May 19, 2014

H. Christopher Frey, PhD, Chair
And Members, Ozone Review Panel
Clean Air Scientific Advisory Committee

C/o Dr. Holly Stallworth
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Dear Dr. Frey and panel members:

We national organizations representing medical societies, public health and patient advocacy organizations write to provide comments to the Clean Air Scientific Advisory Committee as you develop your final recommendations to the U. S. Environmental Protection Agency on the second draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards. Your recommendations will deliver critical advice to the EPA and therefore, must be founded in the strongest requirement of the Clean Air Act: that the NAAQS protect public health with an adequate margin of safety.

Our organizations strongly urge you to recommend a standard or a range for that standard that will meet the Clean Air Act requirement, one that is much more protective than the recommendation included in the second draft Policy Assessment. Our organizations urge you to recommend a range for the 8-hour ozone standard that extends no higher than 60 ppb.

Unfortunately, the recommendation for the 8-hour standard in the second draft Policy Assessment is weak. That range of 70 to 60 ppb is the same recommendation the CASAC provided in the last ozone review, based solely on the available research published through 2006. That range should not be the recommendation of this CASAC, because the post-2006 epidemiologic research documenting evidence of adverse health effects at 60 ppb and below, as well as new chamber study evidence of inflammation at 60 ppb show that the previous range fails to meet the Clean Air Act requirements.

In the prior review and in the 2010 reconsideration, our organizations recommended that the primary 8-hour standard should not be greater than 60 ppb based; we based that recommendation on the chamber studies that showed harm to healthy adults at 60
ppb. (Adams, 2002 and Adams, 2006). Further, the epidemiological evidence had identified a new, but strong association with premature death, with no discernable threshold, that made the risks to the large, vulnerable populations even graver.

The evidence in Adams (2002), Adams (2006), Brown et al (2008) and Kim et al (2011) shows that exposures down to 60 ppb can reduce lung function and cause inflammation that meet the American Thoracic Society’s criteria for judging adversity. The subjects in these chamber studies were healthy young adults. EPA’s Integrated Science Assessment finds that children, the elderly, and people with asthma are more susceptible to ozone than the general population. The chamber studies establish the strongest evidence that concentrations above 60 ppb would provide significant risk not only to many healthy adults, but most critically, to vulnerable/susceptible populations, including children, seniors and people with asthma and other chronic lung diseases.

According to the Integrated Science Assessment, epidemiological studies in Europe and North America have demonstrated consistent, positive associations between ozone air pollution and hospital admissions and emergency department visits for respiratory causes. Generally, mean 8-hour maximum ozone concentrations were less than 60 ppb (p. 2-22).

The analysis presented in the Policy Assessment digs deeper into six epidemiological studies in the U.S. and Canada and provides further real-world evidence that a standard of either 70 ppb or 65 ppb fails to provide adequate protection. These studies (Bell et al., 2006; Cakmak et al., 2006; Dales et al., 2006; Katsouyanni et al., 2009, Mar and Koenig, 2009; Stieb et al, 2009) examined the positive and statistically significant associations from the most serious health threat—premature death—as well as from hospital admissions and emergency department visits. In the majority of locations where increased risk was found, the ozone levels would have met the weaker standards of either 70 or 65 ppb, but would have failed to meet a standard set at 60 ppb. (Policy Assessment, pp. 4-13 to 4-15). The effect estimates are largely influenced by locations with concentrations meeting a concentration of 70 or 65 ppb, demonstrating that such standards would not be effective in protecting public health with an adequate margin of safety.

Supporting 70 to 60 ppb as an acceptable range communicates the wrong message to the EPA. Such a recommendation would risk that range be considered safe and acceptable not only for healthy adults, but also to those large at-risk populations. Such a range would not, could not provide adequate protection to their health.

Since the primary ozone standard directly affects the patients our members treat and the health risks our organizations seek to reduce, we urge you to advise EPA of the need for a much lower, more protective range than recommended in this second draft Policy Assessment.
We appreciate your consideration of our comments.

Yours truly,

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