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**Comments of  
Kevin M. Stewart  
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**on the  
United States Environmental Protection Agency's  
Reconsideration of the  
2008 National Ambient Air Quality Standard for Ozone**

**Before the  
Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel**

**March 3, 2011**

Chairman Samet and members of the Clean Air Scientific Advisory Committee, I am Kevin Stewart, Director of Environmental Health for the American Lung Association of the Mid-Atlantic. I thank the Panel for its work and for the opportunity to comment today. I represent not only the three million people in our four-state service area who suffer from chronic lung disease, but also the tens of millions more who desire to breathe clean air and so protect their good health.

In our service territory alone, the populations potentially at risk from exposure to ozone include:

- 5.4 million infants, children and teens under 18
- 3.5 million persons aged 65 and above
- 500,000 children with asthma
- 1.7 million adults with asthma
- 820,000 persons with chronic bronchitis
- 330,000 persons with emphysema
- 7 million persons with cardiovascular disease, and
- 2.6 million persons living in poverty.

Far from being a small minority, persons falling into one or more of these high risk groups together comprise on the order of half the population. Even if we are to limit our concern to the most vulnerable 10% -- or even 1% -- of these groups, we are still talking about tens or hundreds of thousands of people at unusual risk.

And even more important to remember: Every one of these is a real person, not a nameless statistic. Every one of these people is a human being worthy of our attention, a neighbor, a coworker, a friend, a family member.

Therefore, I would like to call your attention to several considerations on behalf of those sensitive and vulnerable populations.

We must recognize that the individuals who are most at risk to ozone exposure are a minority that is a significant subgroup, but that this is a subgroup that can be lost in studies looking at the population as a whole. Indeed, the point has been made that epidemiological studies of the general population can hide real effects in smaller subgroups, and thus bias conclusions of broad studies toward the null.

We already know that, in studies at 0.08 ppm and higher, those with pre-existing disease suffer more adverse outcomes than healthy individuals; there is no good rationale for supposing that the high risk group would somehow be protected more at the lower levels at which the healthy group continues to exhibit response.

We already know that children and adults with asthma are at increased risk of acute exacerbations of this disease on or shortly after days when ozone concentrations are elevated above background but remain below 0.08 ppm.

Statistically significant decrements in FEV<sub>1</sub> have been shown in different controlled human exposure studies in the proposed range, including the fact that several subjects experienced decreases of 10% or more, a degree of decrease that has been determined to be of clinical relevance in individuals with pre-existing pulmonary or cardiac disease since moderate or severe respiratory symptoms could result.

Given that the controlled human exposure studies have been done among young, healthy adults, it is critical for CASAC always to remember that there are several factors (ventilation patterns, decreased respiratory reserve, impaired health) that may render children, the elderly, and persons with pre-existing lung and heart disease, as potentially even more susceptible.

The EPA's quantitative risk assessment showed significant reductions in risk in going from a 0.074 ppm standard to a 0.064 ppm standard. And because it did not consider all the known adverse outcomes, the risk assessment underestimates those reductions, since many unexamined health outcomes pose risks for sensitive populations. Indeed, because of the much greater likelihood of exposure at relatively lower concentrations, the risk assessment showed that those conditions yield the majority of adverse health effects.

Also, as the Panel has heard, studies have shown that the lower end of CASAC's proposed range, 0.060 ppm, yields greater health benefits than the upper end at 0.070 ppm. Beyond this, ozone-related health effects have been found in many epidemiological studies with mean exposures significantly lower than CASAC's proposed range.

Therefore CASAC's proposed range is, if anything, too *lax* a range for the Administrator to consider. The range does not itself exhibit any margin of safety, but adverse health consequences are shown to occur from one end to the other.

Levels of ozone exposure for which CASAC has reasonable confidence that findings of clinical impacts are demonstrated should be the basis for setting only a "first draft" maximum value for the standard *to protect public health*, then in order to establish a valid usable standard (i.e., a standard with an *adequate margin of safety*), the following two factors should then be taken into consideration:

- Lower levels of ozone exposure for which CASAC has somewhat less confidence that findings of clinical impacts are demonstrated.
- Lower levels of ozone exposure for which CASAC is reasonably confident that findings of sub-clinical adverse impacts are occurring, such as increased inflammation and airway responsiveness.

The American Lung Association of the Mid-Atlantic believes that if CASAC were to follow this kind of analysis, the body of evidence would make it clear that an 8-hour ozone standard *not greater than 0.060 ppm* is the only standard in CASAC's recommended range of 0.060 to 0.070 ppm that meets these criteria for a maximum "first draft" value, and we believe that the evidence is sufficient to show that, for huge numbers of persons in the sensitive and vulnerable populations, even this 0.060 ppm standard is inadequate, according to the Clean Air Act's charge, to protect public health, let alone to provide a margin of safety.

Simply, the NAAQS should tell people the truth about the quality of the air they are breathing. A standard that is billed as including a margin of safety yet allows some people's health to be affected adversely by air pollution fails that test.

We stress that CASAC's role is to help EPA in its statutory duty to set air quality standards based *exclusively on the science*, i.e., to create standards that "protect public health with an adequate margin of safety." It is therefore not the case, as has been posited, that setting a standard itself is a *policy* judgment that weighs the estimated health benefits against the difficulty of implementing effective control strategies to meet any given standard. Rather, the matter of *implementing* a standard – the development of techniques, the setting of attainment dates, the creation of regulatory structures – is, *by law*, a completely independent issue.

A final note: I was trained in engineering, and a margin of safety is, for instance, what you should put into the bridge design and construction so that *even under extremely unlikely worst case circumstances*, the bridge does not collapse – that is, *no one* is killed. I encourage CASAC to keep that model in mind as you recommend margins of safety for national ambient air quality standards.

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