Preliminary Comments from Dr. Michelle Bell on
EPA's *Policy Assessment (PA) for the Reconsideration of the Ozone National Ambient Air Quality Standards (External Review Draft Version 2)*
03-30-23

Chapter 3 – Review of the Primary Standard

1. What are the Panel's views on the approach to considering the health effects evidence and the risk assessment to inform preliminary conclusions on the primary standard? To what extent is the evaluation of the available information, including the key considerations as well as associated limitations and uncertainties, technically sound and clearly communicated?

The discussion of epidemiology in Section 3.3 has text that is not quite correct and text that could be easily misinterpreted. I recommend that the section be reviewed and edited with this in mind. As an example, on page 143, the text notes "Further, epidemiologic studies do not generally include measurements of exposure. Rather, they utilize ambient air concentrations at monitoring sites as surrogates for exposure." The first sentence here is correct, but the second one is not. There are numerous epidemiological studies that use methods of exposure assessment that are not measurements ambient air quality monitors, or not these data alone. Examples include air quality modeling, satellite imagery, and data fusion techniques. The PA correctly notes some of these methods on page 151. Another example is "In considering the exposure circumstances in these epidemiologic studies, we note that these studies generally do not provide information on details of the specific O3 exposure circumstances that may be eliciting respiratory health effects." on page 151. I think I understand what EPA is trying to express here, but the language "specific O3 exposure circumstances" could easily be misinterpreted. The implication is that human exposure studies have specific ozone exposure circumstances and epidemiological studies do not. Again, I think I know what EPA intended to convey here, but it in fact human exposure studies do not have the exposure circumstances of anyone in the real world. Epidemiological studies, that link ambient levels to health endpoints, are assessing exposure at the direct metric used by policy. I suggest revisiting this language to avoid confusion.

The decision to exclude from consideration epidemiological studies with Design Values (DV) above the NAAQS is not scientifically justified. The summary of this rationale is: "In light of this uncertainty regarding to exposure circumstances that might be eliciting observed health outcomes, our use of epidemiologic studies in considering adequacy of the primary standard often starts with the broader question of what are the O3 concentrations in the study locations—and more specifically, whether the studies are indicating the potential for O3-related health outcomes to be occurring when air quality is meeting the existing standard. If concentrations in the study locations are well above those that would meet the current standard, it is more difficult to draw any conclusions about the adequacy of the current standard." on page 151-152. First, the issue of uncertainty regarding exposure circumstances (i.e., the use of ambient air pollution levels) in epidemiology does not mean that a study should be excluded from consideration for setting the standard. The first part of this sentence doesn't match the second part. Second, many studies will include exposures above the NAAQS as well as exposures below the NAAQS. Whether they overall fall above or below the DV is a different question. Studies that have a

DV above the standard, but include exposure below the standard, can be informative regarding the health implications of the current standard. Third, many studies, including those that may have overall ozone levels above the DV, include analysis of health effects at different levels. Several methods exist for such analysis (non-linear functions, subset analysis). Such studies can be highly informative to the health implications of an air quality standard, but could be excluded from consideration under the current framing.