Statement of the American Lung Association on EPA's Second Draft Policy Assessment on the Review of the National Ambient Air Quality Standards for Ozone

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Good afternoon. Thank you for the opportunity to offer some comments on EPA's second draft Policy Assessment for the review of the ozone NAAQS.

New Science Demands a Lower Range

Let me say at the outset that the Policy Assessment proposes an all-too-familiar range for the standard. The range of 60 to 70 ppb (8-hour average standard) is the same as was under discussion in the last review in 2008, and during the reconsideration process. That range was based largely on the science available through 2005. Nine years later, 60 to 70 ppb should not be the default assumption in this review.

The new science demands a fresh look, as reflected in tremendous effort that has gone into the ISA. Based on the evidence in the ISA, we see no justification for maintaining the 60-70 ppb range. The evidence requires a lower range be proposed.

The ISA presents compelling new information:

--a conclusive determination that ozone causes adverse respiratory effects;

-- several additional controlled human exposure studies demonstrating respiratory deficits and inflammation in healthy young adults at **60 ppb**.;

-- stronger findings that the adverse effect of ozone on cardiovascular health are likely causal;

-- new information suggesting reproductive effects, such as increased risk of low birth weight babies;

-- new conclusions about suggestive neurological effects;

--new community health studies strengthening the link between ozone exposure and mortality, even at concentrations below the current standards; and

-- new information about the impact of longer-term exposures on respiratory health endpoints such as pulmonary inflammation and injury, and new onset asthma.

<u>The Scientific Record in this Review Supports a Standard of 55 to 60 ppb.</u>

We concur with the Policy Assessment's conclusion that the current standard is not protective of public health. The draft Risk and Exposure Assessment makes clear that a standard of 70 ppb, at the upper end of the range in the draft Policy Assessment, would provide little incremental benefit over the current standard.

We urge that the Policy Assessment consider a range of 55 to 60 ppb, consistent with strong evidence of adverse effects at 60 ppb and below.

New Chamber Studies Support a Standard of 55 to 60 ppb

There are several additional new chamber studies available that demonstrate respiratory deficits and inflammation in healthy young adults at **60 ppb.**[1] This is substantially more information than was available in the last review when 60 ppb was the lower end of the range recommended by CASAC. The studies indicate that some individuals respond more severely than the group average.

Since harm occurs at 60 ppb for healthy young adults, that level would not provide adequate protection to public health. In the draft Policy Assessment, EPA recognizes that at-risk groups could suffer more serious effects. Standards must be set to protect sensitive populations including responders, children and those with respiratory disease with an adequate margin of safety. It follows that the lower end of the range must be pegged to 55 ppb or below.

EPA Needs to Give Greater Weight to the Epidemiological Studies

In considering the range needed to protect sensitive populations, EPA should give greater weight to the epidemiological studies.

The ISA reviews dozens of epidemiological studies of emergency department visits and hospital admissions and

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[1] Kim et al (2011). Lung function and inflammatory responses in healthy young adults exposed to 0.06 ppm ozone for 6.6 hours. Am J Respir Crit Care Med 183: 1215-1221; Schelegle et al. (2009) concentrations from 60 to 87 parts per billion in healthy humans. Am J Respir Crit Care Med 180: 265-272; Brown et al. (2008). Effects of exposure to 0.06 ppm ozone on FEV1 in humans: A secondary analysis of existing data. Environ Health Perspect 116: 1023-1026.

concludes that the mean 8-hour maximum ozone concentration in these studies was below 60 ppb.

In studies of respiratory mortality, the mean 8-hour maximum concentrations are less than 63 ppb, according to the ISA. Premature deaths and adverse health effects are occurring at concentrations well below the mean.

EPA recognizes, correctly, that the studies do not show a clear threshold for adverse effects. Still the Policy Assessment gives too little weight to the epidemiological evidence of impacts below 60 ppb.

Major multi-city studies conducted outside North America are also excluded.

The draft Policy Assessment uses an over-simplification to dismiss studies from consideration because they were conducted in places that would violate the current standard. Important information can be gleaned from these studies about the distribution of ozone concentrations where the preponderance of adverse health effects occur.

In the analysis of the studies by Silverman and Ito (2010) and Strickland et al (2010), the assessment focuses excessively on whether areas would be in violation of the current standard, in its current form, or would exceed alternative standards, based on the 4th highest daily max.

Past reviews have not interpreted studies in this manner. Indeed the "form" of the standard, which limits the number of exceedances, has in some sense been relied upon to provide a margin of safety.

The epidemiological studies do not justify a range of 60 to 70 ppb and provide strong evidence that a more protective range is needed.

The Ozone Review Must Not be Further Delayed

There is an urgent need to move forward with this review in a timely manner. Millions of Americans have been living with a standard that is not protective of public health for far too long. As EPA noted based on estimates in the REA's case study areas alone, more than two million children suffer ozone concentrations that threaten their health each year. More than 200,000 of those children have asthma, placing them among the most at risk. The Lung Association urges EPA to protect their health without delay.