

**COMMENTS REGARDING EFFECTS THRESHOLDS FOR LONG-TERM MORTALITY RISK
(FOR THE MAY 28, 2014 CASAC TELECONFERENCE ON THE OZONE NAAQS)**

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Prepared on behalf of the Utility Air Regulatory Group**

In my technical comments on the second draft HREA,¹ I noted that:

1. The best fit model for long-term respiratory mortality risk in the original source study, Jerrett *et al.* (2009)² was a threshold model, and in particular that the best fit among alternative thresholds tested was 56 ppb.
2. EPA's "core" estimates of risk should be based on the best fit model, particularly given that prior expectations are that a threshold exists at some level of exposure.
3. Just because a best-fit model does not improve over other models with at least 95% confidence does not mean that it should be rejected for use as a best risk estimate, particularly if the structure of the best-fit model matches better to researchers' a priori, scientifically-based expectation of the relationship's likely shape (in this case, that a threshold is expected to exist at some level of exposure).
4. That EPA's risk estimates are extremely sensitive to whether a threshold is included in the risk analysis
5. When risk estimates are extremely sensitive to a single assumption, that uncertainty should become the central point of the risk analysis, not estimates from a single model.

In response to my comments, EPA produced a memo on April 28, 2014³ that says EPA will do a sensitivity analysis in its final HREA on the effect of a possible threshold. Although EPA stated it would not have these sensitivity analyses completed before the May 28, 2014 CASAC call, it stated that EPA staff "expect that alternative 8-hour standards with levels from 70 to 60 ppb will still reduce estimates risks relative to the current standard." (p. 2). As I will show in this document, EPA's expected conclusion is premature and likely not to be correct. CASAC should require that it see and review a third draft of the HREA that includes EPA's extensive additional analyses because they should make a substantial difference in EPA's conclusions.

¹ Anne E. Smith, "Technical Comments on Second External Review Drafts of the *Health Risk and Exposure Assessment for Ozone and Policy Assessment for the Review of the Ozone NAAQS*. Prepared on behalf of Utility Air Regulatory Group and submitted to docket, March 24, 2014.

² Jerrett M. *et al.* 2009. "Long-Term Ozone Exposure and Mortality." *The New England Journal of Medicine*, 360(11):1085-1095.

³ "Response to Comments Regarding the Potential Use of a Threshold Model in Estimating the Mortality Risks from Long-term Exposure to Ozone in the *Health Risk and Exposure Assessment for Ozone, Second External Review Draft*." Memorandum from Erika Sasser, U.S. Environmental Protection Agency to Holly Stallworth, EPA Science Advisory Board, April 28, 2014.

Although EPA did not intend to complete its threshold-related sensitivity analyses in time for the May 28 meeting, I have done them and present them in this document. All of the calculations in this document use the corrected BenMAP estimation method.

As preface, readers need to understand that evidence of an effects threshold below 60 ppb in the long-term mortality risk relationship does NOT mean the threshold occurs below a NAAQS level of 60 ppb. This is because the form of the NAAQS is different from that of the ozone average used in Jerrett *et al.*, and so a threshold estimate from that study is not directly comparable to the level of an ozone NAAQS. The ozone metric in Jerrett *et al.* is the average over days from April to September of each day's maximum 1-hour ozone level, while the NAAQS level is a 3-year average of the fourth highest daily maximum 8-hour ozone in each individual year. There is no precise or geographically uniform way to convert from the Jerrett metric to equivalency with a NAAQS level. However, the evidence I present below (using the HREA's ozone data) shows that a 56 ppb threshold in the Jerrett *et al.* study is equivalent to a NAAQS level higher than the current standard of 75 ppb in 10 of the 12 of the urban areas studied. In the remaining 2 cities, it appears to be equivalent to a NAAQS level somewhere between 65 and 70 ppb.

SENSITIVITY OF ESTIMATED REDUCTIONS IN RISK AT ALTERNATIVE OZONE STANDARDS

Tables 1 and 2 (on the next page) contain the sensitivity analysis results that reveal the likely inaccuracy in the April 28 memo's statement that EPA staff "expect that alternative 8-hour standards with levels from 70 to 60 ppb will still reduce estimates risks relative to the current standard." (at p. 2). Tables 1 and 2 report the estimated annual premature deaths from long-term ozone exposure in the 12 urban study areas when a 56 ppb threshold model is used (for 2007 and 2009 ozone conditions, respectively). These tables show that:

- In 10 of the 12 cities there is no long-term mortality projected risk when attaining the current 75 ppb standard.
- Risks do not continue to be reduced over the range from 70 to 60 ppb in any city. In 10 of the cities risk is not reduced at all below the 75 ppb standard and in 2 (Denver and Los Angeles), they are not reduced after attaining a NAAQS somewhere above 65 ppb.⁴

⁴ Given the difficulty EPA had with simulating attainment in Los Angeles using its HDDM-based approach, the air quality results for Los Angeles are probably not reliable and should be removed from the HREA (along with New York City).

Table 1. Total Annual Premature Deaths Due to Long-Term Ozone Exposure at Exact Attainment of Alternative Ozone NAAQS Using the 56-ppb Threshold Model (for 2007 ozone, CBSA regions, using corrected BenMAP calculations)

	75 ppb	70 ppb	65 ppb	60 ppb
Atlanta, GA	0	0	0	0
Baltimore, MD	0	0	0	0
Boston, MA	0	0	0	0
Cleveland, OH	0	0	0	0
Denver, CO	28	14	0	0
Detroit, MI	0	0	0	0
Houston, TX	0	0	0	0
Los Angeles, CA	98	7	0	0
New York, NY	0	0	0	0
Philadelphia, PA	0	0	0	0
Sacramento, CA	0	0	0	0
St. Louis, MO	0	0	0	0

Table 2. Total Annual Premature Deaths Due to Long-Term Ozone Exposure at Exact Attainment of Alternative Ozone NAAQS the 56-ppb Threshold Model (for 2009 ozone, CBSA regions, using corrected BenMAP calculations)

	75 ppb	70 ppb	65 ppb	60 ppb
Atlanta, GA	0	0	0	0
Baltimore, MD	0	0	0	0
Boston, MA	0	0	0	0
Cleveland, OH	0	0	0	0
Denver, CO	12	5	0	0
Detroit, MI	0	0	0	0
Houston, TX	0	0	0	0
Los Angeles, CA	129	45	0	0
New York, NY	0	0	0	0
Philadelphia, PA	0	0	0	0
Sacramento, CA	0	0	0	0
St. Louis, MO	0	0	0	0

These threshold sensitivity results are very different from the summary statement in the draft CASAC letter on the HREA regarding the long-term mortality results. In particular, CASAC's draft letter states:

Similarly, the preventable annual mean number of premature deaths from long-term exposure to ozone is estimated to range from 330 to 440 for a level of 70 ppb, 910 to 1160 for a level of 65 ppb, and 1220 to 1500 for a level of 60 ppb, all compared to just meeting the current standard.⁵

The above draft sentence is based solely on no-threshold results, which is all that the present HREA draft contains. However, if EPA's threshold sensitivity results were to be considered, the above sentence would be overstated. For example, if the 56-ppb threshold results (Tables 1 and 2) were used instead of the no-threshold results, that sentence should instead read:

Similarly, the preventable annual mean number of premature deaths from long-term exposure to ozone is estimated to range from 91 to 105 for a level of 70 ppb, 126 to 141 for a level of 65 ppb, all compared to just meeting the current standard. There is no further increase in the preventable annual number of deaths when going from 65 ppb to 60 ppb because all 12 cities' ozone levels are projected to fall below the long-term mortality threshold somewhere above the ozone NAAQS level of 65 ppb.⁶

This illustrates the potential problem that might arise if CASAC finalizes its letter without first seeing and reviewing a third draft of the HREA that incorporates the threshold sensitivity results on long-term mortality risk.

The question of whether long-term mortality risk continues to be reduced over the range from 70 to 60 ppb can only be addressed by the urban study area results because the HREA's national scale estimates are only for a simulation of risk under recent (2006-2008) ozone levels, which exceed even the current 75 ppb standard in parts of the country. No national results are available for how the estimated risk changes as the NAAQS is tightened below the current standard of 75 ppb. Thus, the results for the twelve urban areas presented in Tables 1 and 2 are the only analysis results on which EPA could attempt to draw its conclusion, and they show that long-term mortality risk estimates under a 56 ppb threshold do NOT support a statement that alternative standards all the way down to 60 ppb continue to reduce risks relative to the current standard. For this reason, CASAC should request to see and review third drafts of the HREA and PAD.

The projected total risks at the current standard are also dramatically reduced in the sensitivity case using the 56 ppb threshold, compared to their respective no-threshold risk estimates:

⁵ Draft CASAC letter on HREA, May 12, 2014, p. 2, lines 38-41.

⁶ The numbers in this statement were derived from results in Tables 1 and 2 in the following way. The total mortality across all twelve cities in the 75 ppb case is 126 and 141 for 2007 and 2009 ozone, respectively. This is the maximum amount of long-term mortality that is "preventable." Because all of that risk is eliminated before attaining a NAAQS of 65 ppb, that is the range of preventable deaths associated with both 65 and 60 ppb NAAQS levels. The preventable risk for 70 ppb is the difference in the sum of risks at 70 ppb (column 2 in Tables 1 and 2) and the sum at 75 ppb: (126 minus 21) to (141 minus 50), or 91 to 105.

- Compared to the corrected no-threshold risk estimates, total projected long-term mortality across all 12 cities is 98% lower under the 75 ppb case, and 100% lower (*i.e.*, zero risk) by the 65 ppb case.
- Compared to the estimated risk under the no-threshold assumption, in the 2 cities with non-zero risk under the current standard, the estimated risk is 93% lower for the 75 ppb estimates, 98% lower for the 70 ppb case and 100% lower (*i.e.*, zero risk) by the 65 and 60 ppb cases.

SENSITIVITY OF ESTIMATES OF NATIONAL RISK UNDER 2006-2008 OZONE LEVELS

Although the national-scale risk analysis cannot address the question of whether long-term respiratory risk continues to be reduced over the range from 70 to 60 ppb, it is a useful way to show the aggregated sensitivity of the long-term mortality risk estimates to the many possible alternative assumptions about the level of a threshold that EPA has said it will perform (but would not release prior to May 28). Figure 1 provides the entire set of sensitivity results for that EPA says it will eventually provide.

Figure 1. Sensitivity of National Estimate of Long-Term Respiratory Mortality Risk to Assumed Thresholds from 0 to 60 ppb. (Using additional data provided by Jerrett and Burnett, all 1-P models)

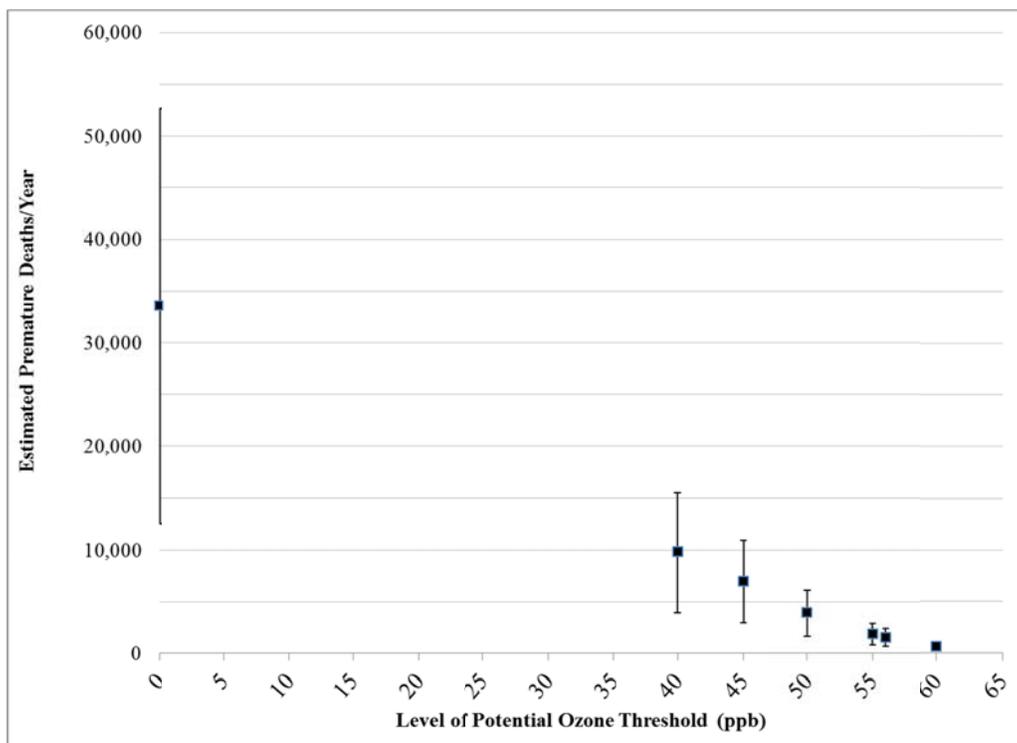


Figure 1 shows that any threshold value from 40 to 60 ppb produces a national risk estimate (for 2006-2008 ozone levels) that is very substantially lower than an estimate using a no-threshold assumption. Any threshold in that range results in risks from 71% to 98% lower than the no-threshold case (using the comparable 1-P model's results). Notably, the central estimate assuming just a 40 ppb threshold is less than the lower-bound of the 95% confidence interval from the no-threshold case. In fact, from 45 ppb upwards, the upper-bound of the 95% confidence intervals of the with-threshold estimates are all lower than the lower-bound of the 95% confidence interval from the no-threshold case. This is a clear example of how an estimate of statistical variance is completely inadequate to represent the uncertainty when there is model uncertainty, such as whether to include a threshold in the model or not.⁷

Thus, the uncertainty that should be stressed in the HREA regarding long-term mortality risk estimates should be the uncertainty about the threshold level; for a discussion of that uncertainty, any "core" estimate should be centered on the threshold that has a best-fit, i.e., at 56 ppb. Later in this document I discuss different dimensions of the evidence that 56 ppb is the best fit, all of which show that a reasonable range for the location of a threshold in the Jerrett *et al.* study is about 53 ppb to 57 ppb. The BenMAP model estimates that national risk using those thresholds varies from about 560 to 4000 premature deaths.⁸ That would be an appropriate uncertainty range for the HREA to report as its core risk, not the 17,000 to 70,000 deaths that EPA will report if it persists in using the no-threshold model for its core risk estimates.

In my March 24, 2014 comments I provided a map of the location of elevated risk under the no-threshold and 56-ppb threshold cases. To show what EPA's many sensitivity cases will look like, Figure 2 on the next page contrasts the map for its no-threshold results to the 40 ppb and 56 ppb threshold case results. The top and bottom panels were in my original comments, while the middle pane contains the results for the lowest of the threshold levels that EPA says it will analyze, 40 ppb. Figure 2 also shows that even geographically, there is much more sensitivity associated with considering *any* threshold than there is across alternative possible thresholds.

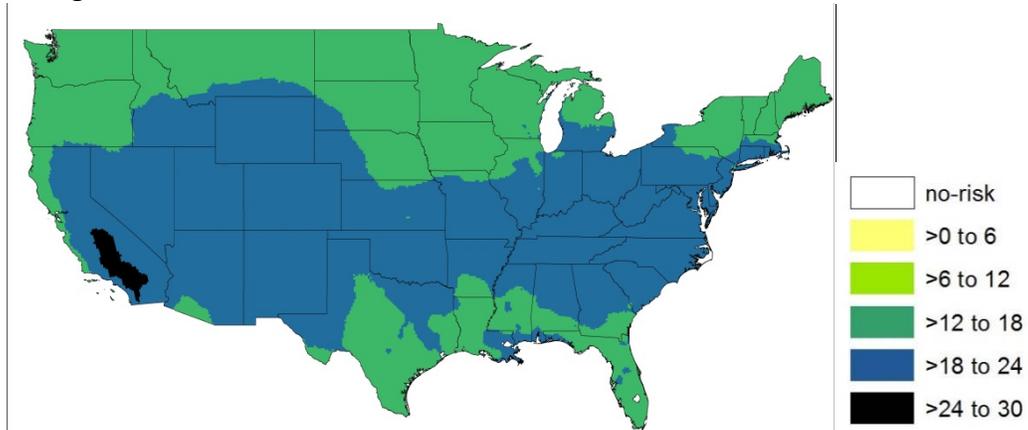
It is important to note that the national-scale risk estimates are for 2006-2008 ozone conditions, which exceed even the current standard of 75 ppb in some parts of the U.S. mapped in Figure 2. The sensitivity to the assumed threshold level would probably be even more pronounced if the national-scale sensitivity analysis could be performed for a map of the U.S. at exact attainment of 75 ppb, or for changes in risk associated with lower alternative standards. That cannot be done with the national-scale data that EPA has developed, but that greater degree of sensitivity can be seen in Tables 1 and 2 above which do have estimates of risk at attainment of alternative levels of the ozone NAAQS.

⁷ This raises the issue of model misspecification: a model that assumes no threshold when one exists is misspecified. Because standard errors do not account for misspecification in the model, the true uncertainties across the various sensitivity results in Figure 1 are larger than their confidence bounds indicate. (Also, coefficient estimates from misspecified models will be biased. I return to this point later in my comments.)

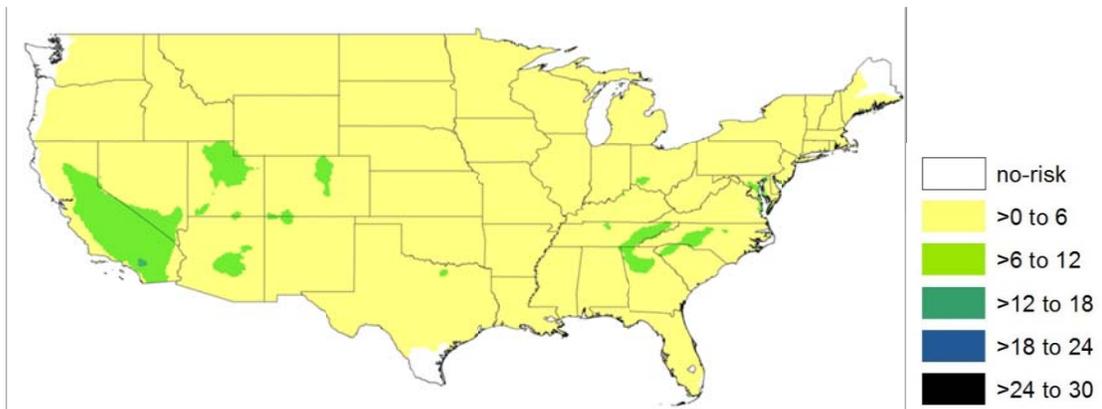
⁸ This range is from the 5th percentile of the 57 ppb model's estimates to the 95th percentile of the 53 ppb model's estimates.

Figure 2. Sensitivity of Long-Term Mortality Estimates to Alternative Models in Jerrett *et al.*
 (Maps Showing Percent of U.S. Respiratory Mortality Attributed to Ambient Ozone 2006-2008)

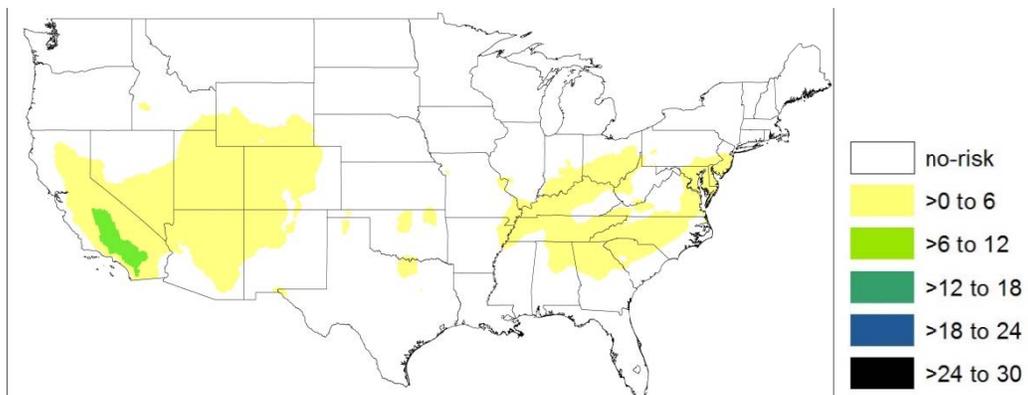
A. Using Jerrett *et al.*'s 2-P No-Threshold Model:



B. Using Jerrett *et al.*'s 40 ppb Threshold Model:



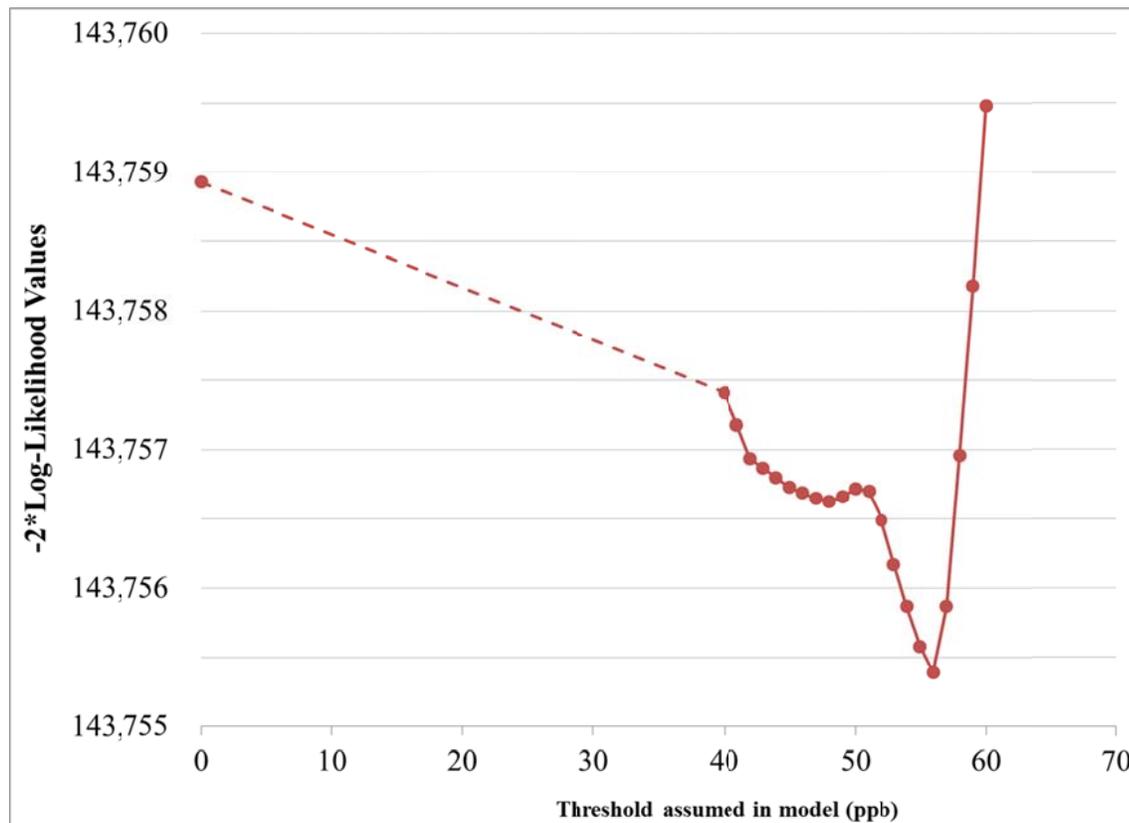
C. Using Jerrett *et al.*'s 56 ppb Threshold Model:



EVIDENCE SUPPORTING EXISTENCE OF THRESHOLD

Up to this point, I have shown that performing the risk analysis using *any* threshold in the range of 40 to 60 ppb makes a marked difference in the projected risk estimates compared to assuming no threshold at all. *Every* threshold that could have been considered by Jerrett *et al.* provides a better fit than Jerrett *et al.*'s no-threshold model.⁹ Figure 3 graphs the $-2 \times \log$ -likelihood values that the authors have provided. A best fit model has the lowest log-likelihood value. Figure 3 shows that the lowest log-likelihood value is at 56 ppb. It also shows that every single threshold model up from 40 ppb has a lower value than for the no-threshold case. Thus, EPA should not consider every threshold level from 0 to 60 ppb as equally plausible. Further, the pronounced minimum narrowly centered around 56 ppb indicates that EPA should not treat thresholds over the entire range of 40 to 60 ppb as equally likely. EPA's analysis should give emphasis to risk estimates from alternative thresholds in the range of about 53 to 57 ppb.

Figure 3. Plot of Goodness of Fit Indicators across All Alternative Assumptions about Location of a Threshold in Jerrett *et al.* ($-2 \times \text{Log-Likelihood Values}$)



⁹ Jerrett *et al.*'s data had only one city with ozone averaging below 40 ppb, which makes it impossible for them to have considered whether a threshold exists between 0 and 40 ppb. However, given the downward trend visible in Figure 3, it is quite obvious that there is evidence within their data that there is a threshold somewhere above 40 ppb.

In an attachment to EPA's April 29 memo, two of the paper's authors mentioned that there is non-monotonicity in how the log-likelihood changes as the assumed threshold is increased, suggesting that this makes it difficult to pinpoint any *specific* threshold value as "best."¹⁰ However, the figure shows that such non-monotonicity is only slight (at around 45-50 ppb) and is followed by a much more profound minimum at 56 ppb. This evidence does not support an inference that the best fit is just as likely to be below 50 ppb as at 56 ppb. The deep and pronounced minimum at 56 ppb indicates a best fit at that point, regardless of the question of whether it differs from no-threshold with *statistical significance*.

The issue of statistical significance has also been raised by EPA as a reason not to use the best-fitting model specification. For example, Jerrett *et al.* notes that the 56-ppb threshold model is not statistically significantly different from the zero-threshold model, but the result is actually borderline: the reported confidence level for accepting the 56-ppb threshold is 94% (compared to a standard convention of 95%). In an attachment to the April 28, 2014 memo, two of the paper's authors further assert that the threshold model is statistically significant using one criterion (the Akaike Information Criterion, AIC) and insignificant under an alternative criterion (the Bayesian Information Criterion, BIC). In summary, there is no consensus among alternative acceptable statistical indicators regarding the degree of classically-measured "confidence" with which the 56 ppb threshold may be accepted, implying ambiguity on any bright-line determination of significance by classical statistical measures.

When the question of significance is so ambiguous, it is not reasonable to ignore the implications of the alternative models in one's *risk* calculations. The only statistical principle that would support adopting the zero-threshold model as the core model rather than a better-fitting threshold model would be if medical professionals held an *a priori* belief that no threshold exists. In fact, the opposite is the case: medical professionals widely expect a diminution of relative risk at lower concentrations, and the surprise has been that air pollution epidemiological studies have not generally identified such a diminution.¹¹ The finding of a non-linearity in the association at lower ozone levels by Jerrett *et al.* is consistent with *a priori* expectations, and it should not be dismissed simply because there is no consensus in classical statistical measures that the extra parameter is sufficiently more informative for predicting the results within the sample of data available. This is because the higher the conservatism used in making a decision to include the threshold in the model, the higher is the probability that the resulting risk estimates will be biased by use of a misspecified model that is missing an important variable. Missing variables produce biased predictions. Biased predictions are a particularly significant concern when attempting to extrapolate outside of the original data, which is exactly what EPA's risk analyses do with results from epidemiological models.

¹⁰ "Non-monotonicity" means the function doesn't smoothly decrease around its minimum, but instead has one or more local minima, which can sometimes create ambiguity about the location of a global minimum. An example of a local minimum in Figure 3 appears around 48 ppb, but this local minimum is too shallow to create much ambiguity regarding whether the more pronounced minimum at 56 ppb should be accepted as the global minimum.

¹¹ See, for example, Vedal *et al.* 2003. "Ozone and Daily Mortality in a City with Low Levels of Pollution." *Environmental Health Perspectives* 111(1):45-51, p. 49.

Therefore, even if the confidence level were much lower but the threshold model still provided a better fit, the appropriate action for the risk analyst would be to highlight the huge policy significance of this very fine line among the alternative models. As is shown above, the alternative models reported in Jerrett *et al.* produce estimates of base risk that differ by over a factor of 25, and range qualitatively from a localized and modest risk increase to a universally large risk. This is an abject degree of uncertainty about what this paper's findings tell us about long-term respiratory mortality risk from ozone in the U.S. As there are no other publications to support any particular conclusion out of this paper, long-term ozone mortality risk estimates based on Jerrett *et al.* do not merit attention in the HREA. If they are to be included at all, the above sensitivity across the threshold assumptions should be the core result that is presented.

There is further new information in the additional materials in EPA's April 28, 2014 memo to support the view that the evidence for a threshold is strongest at about 56 ppb. The coefficient of variation (*i.e.*, the ratio of standard deviation to coefficient) on the slope estimate can now be estimated for each individual threshold assumption. The coefficients of variation follow the pattern in the $-2 \times \log$ -likelihood chart (Figure 3), showing that the confidence interval around the relative risk estimate is tightest at 56 ppb.¹² Also, we can now observe how the relative risk per increment of 1 ppb of ozone (*i.e.*, the slope coefficient of the concentration-response function) varies with the assumed threshold. The pattern consistent one would expect if a threshold is present in the data being analyzed would be that the slope coefficient would rise as the assumed threshold approaches the true value.¹³ That exact pattern is evident in Figure 4.

Finally, strong evidence of the existence of a threshold relationship in the Jerrett *et al.* study is available in a figure in the paper itself, which is reproduced as Figure 5 below. Cakmak *et al.* (1999)¹⁴ argue that analytic methods such nonparametric smoothing and weighted nonlinear regression may be capable of detecting a threshold if it exists in a data set even when exposure misclassification ("measurement error") diminishes the ability of standard linear methods to detect that threshold. They conclude that such smoothing methods should be used first in an epidemiological analysis, and if a threshold pattern emerges, then other statistical indicators should help determine whether the final models should include a threshold or not. The figure provided in Jerrett *et al.* provides such an evaluation of the shape of the relative risk relationship.

Figure 5 not only reveals a pattern characteristic of a threshold relationship, but that pattern indicates that the threshold is located somewhere in the high 50s of ozone average ppb levels. This result in combination with the goodness of fit indicators from the parametric analyses

¹² By tightest, I mean it has the smallest percentage variation around the mean estimate.

¹³ A linear relationship fitted through data that actually contain a threshold will be too flat in the portion of the data above the threshold. If the concentration-response relationship is constrained to not increase until ozone is above some non-zero level (*i.e.*, an assumed threshold level), then the estimated slope fitted to the same data will be higher.

¹⁴ Cakmak S. *et al.* 1999. "Methods for Detecting and Estimating Population Threshold Concentrations for Air Pollution-Related Mortality with Exposure Measurement Error." *Risk Analysis* 19:487-496.

discussed above provides the critical reason why a core risk estimate in the HREA should be based on a threshold model. Uncertainties around the core risk estimate should be based on other plausible threshold values, which should be considered to be in the range of 53 ppb to 57 ppb. Results from the no-threshold model should be treated as suspect rather than as a focus of the HREA's risk analysis; if not eliminated altogether, they should be placed in an HREA appendix.

Figure 4. Relative Risk Coefficient as Function of Assumed Threshold Level (Source: Jerrett and Burnett in EPA Memo of April 28, 2014)

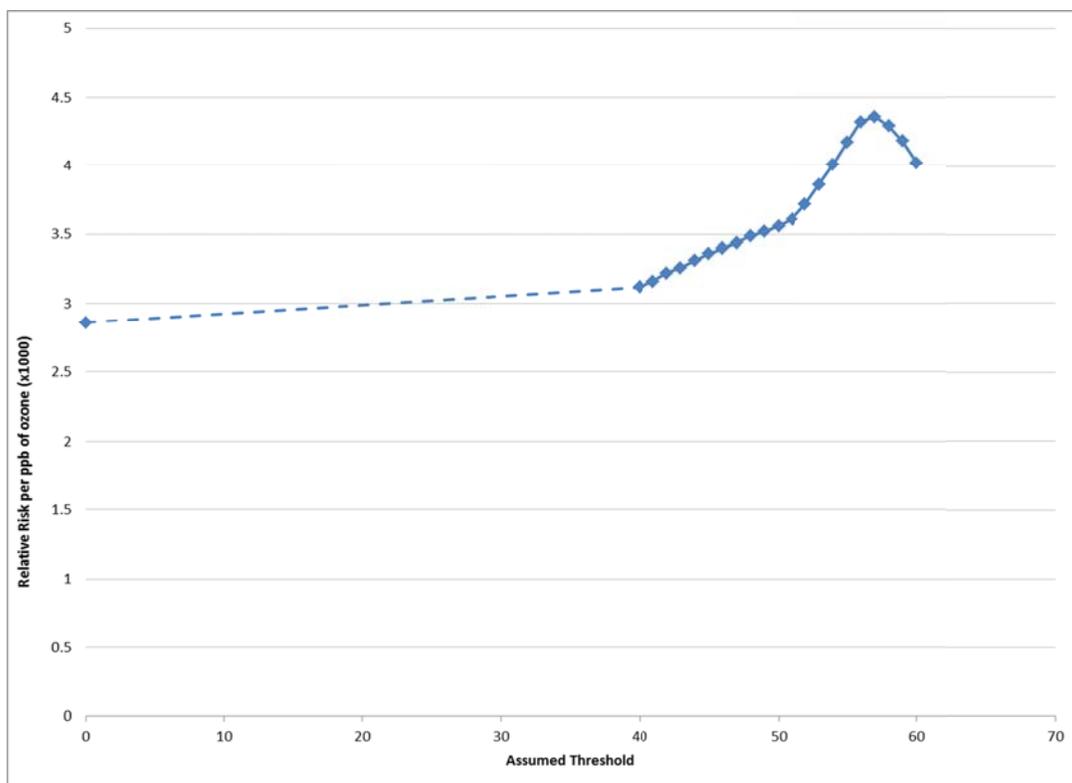
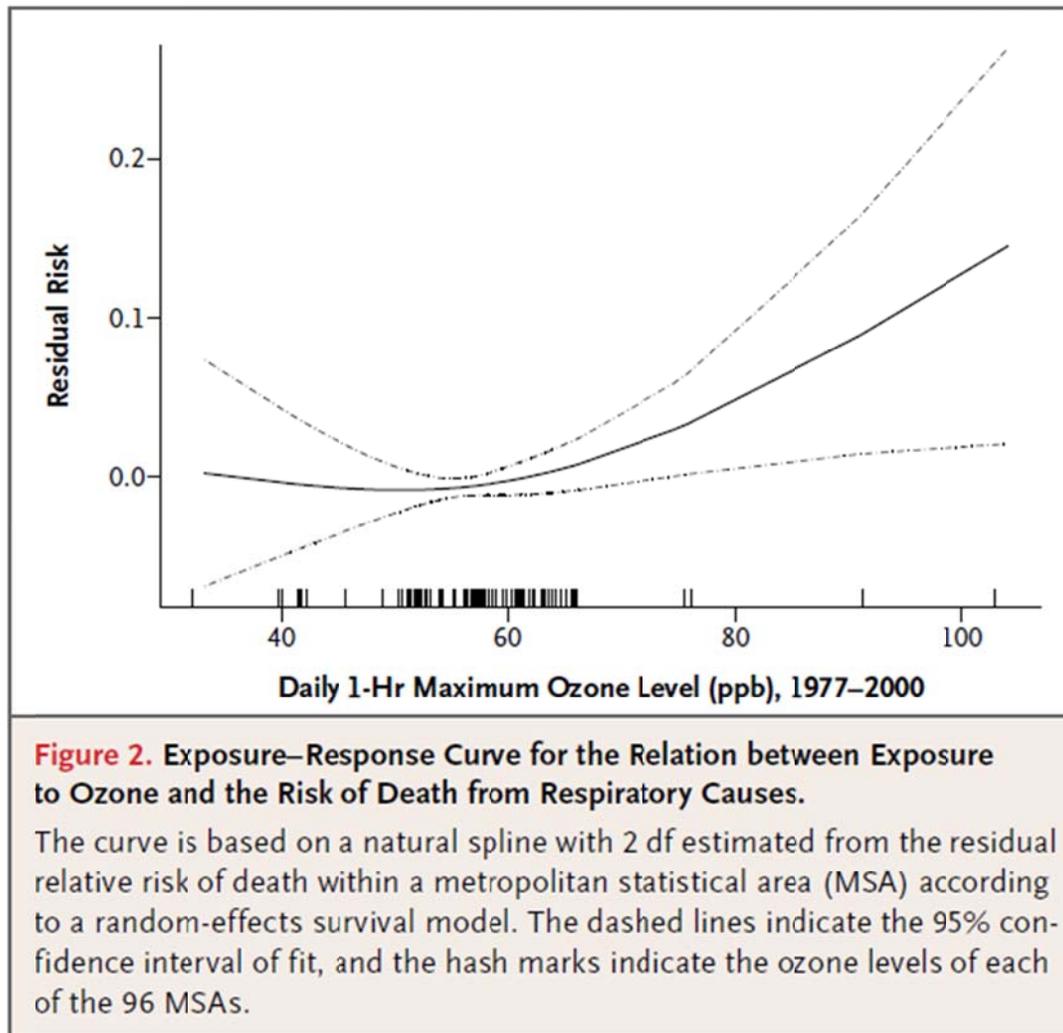


Figure 5. Copy of Figure in Jerrett *et al.* (2009) Providing Evidence of the Data's Threshold-Like Pattern

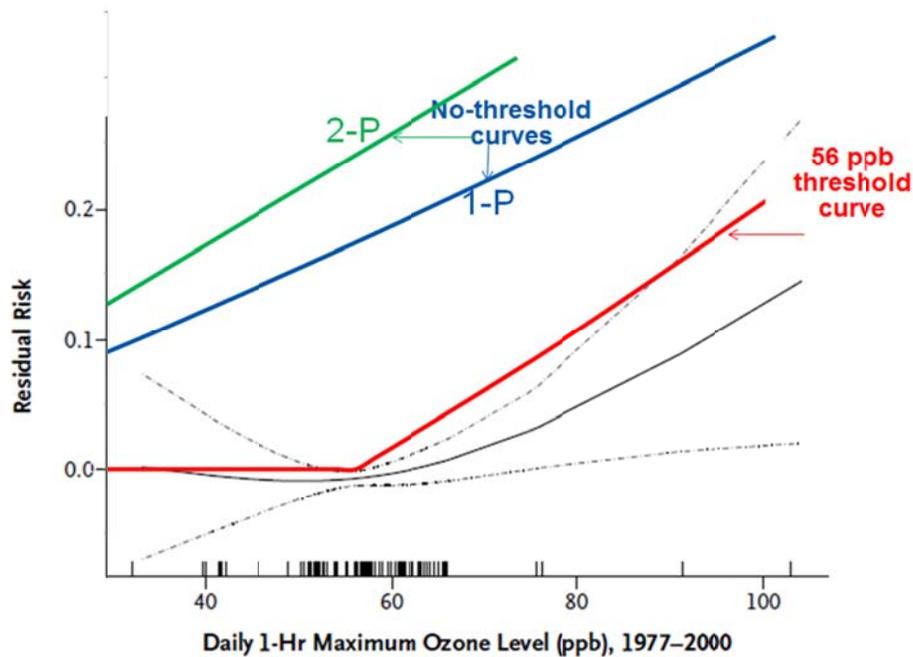


WHY THE NO-THRESHOLD RISK ANALYSIS PRODUCES IMPLAUSIBLY LARGE RISK ESTIMATES

Ignoring the evidence indicating a threshold exists in the mid-50 ppb range naturally leads to pronounced overstatement of the absolute risk level. One needs to be aware that Jerrett *et al.* only considers *relative* risks among cities with average ozone ranging from 33 ppb to 104 ppb ozone levels. The risk calculations in the HREA, however, convert the estimated *relative* risk slopes into assumptions about *absolute* risk, by assuming that relative risk slope estimated across the range 33 to 104 ppb can also inform us about the relative risk between 0 and 33 ppb. When this assumption is made, the HREA risk calculation implies that there is quite substantial residual risk even for the city at 33 ppb. The green line in Figure 6 below shows the residual risks that EPA's current no-threshold core risk calculation assumes over the range 30 ppb and

up, superimposed on the residual risks assessed in the original study. It shows that the residual risk for the city at 33 ppb *relative to 0 ppb* is 14% (i.e., 0.14 on the y-axis) -- even though the study itself can only tell us that that city had zero risk *relative to cities with ozone higher than 33 ppb*.

Figure 6: Residual Risks Implied by Risk Analysis Compared to Residual Risks Observed in Epidemiological Study



It is the risk analysis's assumed risk of 14% from exposures between 0 and 33 ppb that causes the no-threshold results to implausibly conclude that 18.5% of all respiratory mortality was attributable to 2006-2008 ozone levels in the U.S.¹⁵ Given that there appears to be no residual risk even within the Jerrett data between 33 ppb and the high-50 ppb levels, it is especially implausible to assume that there is a positive slope from 33 ppb down to 0 ppb similar to the slope that is detected from 56 ppb to 104 ppb. To argue that this assumption is warranted by the borderline statistical significance of the 56-ppb threshold model is bad practice on the part of the risk analyst. The huge degree of sensitivity of long-term risk estimates to epidemiological models that are statistically indistinguishable is the result that *should* be emphasized as the HREA, if any long-term mortality risk estimate is to be reported. These sensitivity analyses, however, can also be used to argue that long-term mortality risk estimates are not robust enough to merit inclusion in the ozone HREA at all.

This problem arises from the fundamental difference between what an epidemiological study finds and what a risk analysis then assumes. The former is only informative about relative risks

¹⁵ Second Draft HREA, p. 8-8. The 18.5% is based on the estimated 45,000 premature deaths shown in HREA Table 8-1.

within the range of the data it uses; the latter attempts to convert those relative risks into absolute risk estimates. When the risk analysis assumes that a positive relative risk slope exists down to zero yet the epidemiological data themselves do not indicate a positive slope starts until cities exceed about 53 to 57 ppb, the size of the potential error associated with the assignment of absolute risk to exposures below the lowest measured level in the study becomes very large – particularly when the lowest measured level is far above 0 ppb. Figure 6 shows how implied risk at 33 ppb using EPA’s 2-P, no-threshold assumption is about 14% for the city at 33 ppb. It shows that the 1-P, no threshold risk assumption estimates a similarly large absolute risk that the epidemiological evidence does not support (or refute). Figure 6 also shows that if one uses a threshold model (the 56 ppb threshold case being graphed), the residual risks implied by the risk analysis are more in line with the residual risks that are observed in the epidemiological study. Thus, the 56 ppb threshold model also produces a more plausible estimate that 0.8% of respiratory mortality is attributable to 2006-2008 ozone levels rather 18.5%.

These comparisons of the absolute risk estimates from the risk analysis to the more limited relative risk inferences of an epidemiological study provide additional indication that a no-threshold model should not be used in the risk analysis.

CONCLUSIONS

The results and analyses I have presented above make the case for the following:

- CASAC should review third drafts of the HREA and PAD that contain the results of its long-term mortality threshold sensitivity analyses, because our results presented here indicate that EPA’s April 28, 2014 memo’s conclusion that revised risks will continue to decline all the way down to 60 ppb should not be supported by the revised HREA.
- EPA’s analysis of long-term respiratory mortality risks should emphasize uncertainty in estimates across a narrow range of assumed thresholds, from 53 ppb to 57 ppb, and be centered on the best-fit of 56 ppb.
- The no-threshold model should be discarded as implausible, involving assumptions in the risk analysis that cannot be supported by the original epidemiological data.