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Statement of Albert Rizzo, MD, FACP, FACCP
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To U.S. Environmental Protection Agency and
Clean Air Scientific Advisory Committee (CASAC)
Teleconference on Ozone Integrated Review Plan (IRP)

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**Statement of Albert Rizzo, MD, FACP, FACCP
Chief Medical Officer, American Lung Association**

Thank you for the opportunity to provide comments on behalf of the American Lung Association on the draft Integrated Review Plan (IRP) for the Ozone National Ambient Air Quality Standards (NAAQS). The Lung Association will submit comments in full in writing; my presentation represents a brief summary of our comments.

The American Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through education, advocacy and research. For more than 110 years, we have led the fight for healthy lungs and healthy air, whether it's searching for cures to lung diseases, keeping kids off tobacco, or fighting for laws that protect the air we all breathe.

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and timely reviews of the ever-growing evidence, the basis of their protection—the NAAQS—would reflect increasingly outdated science. As a physician, I cannot imagine accepting that my patients would be treated using outdated treatments, when current research showed that they needed different treatments. 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, we are 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. Just to remind all, 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. 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.

Thank you for this opportunity to provide these comments.

