Oral Comments to CASAC on the *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, External Review Draft*

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Thank you. I am Dr. Anne Smith of NERA Economic Consulting. I have prepared these comments with funding from a coalition of industry associations. They are supplemented by more extensive written comments that Dr. Garrett Glasgow and I submitted to CASAC on November 26, 2019. I am going to focus on the Draft PA's estimates of quantitative risks and risk-based considerations.

There are two types of *quantitative* risks calculated in the Draft PA: exposure risk estimates and lung function risk estimates. Both are estimated using a population-simulation model called APEX.

First, I address exposure risks:

- Exposure risks are estimated by simulating ozone exposures while people are physically active and then counting up how often they exceed ozone levels of 60, 70 and 80 ppb. These levels, called exposure "benchmarks," cover the lower end of the range over which clinical evidence suggests some people might start to experience measurable respiratory responses.

- When considering quantitative risk for the 2015 ozone decision, the Administrator gave greatest weight to the exposure risk estimates – most particularly when children's exposures exceeded benchmark levels on multiple occasions per year. The observation that those exposure risk estimates were reduced to minimal levels under the 70 ppb air quality scenarios helped support the 2015 determination that the current standard would be adequately protective.

- The Draft PA provides a completely updated set of exposure risk estimates and states that they remain "similar" to those from the prior ozone review. Table 1 of my written comments (replicated below) provides a side-by-side comparison of children's exposure risk estimates under the current standard – as calculated in 2014 and now; it supports the Draft PA's statement. Actually, our table shows the updated estimates of children's exposure risks are lower than before.

Table 1. Averages of Draft PA's Benchmark Exceedance Risks Compared to Those in 2014 HREA for the 70 ppb Standard for the 7 Cities in Both Documents (% of all children while at elevated exertion)

		At Least Two Exposures				At Least One Exposure	
		60 ppb		70 ppb		80 ppb	
		Average	Maximum	Average	Maximum	Average	Maximum
All Cities	**Draft PA**	0.6 – 1.7	2.8	<0.1	0.1	0 - <0.1	0.1
	HREA 2014	1.5 – 3.2	7.1	0 – 0.1	0.4	0 – 0.1	0 – 0.2

Notes: (1) The 2014 HREA reported values that rounded to less than 0.1 as "0." Thus, all the values of "0" in the table above should be interpreted as "<0.1," as is used in the Draft PA; (2) The 7 cities that are included in the averages in the above table are the cities in the Draft PA excepting Phoenix (which was not analyzed in the 2014 HREA).

I now turn to the risk category known as lung function risk:

- These are estimates of how often the ozone exposures simulated by APEX might result in various amounts of reduction in peoples' normal levels of FEV1. These risk calculations require the extra step of putting APEX's ozone exposure estimates through an "exposure-response" function.

- Exposure estimates are already subject to uncertainty, but this extra step greatly increases uncertainties because it requires multiple complex assumptions to convert data from clinical studies into an estimate of an exposure-response function.

- The Draft PA presents risk results for two different exposure-response models, one called the "E-R" model and the other called the "MSS" model. Both models rely on data from the same set of clinical studies but *produce very different risk estimates*. This, in itself, signals a large degree of model uncertainty in lung function risk estimates – *Which model is more reliable*?

Our written comments show substantial uncertainties around both models' estimates, but do not explain the large gap between them. We are, however, impressed by a sensitivity analysis in Appendix 3D of the Draft PA. It shows that most of MSS's higher lung function risks occur when predicted ozone exposures are very low – such as, lower than 40 ppb. This portion of the lung function risk estimates is less reliable because there is far less evidence of actual lung function responses at such low exposures. This is true for *either* model but affects the MSS model results much more than the E-R model results. Thus, it is reasonable to give more weight to lung function risk estimates from the E-R model than the MSS model. This situation, however, also raises the question of how much the lung function risk estimates *per se* can improve inferences about the public health compared to relying primarily on the associated benchmark exposure risks also from APEX.

Epidemiologic-based risks:

In contrast to the lung function risk estimates, epidemiologic-based risk calculations would be much more affected by scientific uncertainties, due to a wider range of data limitations — such as, measurement error, exposure-window uncertainty, and potential co-pollutant effects.

In fact, the Draft PA does not provide *any* quantitative risk estimates with an epidemiologic basis. It limits its reliance on epidemiological papers to its qualitative, "evidence-based" reasoning. This is a reasonable approach until the Agency develops methods to quantify and integrate model uncertainties into its epidemiologic-based risk calculations.

Lacking integrated uncertainty analysis, epidemiologic-based risk estimates played a minimal role in the 2015 ozone NAAQS decision, and would have had no improved usefulness now.