



**Statement of Lorraine Gershman before CASAC on Controlled Human Ozone Exposure  
Study Evaluation by Goodman *et al.* (2013)  
American Chemistry Council  
March 26, 2014**

Thank you for the opportunity to speak today. My name is Lorraine Gershman, and I am representing the American Chemistry Council (ACC)<sup>1</sup>. ACC represents the leading companies engaged in the business of chemistry. We are here today to highlight our belief that EPA's existing 75 parts per billion (ppb) ozone National Ambient Air Quality Standard (NAAQS), achieved through a series of significant emission control programs, will continue to provide ample protection of public health. ACC believes in appropriately peer-reviewed sound science, and would support a new standard if the science demonstrated that it is justified.

My comments today will focus on the controlled human exposure studies and I will try to put those results in the context of the broader Health Risk and Exposure Assessment (US EPA, 2014).

In the second draft Health Risk and Exposure Assessment (REA; US EPA, 2014), EPA evaluated ozone exposures at benchmark levels of 60, 70, and 80 ppb. Because the Agency concluded that controlled human ozone exposure studies indicate adverse lung function decrements can occur with ozone exposures as low as 60 ppb, EPA selected 60 ppb as the lowest benchmark for evaluation in the REA.

As presented in the REA (see for example Table 6-3), it is hard to see which of the controlled human exposure studies were statistically significant and showed effects that were adverse (with an FEV<sub>1</sub> > 10%). Thus, I would like to bring to your attention a recent review by Goodman *et al.* (2013) which uses an adverse effects/causation framework to evaluate many of the same controlled exposure studies. This publication shows that that ozone effects are statistically significant only above 70 ppb, and potentially adverse only at or above 80 ppb. Therefore, based on the results of the controlled human exposure studies, lowering the standard will not result in additional public health benefits compared to the current level of the standard.

The Goodman *et al.* (2013) evaluation included the studies on which EPA based its conclusion that adverse effects occur at 60 ppb. These studies evaluated healthy young adults who were exercising and exposed to controlled concentrations of ozone through a face mask or an environmental chamber for up to 6.6 hours per day. Goodman *et al.* found consistent evidence that exposures of 80 ppb and greater were associated with statistically significant lung function decrements. At levels less than 88 ppb, lung function decrements were transient and reversible and did not appear to interfere with normal activity or result in

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<sup>1</sup> *The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$770 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for twelve percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.*



permanent respiratory dysfunction. Statistically significant decrements occurred at levels around 70 ppb, but these effects did not meet the criteria for an adverse effect on lung function. At levels at or around 60 ppb, lung function decrements were reported to be statistically significant in some, but not all, studies. However, Goodman *et al.* found that statistical significance at 60 ppb was only achieved when the analysis used less appropriate statistical tests or only a subset of the available data. Taken together, these findings suggest that lung function effects at 60 ppb are isolated and likely attributable to factors other than ozone.

In addition, as the REA also points out, at 60 and 70 ppb, the small decrements in lung function are not considered to be clinically relevant by the American Thoracic Society or European Respiratory Society (ERS). For example, ERS stated that measurements of lung function decrements used in the controlled exposure studies (forced expiratory volume in 1 second, FEV<sub>1</sub>) should exceed 5% to overcome normal variability of these measurements over the course of a day. In fact, according to Pelligrino, in the 2005 ERS report, "When using per cent change from baseline as the criterion, most authorities require a 12–15% increase in FEV<sub>1</sub> and/or FVC as necessary to define a meaningful response." This was not the case for observed FEV<sub>1</sub> decrements associated with exposures to 60 and 70 ppb ozone. Furthermore, small changes (such as those Goodman *et al.* discussed at levels less 88 ppb) represent a lesser degree of adversity than irreversible and sustained changes in the respiratory system.

The findings of the controlled human studies should be kept in mind when interpreting the findings presented in Table 6-4 and Figure 9-9 of the REA. In these exhibits, EPA focuses on the changes in the percent of the population showing the chosen effect. No ranges are provided, no uncertainty bounds are shown, and in Figure 9-9, no baseline is provided. Without a baseline figure, the percent reductions are misleading and readers are likely to assume that they represent large health improvements. Without uncertainty bounds, it is not clear whether reductions are statistically significant, or whether the changes are simply within the range of model uncertainty. Although we do not have enough time and information to conduct an independent evaluation of EPA's results, it is important to remember, as shown clearly in Figure 1 of Goodman *et al.* 2013, that an exposure level of 60 ppb is not associated with significant changes in FEV<sub>1</sub> and no group mean changes that are >10%. These results should be considered in how the REA findings are presented in the Policy Assessment.

## References

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