Comments to Clean Air Scientific Advisory Committee/EPA on EPA's Policy Assessment in the Reconsideration of the National Ambient Air Quality Standards for Ozone

From: Shyamala Rajan, PhD, National Director of Policy for Healthy Air, American Lung Association March 29, 2023

Good Morning

Thank you for this opportunity to comment.

I am Dr. Shyamala Rajan, National Director of Policy for Healthy Air for the American Lung Association. The Lung Association has long advocated for a strict implementation of the requirements in the Clean Air Act related to the setting and enforcing of National Ambient Air Quality Standards for criteria pollutants to protect the health of ALL communities and vulnerable groups.

Last summer, we submitted detailed written and oral comments strongly disagreeing with EPA's flawed evaluation of scientific data and its wrong conclusion in its first draft Policy Assessment that current O_3 NAAQS do not need revision. We provided a scientific rationale and the application of a margin of safety to account for uncertainties associated with inconclusive scientific information to revise the current standard to 60 ppb to protect public health. Today we reiterate those comments and make additional ones.

In this PA, EPA sets out to answer two questions:

- 1. Does information call into question the adequacy of protection afforded by the existing standard(s)?
- 2. If so, what are the potential alternative standards appropriate for consideration?

By answering the first question in the negative, EPA has precluded the possibility of having to consider potential alternative standards. Science must guide policy in setting NAAQS - it is required by the Clean Air Act. The science clearly shows that the current standard is inadequate to protect human health. But EPA's draft policy assessment fails in several key ways:

- by applying the PECOS framework arbitrarily and inconsistently to restrict scientific consideration to research studies from only the US and Canada and dismissing data from the rest of the world,
- by downgrading causality determinations for cardiovascular health and mortality from short-term ozone exposures from likely causal to suggestive without a scientific basis,
- by down weighting epidemiological studies and relying heavily on controlled human exposure studies,

EPA has once again reached a conclusion that the current standards are adequate to protect human health with an adequate margin of safety to protect vulnerable subpopulations and fails to identify any alternatives.

It is incumbent upon CASAC to recommend changes to the Policy Assessment to identify potential alternative standards at least as low as 60 ppb as were identified by the EPA staff and recommended by CASAC ozone panels in the 2008 NAAQS review, the 2011 reconsideration of

that review, and again in the 2015 review. The science supporting more protective standards has only become stronger over the past decade and a half.

The 2006 "CASAC unanimously recommends that the current primary ozone NAAQS be revised and that the level that should be considered for the revised standard be from 0.060 to 0.070 ppm, with a range of concentration-based forms from the third- to the fifth highest daily maximum 8-hr average concentration. While data exist that adverse health effects may occur at levels lower than 0.060 ppm, these data are less certain and achievable gains in protecting human health can be accomplished through lowering the ozone NAAQS to a level between 0.060 and 0.070 ppm."¹

The 2011 CASAC: "(W)e reaffirm that the evidence from controlled human and epidemiological studies strongly supports the selection of a new primary ozone standard within the 60 - 70 ppb range for an 8-hour averaging time."²

The 2015 "CASAC deliberated at length regarding advice on other levels that might be considered to be protective of public health with an adequate margin of safety. For example, the recommended lower bound of 60 ppb would certainly offer more public health protection than levels of 70 ppb or 65 ppb and would provide an adequate margin of safety. Thus, our policy advice is to set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account your judgment regarding the desired margin of safety to protect public health, and taking into account that lower levels will provide incrementally greater margins of safety."³

Members of the National Academies who reported on the Causality Determination Framework and also members of this committee urged extreme caution in applying PECOS. Using this tool, EPA evaluated only those epidemiologic studies whose locations were in the U.S. and Canada "to provide a focus on study populations and air quality characteristics that are most relevant to circumstances in the U.S." Note that Canada's air quality is controlled by more stringent ambient air quality standards for all criteria pollutants than those of the US. For ozone, Canada set a national standard of 63 ppb in 2015, which is currently at 62 ppb, and which will be reduced to 60 ppb in 2025.⁴ There is evidence of causality of significant respiratory illness at exposures at 60 ppb or lower from both CHE studies assessed in the ISA^{5,6,7} and from a very recent epidemiological study from China⁸ which EPA has excluded from consideration. The US studies show statistically significant decreased lung function and increased inflammation in the airways of healthy adults at 60 ppb which would lead to the conclusion that there are more acute symptomatic illness in vulnerable populations. The Chinese study of a very large cohort of children concluded that exposure to ambient O₃ concentration above 40 ppb contributed to an

¹ Clean Air Scientific Advisory Committee (CASAC). (2006). <u>Peer Review of the Agency's 2nd Draft Ozone Staff Paper</u>. EPA-CASAC-07-001; page 5

² Letter from Dr. Jonathan M. Samet, Chair, Clean Air Scientific Advisory Committee, to Lisa P. Jackson, Administrator, U.S. Environmental Protection Agency, March 30, 2011

³ CASAC. (2014). <u>Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality</u> <u>Standards</u>, EPA-CASAC-14-004; pages 2-3

⁴ Canada Air Quality (ccme.ca)

⁵ Adams, W. C. (2006). <u>Comparison of chamber 6.6-h exposures to 0.04–0.08 ppm ozone via square-wave and triangular profiles</u> on pulmonary responses. *Inhalation Toxicology*, *18*(2):127–136.

⁶ Brown, J. S., Bateson, T. F., & McDonnell, W. F. (2008). <u>Effects of exposure to 0.06 ppm ozone on FEV1 in humans: a secondary</u> analysis of existing data. *Environmental health perspectives*, *116*(8), 1023–1026.

⁷ Kim, C. S. et al. (2011). <u>Lung Function and Inflammatory Responses in Healthy Young Adults Exposed to 0.06 ppm Ozone for 6.6 Hours</u>. *American Journal of Respiratory and Critical Care Medicine, 183*(9).

⁸ Huang, W., Wu, J., & Lin, X. (2022). Ozone Exposure and Asthma Attack in Children. Frontiers in pediatrics, 10, 830897

increased risk of acute asthma attacks. These ISA data alone strongly support strengthening the current standard. Ozone, unlike PM, is a pure chemical and its health effects should be the same throughout the world.

Because the current standard of 70 ppb is inadequate to protect public health, finalizing this Policy Assessment without considering alternatives is entirely unacceptable. Doing so invalidates this reconsideration process which was started explicitly to ensure a robust scientific review to inform the policy. It also goes against the requirements of the CAA.

Also unacceptable is the time EPA is planning to take in completing this reconsideration process. EPA anticipates that it cannot be completed any more expeditiously than the end of 2024 based on "the time that was necessary for the CASAC to complete its science review, the time that EPA needed to update the draft PA" and steps to follow. In this reconsideration, the EPA did not prepare a new ISA and CASAC deliberations on the science concluded last year. Now at the end of March 2023, CASAC's review of the draft policy assessment is underway. With the bulk of the reconsideration process having been completed, EPA has three remaining steps - developing a final PA, guided by CASAC advice and public comments, then proposing and later finalizing its decision after considering public comment. There is absolutely no justification for extending these last steps for nearly two years. Delaying the final decision until the end of 2024 will adversely affect public health not only in this review but into the long future as it will delay future NAAQS reviews on the 5-year cycle.

Lastly, releasing a 1000+ page policy document without a table of contents (which takes only a couple of minutes to put in) and a summary to inform what is in the document and how it is laid out denies a robust public engagement and constrains the public from providing thoughtful substantial comment.

We rely on you CASAC members to balance the need for a thorough assessment of EPA's conclusions in its PA with the urgent need for a timely conclusion of the process and to advise the EPA Administrator to set the ozone standard at no higher than 60 ppb. EPA should complete the reconsideration process no later than April 2024.

Thank you.