean more than 3.8 million outdoor workers have asthma. Centers for Disease Control and Prevention. National Health Interview Survey, 2017. Analysis by the American Lung Association Epidemiology and Statistics Unit Using SPSS Software.

¹² Comments submitted by Albert Rizzo, Chief Medical Officer, American Lung Association to EPA on the ozone draft Integrated Science Assessment, December 2, 2019. <https://www.regulations.gov/document?D=EPA-HQ-ORD-2018-0274-0031>

¹³ Letter from Christopher Frey, Chair, Clean Air Scientific Advisory Committee to Gina McCarthy, Administrator, U.S. Environmental Protection Agency. CASAC Review of the EPA's Second Draft Policy Assessment for the Review if the Ozone National Ambient Air Quality Standards. June 24, 2014.