COMMENTS OF THE UTILITY AIR REGULATORY GROUP ON THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE; PROPOSED RULE 79 Fed. Reg. 75234 (Dec. 17, 2014)

Docket EPA-HQ-OAR-2008-0699

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EXECUTIVE SUMMARY

On December 17, 2014, the U.S. Environmental Protection Agency ("EPA" or "the Agency") published a proposed rule to revise the National Ambient Air Quality Standards ("NAAQS" or "Standards") for ozone ("O_3") at 79 Fed. Reg. 75234 ("Proposed Rule"). EPA seeks comment on its plans for a further incremental reduction in the level of the O_3 primary and secondary NAAQS to within the range of 0.070 parts per million ("ppm") to 0.065 ppm. EPA is also taking comment on retaining the existing 0.075 ppm Standards that were set in 2008. Further, EPA has requested comment on reducing the primary Standard to as low as 0.060 ppm. Similarly, EPA has requested comment on an alternative secondary Standard taking a W126 form and set at a level within the range of 13 to 17 ppm-hrs. EPA has also requested comment on adopting such a secondary Standard with a level within the range extending below 13 ppm-hrs down to 7 ppm-hrs.

These are the comments of the Utility Air Regulatory Group ("UARG") on the Proposed Rule. UARG is a voluntary group of electric generating companies and national trade associations. UARG's purpose is to participate on behalf of its members in Clean Air Act ("CAA" or "the Act"), 42 U.S.C. §§ 7401-7671q, proceedings that affect the interests of electric generators. UARG does not support EPA's proposed revisions to the O_3 NAAQS or the related regulatory changes in the Proposed Rule. As a preliminary matter, the Proposed Rule is flawed because:

- EPA fails to explain how it determined what level of protection is requisite to protect public health with an adequate margin of safety, despite acknowledging that the NAAQS are not zero-risk Standards.

- EPA does not properly consider the importance of background O_3 concentrations (concentrations that are due to emissions from foreign or non-anthropogenic U.S. sources).

    - EPA recognizes that the Act does not require the Agency to set NAAQS at background levels and that it "may consider proximity to background levels as a factor in the decision whether and how to revise the NAAQS when considering levels within the range of reasonable values . . . ." 79 Fed Reg. at 75242.

    - EPA does not actually consider background O_3 in its proposal to modify the NAAQS, however. This omission is particularly concerning because current background O_3 levels are close to, or even exceed, the present NAAQS, and background levels are projected to increase.

UARG recommends that the Administrator retain the current primary Standard because the scientific evidence does not demonstrate that a more stringent Standard is necessary to protect public health with an adequate margin of safety. Specifically, UARG emphasizes that:

- The Administrator places the most weight on controlled human exposure studies when determining whether the current primary NAAQS provides sensitive populations with the requisite protection against adverse effects, and those studies do not support revision of the current primary Standard.

    - The studies EPA relies on do not show that the current Standard is inadequate. None of them found a statistically significant group mean forced expiratory volume in 1 second ("FEV_1") decrement $\geq$ 10%, which is the benchmark EPA focuses on for sensitive groups such as asthmatics.

    - EPA's focus on responses from a few individuals, rather than the group mean, is scientifically inappropriate and inconsistent with the CAA. The studies EPA cites were not designed to have individuals represent portions of any larger group, and the Administrator provides no explanation or justification for why these individuals can be viewed as representative of a subpopulation. Looking to individual results transforms the CAA's concern with *public* health to a focus on effects in a handful of individuals. Impacts on a small number of people do not implicate the health of an entire subpopulation, especially when these FEV_1 decrements are small, temporary, and reversible.

    - EPA's description of "adverse health effects" should be revised to remedy the substantial confusion it creates over what EPA considers to be an adverse health effect.

- EPA appropriately places less weight on the epidemiological studies but still over-emphasizes their value in determining the adequacy of the current Standard.

    - The epidemiologic evidence EPA relies on has significant limitations and is highly uncertain, and thus EPA's analysis would be significantly improved by

using Integrated Uncertainty Analysis ("IUA"), as recommended by the National Academy of Sciences ("NAS"). Because some level of risk above 0 is acceptable and there are multiple important uncertainties with the epidemiologic evidence, EPA needs a clear framework for determining both the level of effects that is sufficient to imperil public health and how certain the evidence of those effects should be. IUA presents an improved method for dealing with uncertainty and improving the quality of public comments EPA receives.

- The majority of these studies were conducted in areas that did not attain the current O_3 NAAQS, so they are of limited value in assessing whether associations between O_3 and health endpoints remain after the Standard is attained.

- The studies that EPA focuses on have important limitations, as Gradient points out in its comments, including failing to control for many potential confounders.

- Questions remain about whether observed associations with O_3 are confounded by such factors as errors in exposure estimates, temperature, or other pollutants. Unexplained heterogeneity in these studies, where different cities and geographic regions of the U.S. have different results, calls into question their value and obscures the possibility of a threshold for effects from short-term or long-term O_3 exposure.

- The risk and exposure evidence does not support revising the current Standard because it greatly overestimates risk. As the re-analysis by Smith & Glasgow (2015) shows, EPA's morbidity and mortality estimates from short-term O_3 exposures are highly sensitive to the possibility of a threshold. A threshold for health effects is medically plausible, and is in fact the best fit model for mortality from long-term O_3 exposure. Therefore EPA should reconsider its risk estimates, which if re-analyzed properly and incorporated into an IUA would show that the current Standard protects public health with an adequate margin of safety.

EPA has ample justification to support a decision to retain the current primary Standard and can easily explain a divergence from the Clean Air Scientific Advisory Committee's ("CASAC" or "Committee") advice to revise the current Standard. CASAC's advice was based on policy choices that are the domain of EPA, not CASAC, and CASAC was not properly informed about the relevance of background O_3 in determining whether to revise the NAAQS. Further, there are significant uncertainties in the scientific evidence that support retaining the current Standard.

EPA understates the costs of and overstates the quantifiable benefits from a more stringent NAAQS. The cost of a NAAQS revision even at the top of the range EPA has proposed would, by the Agency's own estimate, be more than $3.9 billion in the only year that EPA evaluated. The costs in that year are likely to be even greater than EPA has predicted and will, in any event, continue to accrue. Moreover, in light of the science discussed above, any health benefits from a revised O_3 NAAQS would be highly uncertain. Accordingly, the costs of a revised Standard would likely exceed any quantifiable O_3-related benefits.

There is no need for EPA to revise the Air Quality Index ("AQI") such that it would suggest that air quality has degraded when it has, in fact, improved. Retention of the current AQI would allow continued provision of uniform information on air quality. Furthermore, it would advise the public if O_3 levels were to rise substantially above the level that the Administrator judged protective of the health of even sensitive population groups, allowing an adequate margin of safety.

The available scientific evidence also does not support revising the existing secondary NAAQS to a level within the range of 0.065 and 0.070 ppm nor does it support adoption of a secondary Standard in a W126 form.

- EPA's proposal to revise the secondary NAAQS is driven by the welfare effect of relative biomass loss in trees. The science addressing this effect is, however, severely limited.
    - EPA has based its proposal on studies addressing only 11 tree species, approximately 0.8% of American tree species. The Agency cannot assume these tree species are representative.
    - EPA relies on exposure-response ("E-R") functions derived from effects observed in tree seedlings. Seedling effects do not predict effects in mature trees.
    - EPA rightly concludes that a 2% biomass loss benchmark for adversity is unreliable and that the risk estimates and CASAC evaluations relying on that benchmark cannot form a basis for revising the current secondary NAAQS.

- The remaining welfare effects EPA describes do not provide adequate bases for revising the secondary NAAQS, as the Proposed Rule appears to acknowledge. It is inappropriate to attempt to address crop yield loss through a secondary NAAQS given active management of crops and the competing market interests that could be affected by regulation. Visible foliar injury, on the other hand, cannot be reliably evaluated for adversity given the lack of available information.

- EPA has provided ample support for its proposal to retain the current form of the secondary Standard.

    - Evidence in the record demonstrates that the current secondary Standard will provide protection within the range of 13 to 17 ppm-hrs, the range EPA proposes to determine is "requisite to protect the public welfare." *Id*. at 75336. Accordingly, EPA should not adopt a Standard taking a W126 form.

    - EPA has also adequately explained its decisions to deviate from CASAC's advice with respect to adopting a Standard taking a W126 form and CASAC's technical conclusions on which that advice was based. EPA has, for instance, demonstrated that the 2% biomass loss benchmark that CASAC relied on is unreliable and does not have a scientific basis. EPA has also adequately explained its decision to proposed a different range of protective W126 levels than CASAC and to retain the form of the current NAAQS based on scientific information not previously presented to CASAC and because those matters are ultimately policy choices more appropriately made by EPA.

Not only would revision of the NAAQS be unwarranted and inappropriate, the Proposed Rule does not adequately address how such a NAAQS could be implemented. For example:

- The Proposed Rule indicates that EPA plans to propose a new State Implementation Plan ("SIP") Requirements Rule no later than the time it finalizes designations. EPA has had trouble meeting this schedule with respect to past NAAQS revisions, however. For example, EPA had not promulgated a rule concerning SIP requirements when it promulgated designations for the 2008 O_3 NAAQS, and the Agency has yet to publish in the *Federal Register* proposed regulations to govern SIPs for the 2012 fine particulate matter ("$PM_{2.5}$") NAAQS even though it finalized designations for that Standard in January 2015.

- The grandfathering program that EPA proposes for new source permitting would apply only to a very limited number of applications for permits to construct or modify sources.

- The program that EPA describes for other sources seeking such permits in the period between NAAQS promulgation and designations is not adequately developed, likely leading to significant permitting delays.

- EPA has not yet explained its plans for designating an air quality model for O_3 permitting, although it has granted a rulemaking petition to do so.
- EPA has not explained how the offset program that it discusses would work, although the requirement to obtain offsets would apply to some new permit applicants upon promulgation of a revised NAAQS.

- None of the three programs that EPA cites as providing regulatory relief when high O_3 levels occur due to background has provided reliable relief in the past, calling into question their ability to do so with a Standard that is even closer to background O_3 levels.

In short, the scientific record does not justify revision of the NAAQS to a level within the range that EPA has proposed, a Standard that would be near, or even at, background in some places. Furthermore, EPA is unprepared to implement any such NAAQS revisions. Under these circumstances, EPA should reaffirm the existing Standards and continue to implement them. It should defer any further consideration of more stringent Standards until the next review.

COMMENTS OF THE UTILITY AIR REGULATORY GROUP
ON THE
U.S. ENVIRONMENTAL PROTECTION AGENCY'S
PROPOSED RULE ON THE OZONE NATIONAL AIR QUALITY STANDARDS
79 Fed. Reg. 75234 (Dec. 17, 2014)

Docket ID No. EPA-HQ-OAR-2008-0699

March 17, 2015

The current primary and secondary National Ambient Air Quality Standards ("NAAQS" or "Standards") for ozone ("O_3") are set at a level of 0.075 parts per million ("ppm") and have the averaging time and form of the three-year average fourth highest daily maximum eight-hour concentration of O_3. 40 C.F.R. § 50.15. The U.S. Environmental Protection Agency ("EPA" or "Agency") is currently reviewing those Standards. On December 17, 2014, EPA published a proposal to revise them. 79 Fed. Reg. 75234 (Dec. 17, 2014) ("Proposed Rule"). EPA proposed

> to revise the primary standard to a level within the range of 0.065 to 0.070 parts per million (ppm), and to revise the secondary standard to within the range of 0.065 to 0.070 ppm, which air quality analyses indicate would provide air quality, in terms of 3-year average W126 index values, at or below a range of 13-17 ppm-hours.

Id. at 75234. EPA also proposed changes to the Air Quality Index ("AQI"), *id*. at 75310-11, and the Prevention of Significant Deterioration ("PSD") program for O_3. *Id*. at 75375-80. In addition, the Agency discussed other aspects of its plans for implementation of a revised NAAQS. *Id*. at 75369-75.

EPA has requested public comment on "the Administrator's proposed decision to revise the current primary O_3 standard and the option of retaining that standard," *id*. at 75236, as well as soliciting comments "on alternative standard levels below 65 ppb, and as low as 60 ppb," *id*. at 75310. The Agency also solicits comment on the Administrator's proposal "to revise the level of

the current secondary standard to within the range of 0.065 to 0.070 ppm," on "the alternative approach of revising the secondary standard to a W126-based form, averaged over three years, with a level within the range of 13 ppm-hrs to 17 ppm-hrs," or "below 13 ppm-hrs down to 7 ppm-hrs," and on "retaining the current secondary standard without revision . . . ." *Id*. at 75237. Finally, the Agency solicits comment on various matters related to implementation of a revised NAAQS. *See id*. at 75369-74.

These are the comments of the Utility Air Regulatory Group ("UARG") on the Proposed Rule. UARG is a voluntary group of electric generating companies and national trade associations. The vast majority of electric energy in the United States is generated by individual members of UARG or by other members of UARG's trade association members. UARG's purpose is to participate on behalf of its members in Clean Air Act ("CAA" or "Act"), 42 U.S.C. §§ 7401-7671q, proceedings, that affect the interests of electric generators. Sources owned and operated by members of UARG are among those that that must bear the burden of implementing the O_3 NAAQS, and consequently UARG has long participated in CAA proceedings related to the review and implementation of those Standards. UARG has submitted comments on drafts of the critical documents in this review cycle: the Integrated Science Assessment ("ISA")[1], the Health Risk and Exposure Assessment ("HREA"),[2] the Welfare Risk and Exposure Assessment ("WREA"),[3] and the Policy Assessment ("PA ").[4] UARG also participated in the public

[1] EPA, EPA/600/R-10/076F, Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Feb. 2013), Docket ID No. ID No. EPA-HQ-OAR-2008-0699-0405.

[2] EPA, EPA-452/R-14-004a, Health Risk and Exposure Assessment for Ozone, Final Report (Aug. 2014), Docket ID No. EPA-HQ-OAR-2008-0699-0233.

[3] EPA, EPA-452/R-14-005a, Welfare Risk and Exposure Assessment for Ozone, Final (Aug. 2014), Docket ID No. EPA-HQ-OAR-2008-0699-0234.

[4] EPA, EPA-452/R-14-006, Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (Aug. 2014), Docket ID No. EPA-HQ-OAR-2008-0699-0404.

meetings and provided comments to the Clean Air Scientific Advisory Committee ("CASAC" or "Committee") in its review of drafts of the ISA, HREA, WREA, and PA.

For the reasons discussed below, UARG does not support EPA's proposed revisions to the O_3 NAAQS or the related regulatory changes that EPA is proposing. Instead, UARG recommends that EPA and the states focus on implementation of the current O_3 NAAQS. Furthermore, EPA needs to develop appropriate and effective programs and tools to implement any revised NAAQS before revision could be deemed appropriate.

I. Background

A. The Process for Setting and Review of NAAQS

The CAA requirements for NAAQS are contained in sections 108 and 109.[5] Section 109(b) directs EPA's Administrator to promulgate NAAQS to limit the allowable level of certain pollutants in the ambient air. O_3 is one such pollutant. The CAA requires that primary NAAQS to be set at the level requisite to protect public health, "allowing an adequate margin of safety." CAA § 109(b)(1). Secondary NAAQS must be set at the level that protects public welfare from "any known or anticipated adverse effects . . . ." *Id*. § 109(b)(2). These Standards are based on air quality criteria that are to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [the regulated] pollutant in the ambient air, in varying quantities." *Id*. § 108(a)(2).[6] These air quality criteria and the NAAQS themselves must be reviewed at least every five years and revised "as may be appropriate in accordance with" §§ 108 and 109(b) of the Act. *Id*. § 109(d)(1).

[5] 42 U.S.C. §§ 7408 & 7409. Citations hereinafter are given only to the Act.

[6] EPA staff also generally prepares an ISA, WREA, HREA, and PA as part of the NAAQS review process.

In setting and reviewing NAAQS, EPA's Administrator receives advice from an independent scientific review committee, CASAC. *Id*. § 109(d)(2)(A). CASAC reviews EPA's air quality criteria and NAAQS and recommends appropriate revisions to them. *Id.* § 109(d)(2)(B). The Committee also:

> (i) advise[s] the [EPA] Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe[s] the research efforts necessary to provide the required information, (iii) advise[s] the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise[s] the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

Id. § 109(d)(2)(C).

Although EPA's Administrator alone is responsible for establishing NAAQS,[7] she must explain the reasons for her actions, including why her actions "differ[] in any important respect from" CASAC's recommendations. *Id.* § 307(d)(3), (6)(A). CASAC's scientific analysis is entitled to greater deference, however, than is its policy judgment regarding the appropriate NAAQS. *Mississippi v. EPA*, 744 F.3d 1334, 1355 (D.C. Cir. 2013).

As EPA recognized in the Proposed Rule, the United States Supreme Court has held that primary NAAQS must be set "at the level that is 'requisite' – that is, not lower or higher than is necessary – to protect the public health with an adequate margin of safety . . . ." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 475-76 (2001).[8] These Standards need not be set at background levels or eliminate all risk. *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1155 n.51 (D.C. Cir. 1980). Although the selection of any particular approach for providing an adequate margin of

[7] *See Id*. § 301(a)(1) (noting that the Administrator may not delegate responsibility for rulemaking).

[8] By analogy, secondary NAAQS must be at the level neither higher nor lower than necessary to protect public welfare from known or anticipated adverse effects.

safety "is a policy choice of the type that Congress specifically left to the Administrator's judgment," *id*. at 1162, the Administrator's discretion as to the approach for providing an adequate margin of safety does not vitiate the requirement that a NAAQS be no more stringent than necessary. As the Supreme Court has recognized, this requirement is what provides an intelligible principle that prevents the NAAQS-setting provision of the Act from being an unconstitutional delegation of legislative authority. *Whitman*, 531 U.S. at 473-74.

In setting NAAQS, the Administrator can consider proximity to background O_3 levels – that is levels of O_3 in ambient air that result from sources not controllable through domestic programs under the Act.[9] In the Proposed Rule, EPA acknowledges that closeness to background O_3 can be considered in a NAAQS review, stating: "The EPA may consider proximity to background levels as a factor in the decision whether and how to revise the NAAQS when considering levels within the range of reasonable values supported by the air quality criteria and judgments of the Administrator." *Id*. at 75242-43 (citing *Am. Trucking Ass'ns, Inc. v. EPA*, 283 F.3d 355, 379 (D.C. Cir., 2002).[10]

[9] EPA characterizes background O_3 as O_3 that "may not be suited to domestic control measures" and is due to "a combination of non-local sources like international transport, stratospheric O_3, and O_3 originating from wildfire emissions." 79 Fed. Reg. at 75242.

[10] EPA also asserts that neither technological feasibility nor attainability are relevant considerations when setting NAAQS. *Id*. at 75238 (citing *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981)). In *Costle*, the court rejected a claim by the city of Houston that an earlier O_3 NAAQS was arbitrary and capricious because "natural factors" rendered that Standard unattainable in that city, opining that EPA "need not tailer national regulations to fit *each* region of locale." 665 F.2d at 1185 (emphasis added) (citation omitted). The *Costle* case, which pre-dates the *American Trucking* case cited above by twenty years, does not, however, address the situation in which – as here – a potential standard would be unattainable in much of the country even if there were no U.S. anthropogenic emissions of the pollutants and its precursors. Indeed, although the Supreme Court has stated that Congress anticipated that NAAQS might be "technology-forcing," *Whitman*, 531 U.S. at 491-92, it has not indicated that NAAQS may be set at levels that are unattainable due to background O_3. Unattainability due to background O_3 levels is not a situation that could be addressed by new technology. Thus, existing case law does not preclude EPA's consideration of background O_3 in revising a NAAQS when background O_3 would render compliance with a revised NAAQS impossible.

B. NAAQS Implementation

Although EPA establishes NAAQS, each state has primary responsibility for ensuring that air quality within its borders meets them, CAA § 107(a)**,** with oversight from EPA. The Act mandates timelines and implementation measures for states and EPA. Some aspects of NAAQS implementation begin as soon as a new or revised standard becomes effective. Others occur by statutory deadlines triggered by the promulgation of new or revised NAAQS. Within a year after NAAQS promulgation or revision, each state must provide EPA with designations of areas within the state's boundaries that describe each area's status as attainment (meets NAAQS), nonattainment (exceeds NAAQS or contributes to air quality in a nearby area that exceeds NAAQS), or unclassifiable (lacking adequate information to make a designation). *Id*. § 107(d)(1)(A). EPA may modify these designations after providing the state with an opportunity to comment. *Id*. § 107(d)(1)(B)(ii). EPA promulgates designations no later than two years after promulgation of a NAAQS, but may take an additional year. *Id*. § 107(d)(1)(B)(i). If a state fails to submit designations, EPA nevertheless makes the designations. *Id*. § 107(d)(1)(B)(ii). It is important for the designations to be correct because designating an area as nonattainment has substantial consequences for new and existing sources within that area. When an area is designated nonattainment for O_3, it is given a classification as marginal, moderate, serious, severe or extreme based on how much the NAAQS is being exceeded. *Id*. § 181(a)(1) Table 1. The classification to which an area determines the deadline for it to be brought into compliance with the NAAQS. These deadlines range from three to twenty years after an area is designated as nonattainment. *Id*.

Revision of a NAAQS also triggers requirements for each state to prepare, adopt, and submit to EPA an infrastructure State Implementation Plan ("SIP") for the entire state. *Id*. § 110(a)(1). This SIP, which must be submitted within three years after the promulgation of a

NAAQS (or any revision thereof), must include ambient air quality monitoring and data systems, programs for enforcement of control measures, and adequate authority and resources to implement the plan. *Id.*; *see also Infrastructure SIP Requirements* , EPA, http://www.epa.gov/airquality/urbanair/sipstatus/infrastructure.html (last visited Mar. 13, 2015) ("Element Reports"). States with nonattainment areas must also submit a series of specific additional SIP elements for those areas over a period of six months to four years that are intended to ensure that the NAAQS is attained in each area by the compliance deadline associated with its classification. CAA § 182. The specific elements required for a nonattainment area depend on its classification. States' submissions are reviewed and must be approved by EPA. *Id*. § 110(k). Should a state fail to submit a required SIP element or to modify a SIP submission as required by EPA, EPA must impose a Federal Implementation Plan ("FIP") for the area and may impose specified sanctions. *Id*. § 110(c)(1), (m).

The Act also contains a PSD program to ensure continued attainment in areas that meet a NAAQS.[11] This program, which may be run by a state or by EPA, requires that construction or modification of a "major" source (a source with emissions greater than a specified threshold) in any area that has not been designated "nonattainment" obtain a permit. *Id*. § 165(a). To obtain a PSD permit, the owner or operator of the source must demonstrate inter alia that emissions from the source "will not cause, or contribute to, air pollution in excess of" any NAAQS. *Id*. § 165(a)(3). EPA interprets the Act as requiring applicants to make this demonstration for a new or revised NAAQS as soon as the NAAQS becomes effective. Memorandum from Stephen D. Page, Dir., OAQPS, EPA, to Air Div. Dirs. & Deputies, Regions I-X, EPA, Regarding Applicability of the Federal Prevention of Significant Deterioration Permit Requirements to New

[11] States must also adopt SIP elements to address new sources in nonattainment areas. *See, e.g.*, *id*. §§ 172(c)(5), 173, 182(a)(4).

and Revised National Ambient Air Quality Standards at 3 (Apr. 1, 2010), Docket ID No. EPA-HQ-OAR-2007-0492-0410.

C. O_3 NAAQS Perspective

The first NAAQS for photochemical oxidants, including O_3, were promulgated in 1971. 36 Fed. Reg. 8186, 8187 (Apr. 30, 1971). Those NAAQS were superseded in 1979 by O_3-specific NAAQS of 0.12 ppm with a 1-hour averaging time that were not to be exceeded more than once a year. 44 Fed. Reg. 8202 (Feb. 8, 1979). After reaffirming those Standards in 1993, 58 Fed. Reg. 13008 (Mar. 9, 1993), EPA replaced them in 1997 with NAAQS that limited the fourth-highest daily maximum 8-hour average O_3 concentration, averaged over three years, to 0.08 ppm, 62 Fed. Reg. 38856 (July 18, 1997). The United States Court of Appeals for the District of Columbia Circuit initially remanded the 1997 Standards to EPA, holding that "the construction of the Clean Air Act on which EPA relied in promulgating [them] effects an unconstitutional delegation of legislative power," *Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1033 (D.C. Cir. 1999), *aff'd in part, rev'd in part sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001). The Supreme Court reversed the D.C. Circuit, holding that the requirement that EPA set NAAQS "at the level that is 'requisite' – that is, not lower or higher than is necessary— to protect the public health with an adequate margin of safety," provided the intelligible principle that rendered the NAAQS program constitutional. *Whitman*, 531 U.S. at 475-76. On remand, the D.C. Circuit upheld the 1997 NAAQS as neither arbitrary or capricious. *Am. Trucking Ass'ns*, 283 F.3d at 358.

In 2008, EPA again revised the O_3 NAAQS by lowering the level of both the primary and the secondary 8-hour Standards from 0.08 ppm to 0.075 ppm. 73 Fed. Reg. 16436, 16436 (Mar. 27, 2008). After a significant delay, due to EPA beginning and then abandoning a voluntary proceeding to reconsider those Standards, the D.C. Circuit denied petitions for review of the

primary NAAQS. *Mississippi*, 744 F.3d at 1348. The court found EPA's interpretation of the public health effects evidence to be "reasonabl[e] and not "arbitrary and capricious." *Id*. at 1345, 1353.[12] The court remanded EPA's decision on the secondary NAAQS, however, because EPA had not identified the level of protection that was "requisite to protect the public welfare." *Id.* at 1361-62.

The present review was announced in September 2008, while EPA's administrative reconsideration of the 2008 NAAQS and petitions for judicial review of those Standards were still pending. 73 Fed. Reg. 56581 (Sept. 29, 2008). CASAC reviewed EPA's drafts of the ISA, HREA, WREA, and PA, leading to EPA's December 2014 Proposed Rule that is the subject of these comments.

II. EPA's Proposed Rule Fails to Explain What Level of Protection is Requisite to Protect Public Health

The most fundamental problem with the Proposed Rule is that it fails to explain how EPA determined what level of protection is requisite to protect public health with an adequate margin of safety. EPA has stated it believes "that a population-level threshold has not been identified below which it can be concluded with confidence that O_3-attributable effects do not occur ([ISA § 2.5.4.4])." 79 Fed. Reg. at 75244. In the PA, EPA used the "general approach" of "characterizing confidence in the extent to which O_3-attributable effects occur, and the extent to

[12] The court did not, as EPA implies, find that EPA had "properly interpreted" the clinical or epidemiological evidence. 79 Fed. Reg. at 75240. In fact, the court explained, "Reasonable people might disagree with EPA's interpretations of the scientific evidence, but any such disagreements must come from those who are qualified to evaluate the science, not us. We are satisfied that *EPA's interpretations are permissible*, and that is enough." *Mississippi,* 744 F.3d at 1345 (emphasis added). Nor did the D.C. Circuit "specifically endorse[] the weight of evidence approach utilized by the EPA in its deliberations." 79 Fed. Reg. at 75240 (citing *Mississippi*, 744 F.3d at 1344). Instead, the D.C. Circuit merely expressed approval of the basic idea of a "weight of the evidence" approach because "one type of study might be useful for interpreting ambivalent results from another type," and then concluded that it would "not second-guess EPA's interpretations of, or the conclusions it drew from, this evidence." 744 F.3d at 1344-45. This is far from a "specifically endors[ing]" EPA's particular approach to a weight of the evidence analysis.

which such effects are adverse, over the ranges of O_3 exposure concentrations evaluated in controlled human exposure studies and over the distributions of ambient O_3 concentrations in locations where epidemiologic studies have been conducted." *Id*. Yet this approach fails to answer the critical issue UARG raises here: what *portion* of a subpopulation must experience O_3-related health effects in order to constitute a *public health threat*, as compared to a risk of harm to only a few individuals?

This question is of particular significance because, as EPA notes in the Proposed Rule, the Act's legislative history indicates that Congress was focused on protecting *subpopulations*, not *individuals*. The Proposed Rule states:

> The legislative history of section 109 indicates that a primary standard is to be set at "the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population," and that, for this purpose, "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group."

Id. at 75237 n.1 (citing S. REP. NO. 91-1196, at 10 (1970)). EPA also recognizes that "the CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentrations, . . . but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety." *Id*. at 75238 (internal citations omitted). As the Supreme Court stated in *Whitman*, CAA § 109 requires EPA "to set air quality standards at the level that is 'requisite' that is, not lower or higher than is necessary—to protect the public health with an adequate margin of safety . . . ." 531 U.S. at 475-76.

Justice Breyer's concurrence in *Whitman*, which was recently cited approvingly by the D.C. Circuit in *Mississippi*,[13] provides additional insight into the CAA's intended purpose.

[13] *Mississippi*, 744 F.3d at 1343 ("Determining what is 'requisite' to protect the 'public health' with an 'adequate' margin of safety may indeed require a contextual assessment of acceptable risk. . . . Such is the nature of policy.") (citing *Whitman*, 531 U.S. at 494-95 (Breyer, J., concurring in part and concurring in the judgment)).

Justice Breyer noted that the CAA "by its express terms, does not compel the elimination of all risk . . . ." *Whitman*, 531 U.S. at 494. Protecting public health with an adequate margin of safety does not require "a world that is free of all risk—an impossible and undesirable objective." 531 U.S. at 494 (citing *Indus. Union Dep't. v. Am. Petroleum Inst.*, 448 U.S. 607, 642 (1980) (plurality opinion) (the word "safe" does not mean "risk-free")). Justice Breyer further emphasized that "the words 'requisite' and 'public health'" should not be "understood independent of context." 531 U.S. at 494. For example, "[w]e consider football equipment 'safe' even if its use entails a level of risk that would make drinking water 'unsafe' for consumption." *Id*. His concurrence counseled that "what counts as 'requisite' to protecting the public health will similarly vary with background circumstances, such as the public's ordinary tolerance of the particular health risk in the particular context at issue." *Id*.

The Proposed Rule fails to explain EPA's view of what is requisite. EPA has not explained how it has drawn the line between protecting "the sensitive group," which the CAA requires, and protecting every sensitive individual, which it does not.[14] EPA has not explained how far above zero-risk it believes is appropriate or how close to background is acceptable. EPA has failed to explain how the current standard is inadequate on this specific basis. These are critical policy decisions that influence how EPA interprets the scientific evidence, yet EPA has failed to articulate its current position in the Proposed Rule.

[14] EPA might contend that the portion of a subpopulation that must be affected to constitute a threat to the health of the group should vary based on factors, such as the severity of the harm. EPA's "general approach" in the PA partially reflects this idea but the Proposed Rule fails to articulate where these lines were actually drawn. The Administrator states that "the exposures and risks [in the HREA] projected to remain upon meeting the current standard can reasonably be judged to be important from a public health perspective," 79 Fed. Reg. at 75291, but there is no explanation given for how this was determined. While it is logical to assert that it takes fewer emergency room visits to imperil the public health than forced expiratory volume in 1 second ("FEV_1") decrements that are accompanied with respiratory symptoms, knowing this generally does not aid the public in making specific comments on the Proposed Rule.

This omission is key because it drastically reduces the value of public participation, including the notice and comment process on this Proposed Rule.[15] Section 307(d)(6)(B) of the CAA requires EPA respond to "significant comments, criticisms, and new data submitted in written or oral presentations during the comment period." However, this requirement is meaningless if the public does not understand what is driving EPA's decision. How can the public know if their comments are likely to be significant if they do not understand how EPA evaluates public health risk? How is the public to provide any useful input if it is unaware of how EPA distinguishes between levels and types of risk? If the CAA does not require the elimination of all risk, and EPA believes there is no population threshold, then any NAAQS the Agency promulgates will leave some amount of risk. For the public to provide significant comments, it must know how EPA plans to draw the line between acceptable and unacceptable risk. The Proposed Rule does not provide this framework, which reduces the utility of the public comment process. UARG recommends that the Administrator retain the present standard as she works to address these issues in the next NAAQS review.

It is arbitrary and capricious for EPA to fail to articulate its policy on these important questions, even considering the discretion that the Administrator has in setting the standard with an adequate margin of safety. Given that EPA believes there is no population threshold for O_3 effects – a belief that UARG believes must be tempered in light of the uncertainty in the science – under EPA's perspective, any revision of the NAAQS to lower its level or otherwise increase

[15] The Plain English Guide to the Clean Air Act - Public Participation, EPA, http://www.epa.gov/airquality/peg_caa/public.html (last updated Oct. 28, 2014) ("Public participation is a very important part of the 1990 Clean Air Act."); National Ambient Quality Standards - Process of Reviewing the National Ambient Air Quality Standards, EPA, http://www.epa.gov/ttn/naaqs/review.html (last updated Mar. 13, 2015) ("**Rulemaking:** Taking into consideration the information in the ISA, REA(s), and PA and the advice of CASAC, EPA develops and publishes a notice of proposed rulemaking that communicates the Administrator's proposed decisions regarding the review of the NAAQS. A public comment period . . . follows publication of the notice of proposed rulemaking. *Taking into account comments received on the proposed rule, EPA issues a final rule*.") (emphasis added)).

its stringency would reduce public health risk and increase protection for some members of a sensitive subpopulation. But merely reducing risk is insufficient under the CAA, which demands that EPA set the level no lower than necessary. In order to know what level is lower than *necessary*, there must be some understanding of what risks are acceptable. Yet EPA's Proposed Rule contains inadequate information for the public to understand what risks EPA has determined are acceptable.

UARG also recommends that EPA remove statements that express understandings of adversity that are contrary to the CAA. For example, part of the American Thoracic Society ("ATS") guidelines that EPA quotes in the Proposed Rule blatantly contradicts the CAA's requirement that the NAAQS be set no higher or lower than necessary. Regarding risks to the public health, the Proposed Rule states that the ATS guidelines consider "[e]xposure to air pollution that *increases the risk of an adverse effect* to the entire population is adverse, even though it may not increase the risk of any individual to an unacceptable level." 79 Fed. Reg. at 75263 (emphasis added). The Proposed Rule expands on this concept by explaining as an example that:

> a population of asthmatics could have a distribution of lung function such that no individual has a level associated with clinically important impairment. Exposure to air pollution could shift the distribution to lower levels that still do not bring any individual to a level that is associated with clinically relevant effects. However, this would be considered to be adverse because individuals within the population would have diminished reserve function, and therefore would be at increased risk to further environmental insult . . . .

Id. (internal citation omitted). This definition of "adverse" lacks any limiting principle, particularly if EPA continues to believe there is no population threshold. The lack of a threshold means that *any reduction* in the NAAQS will reduce the risk of an adverse effect. Under this framework, EPA need not show that there will be any adverse effects to *any* individual, just that the current standard represents a higher risk for the population overall, to justify a NAAQS

revision. EPA could use this framework over and over to justify repeatedly revising the NAAQS downward for any pollutant, like O_3, for which it has identified no threshold for effects. This is contrary to the principle that NAAQS need not be set a "zero risk" level, and should not be included in the Proposed Rule, or any future rule, as part of EPA's analysis of what constitutes adverse health effects.

III. EPA Fails To Take Background Air Quality Into Account Properly In Proposing a Range for Revised NAAQS.

Presence of O_3 in ambient air in the U.S. is attributable to a number of causes. Anthropogenic emissions of O_3 precursors – including volatile organic compounds ("VOC"), nitrogen oxides ("NOx"), methane ("CH_4"), and carbon monoxide ("CO") – in the U.S. contribute to the formation of O_3. *See* 79 Fed. Reg. at 75241. O_3 in ambient air may also result from natural sources such as stratospheric O_3, wildfires and vegetative emissions. *Id*. Furthermore, O_3 in the U.S. can result from transport of O_3 and O_3 precursors from other countries.[16] The term "background" refers to O_3 resulting from such natural and international sources "that may not be suited to domestic control measures". *See id.*[17]

Background O_3 levels are variable, PA at 2-17, but they can be substantial. EPA reports seasonal mean background concentrations of as much as 50 parts per billion ("ppb"). PA at 2-18. Peak 8-hour average background levels – those matching the averaging time for the present

[16] EPA notes that certain modeling studies indicate that climate change "has the potential to cause increases in" concentrations of O_3 in ambient air. 79 Fed. Reg. at 75242/2. Because climate change is recognized to be a global phenomenon, O_3 attributable to climate change should arguably be considered a constituent of background O_3. Indeed, any increase in O_3 levels due to climate change would be a long-term phenomenon, whereas NAAQS and nonattainment of them is a comparatively short-term issue.

[17] In its most recent review of the O_3 NAAQS, EPA focused on "Policy Relevant Background," or "PRB", which it defined as "the [O_3] concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of precursors (e.g., VOC, NOx, and CO) in the U.S., Canada, and Mexico," 73 Fed. Reg. at 16443 n.13, when discussing O_3 background. The alternative focus here on what EPA sometimes calls "U.S. Background" (i.e., O_3 levels that are not attributable to anthropogenic activities in the U.S.) is appropriate.

and proposed O_3 NAAQS – must necessarily be higher. EPA acknowledges that on some days, the proportion of total O_3 due to background is "much larger" than 37%. PA at 2-21. Indeed, as EPA recognizes, "[T]here can be episodic events with substantial background contributions where O_3 concentrations approach or [even] exceed the level of the current NAAQS (*i.e.*, 75 ppb). 79 Fed. Reg. at 75242.

A recent study conducted in Clark County, Nevada confirms that background O_3 levels are already close to the current standard and could cause exceedances of a lower NAAQS level. The study reports:

> The mean surface [maximum daily 8-hour average] ozone at Jean, NV in rural Clark County was 67 ppbv during May and June of 2013, which is only 8 ppbv less than the current 2008 NAAQS and greater than some values that are currently being considered . . . . The number of days in Clark County during the 43-day [Las Vegas Ozone Study ("LVOS")] field campaign would have increased from 3 to 14 if the NAAQS had been 70 ppbv instead of 75 ppbv, and from 3 to 25 if the NAAQS had been 65 ppbv. In other words, *exceedances of the NAAQS generated by high background concentrations and stratospheric intrusions would have occurred on 60% of the days during LVOS*, making these events the rule rather than the exception.

A.O. Langford, *et al*., *An Overview of the 2013 Las Vegas Ozone Study (LVOS): Impact of Stratospheric Intrusions and Long-Range Transport on Surface Air Quality*, ATMOSPHERIC ENV'T 1, 18 (2014) (emphasis added). *See also* Lin Zhang, *et al*., *Improved Estimate of the Policy-Relevant Background Ozone in the United States Using the GEOS-Chem Global Model with 1/2° x 2/3° Horizontal Resolution Over North America*, 45 ATMOSPHERIC ENV'T 6769, 6775 (2011), *available at* http://dx.doi.org/10.1016/j.atmosenv.2011.07.054 (reporting "some occurrences" of background O_3 levels above 60 ppb and noting high background O_3 concentrations in the intermountain West "suggest that special consideration may be needed in

the NAAQS-setting process."). In the face of increasing international emissions, background is expected to be an even greater problem, especially if EPA lowers the primary NAAQS.

Nor are high background concentrations limited to the west or to high elevations. EPA has explained that high background concentrations are also found in northern New York and "other areas bordering Canada and Mexico." ISA at 2-6. In addition, the Agency has recognized, "[T]he influence of background sources on high surface O_3 concentrations is not always confined to high elevation sites," particularly in areas impacted by O_3 formed due to Asian emissions. ISA at 3-39.

Moreover, background O_3 levels appear to be increasing. The Electric Power Research Institute ("EPRI") has analyzed historic background trends and future projections and concluded that "[U.S. background O_3] concentrations have steadily increased from 1970 to 2005 in the western U.S. and will continue to increase from 2005 to 2020." EPRI, Comments on National Ambient Air Quality Standards for Ozone at 4 (Mar. 5, 2015), Docket ID No. EPA-HQ-OAR-2008-0699-1394 (hereinafter "EPRI Comments"). This trend is being driven by increasing emissions from Asia and Mexico. *Id*. at 4, 25, 29; *see also* O.R. Cooper, *et al*., Increasing Springtime Ozone Mixing Ratios in the free Troposphere Over Western North America, 463 NATURE 344, 344 (2010). EPRI concluded in its comments that their results:

> suggest how difficult it would be to meet the lower level of the range of ozone standards proposed in cities in the western and southwest U.S., given that the 4th highest daily maximum 8-hour [U.S. Background O_3] concentrations in those locations are predicted to be close to 65 ppb in 2020.

EPRI Comments at 25.

Given the proximity of background O_3 levels to the present NAAQS, the fact that background is increasing, and the more stringent alternatives that EPA has proposed, the role that background pollutant levels plays in deciding on the appropriate level for a NAAQS is a key

question in this rulemaking. EPA recognizes that the Act does not require the Agency to set NAAQS at background levels, 79 Fed. Reg. at 75238, and acknowledges that it "may consider proximity to background levels as a factor in the decision whether and how to revise the NAAQS when considering levels within the range of reasonable values." *Id*. at 75242. Nevertheless the Agency asserts that it must "set the NAAQS at levels requisite to protect public health and welfare without regard to the source of the pollutant." *Id*. Thus, when explaining her decision to propose to reduce the level of the primary NAAQS from 75 ppb to within the range of 70 ppb to 65 ppb, the Administrator does not acknowledge that background O_3 levels would, at least in some locations, approach or exceed the level of a NAAQS within this range.[18]

In fact, to the extent that the Administrator believes that she may set NAAQS at a level that would be exceeded by background O_3 levels, she has misinterpreted the Act. The Act places the burden on "each state" to develop a plan specifying how the NAAQS "*will* be achieved and maintained . . . ." CAA § 107(a) (emphasis added). States are subject to rigid schedules to submit plans to bring areas into compliance with NAAQS or risk sanctions. *Id*. § 110(m). Failure of an area to attain the O_3 NAAQS can result in punishing fees on stationary sources within that area. *Id*. § 185. Background O_3, whether attributable to natural or international sources, is plainly beyond a state's control. Congress would not have intended to punish states or the sources therein for failing to do the impossible and reduce background O_3. Indeed, in its report on the 1977 Amendments to the Act, the House of Representatives specifically explained

[18] The Administrator only mentions background in passing in her justification for not considering further standards more stringent than 65 ppb. *SeeId*. at 75310. She apparently believes that the Agency has policies in place adequate to provide regulatory relief for situations in which background O_3 would lead to NAAQS exceedances. *Id*. at 75242, 75382-85. The availability of such regulatory relief, even if it were useful, would not excuse the Administrator's failure to take background O_3 levels properly into account in revising the NAAQS, as discussed herein. Moreover, as is discussed subsequently, the cited policies do not provide significant relief for situations in which background O_3 leads to NAAQS exceedances.

that it did not intend NAAQS to be set a background levels. *See* H.R. REP. NO. 95-294, at127 (1977), *reprinted in* 1977 U.S.C.C.A.N. 1077, 1206 ("Some have suggested that since the standards are to protect against all known or anticipated effects and since no safe thresholds can be established, the ambient standards should be set at zero or background levels. Obviously, this no-risk philosophy ignores all economic and social consequences and is impractical.").

IV. Implementation of the 2008 O_3 NAAQS Should Proceed Prior To Any Determination Being Reach that NAAQS Revision Is Appropriate.

The Administrator asserts that attaining the 2008 NAAQS could bring important public health benefits: "As an initial matter, the Administrator concludes that reducing precursor emissions to achieve O_3 concentrations that meet the current primary O_3 standard will provide important improvements in public health protection, compared to recent air quality." 79 Fed. Reg. at 75287. Very little has been added to the body of knowledge available to EPA regarding the health effects of O_3 since that Standard was established, particularly at levels likely to occur once it is attained. Implementation of the current Standard is in the early stages because of the delay caused, at least in part, by EPA's reconsideration of the 2008 standards. Just over a year after EPA issued its final rule revising the NAAQS from 0.08 ppm to 0.075 ppm, EPA announced it was initiating a rulemaking to reconsider the 2008 standards. 79 Fed. Reg. at 75240. Although EPA abandoned the reconsideration effort in the fall of 2011, *id.*, designations and classifications for the 2008 NAAQS were not finalized until mid-2012. 77 Fed. Reg. 34221 (June 11, 2012); 77 Fed. Reg. 30088 (May 21, 2012). It was not until May of 2013 that EPA proposed regulations addressing requirements for SIPs for areas designated nonattainment for that standard, 78 Fed. Reg. 34178 (June 6, 2013), and the final SIP Requirements Rule was not published in the *Federal Register* until almost two years later at 80 Fed. Reg. 12264 (Mar. 6,

2015).[19] Therefore, states have not yet had an opportunity to respond to these new implementation requirements for the 227 counties are currently listed as nonattainment for the 2008 NAAQS.[20]

Although implementation of the 2008 O_3 NAAQS has been delayed, UARG notes that O_3 concentrations in ambient air have decreased substantially since they were first regulated. Thus, health risks from O_3 have decreased. Thus, EPA has stated that emissions of the O_3 precursors NO_x and VOC, decreased by 52% and 53%, respectively, between 1980 and 2013.[21] O_3 air quality has improved in association with these emission decreases, but at a less than 1:1 ratio.[22] On an 8-hour basis – the averaging time for the present O_3 NAAQS – O_3 air quality improved 33% between 1980 and 2013, with 18% of that improvement coming since 2000.

Reductions in O_3 precursor emissions come at a steep price, however. For example, EPA reports the cost per ton of NOx emission reductions for rules issued between 1997 and 2008 to be as much as $11,340 (2010$).[23] Economic theory suggests that future emission reductions, including those to attain the 2008 O_3 NAAQS, will be even more expensive.

Once the 2008 NAAQS has been fully implemented, with its attendant benefits and costs, EPA will be in a better position to evaluate whether further revision of the O_3 NAAQS is appropriate. Revision of the NAAQS now would be premature in light of the scientific

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[19] Those regulations are not effective until April 6, 2015, after the filing deadline for these comments.

[20] *8-Hr Ozone (2008) Nonattainment Area Summary*, EPA, http://www.epa.gov/oaqps001/greenbk/hnsum.html (last updated Jan. 30, 2015).

[21] Air Trends – Air Quality Trends, EPA, http://www.epa.gov/airtrends/aqtrends.html (last updated Oct. 8, 2014).

[22] *See* Charles L. Blanchard & George M. Hidy, Envair, Effects of Past and Projected NO_x Emissions on Ozone in the Continental U.S. at 7 (Mar. 11, 2015), Docket ID No. EPA-HQ-OAR-2008-0699-1561 ("[T]he O_3 concentration decreases were less than 1:1 proportional to the NO_2 declines (i.e., a 1% NO_2 decrease yielded less than a 1% O_3 decline . . . .)

[23] EPA, EPA-452/P-14-006, Regulatory Impact Analysis of the Proposed Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone at 7-14 to 7-15 Table 7-4 (Nov. 2014), Docket ID No. EPA-HQ-OAR-2013-0169-0013 ("RIA").

uncertainties discussed below. Moreover, revision now would likely disrupt planning for implementation of the 2008 Standard, resulting in a delay of the health benefits that the Administrator anticipates from attaining it.

V. The Scientific Evidence Does Not Indicate that a More Stringent Standard is Requisite to Protect Public Health

A. The Human Exposure Studies Do Not Support a More Stringent Standard

A key flaw in the Proposed Rule is its interpretation of evidence from controlled human exposure studies. This flaw is critical because the Proposed Rule, and supporting documents, place a heavy emphasis on these studies. *See, e.g.*, 79 Fed. Reg. at 75244 ("Controlled human exposure studies provide data with the highest level of confidence since they provide human effects data under closely monitored conditions and can provide exposure response [("E-R")] relationships."); *id.* ("[Controlled human exposure] studies are particularly useful in defining the specific conditions under which pollutant exposures can result in health impacts, including the exposure concentrations, durations, and ventilation rates under which effects can occur."). The Administrator's determination that the current standard is not adequately protective of public health is based in large part on the human exposure studies. *Id*. at 75288 ("[T]he Administrator agrees . . . that controlled human exposure studies provide the most certain evidence indicating the occurrence of health effects in humans following exposures to specific O_3 concentrations. . . . Therefore, she places the most weight on information from these controlled human exposure studies."). The Proposed Rule and supporting documents have failed to weigh these studies correctly and have improperly interpreted their results. For the reasons detailed below, UARG requests the Administrator reconsider her evaluation of the human exposure evidence.

1. The Weight of the Human Exposure Evidence Does Not Demonstrate That the Current Standard Is Inadequate to Protect Public Health

Contrary to the Proposed Rule's conclusion, the weight of the human exposure evidence does not indicate that the current standard fails to protect public health with an adequate margin of safety. To understand how the Proposed Rule misinterprets these studies, it is helpful to review their basic structure. All the controlled human exposure studies upon which the Proposed Rule relies, except for one (Kim, *et al.* (2011)[24]) used the protocol from Folinsbee, *et al.* (1988)[25]. In the Folinsbee, *et al.* (1988) protocol, subjects are exposed to either filtered air or one of five different concentrations of O_3 over the course of 6.6 hours. This time included "six 50-minute exercise bouts at a mean equivalent ventilation rate of 20 L/minute/m^2 body surface area (BSA)" and a 35-minute lunch break "taken at rest in the chamber at the Hour 3 O_3 concentration."[26] "[T]his level of exertion was intended to simulate work performed during a day of heavy to severe manual labor in outdoor laborers." Schelegle, *et al.* (2009) at 265 (internal citations and quotation marks omitted). These studies focus on FEV_1, the measure of the forced expiratory volume during the first second of a forced expiration. FEV_1 has natural variability and the decrements observed in these studies, even decrements EPA characterizes as moderate, were temporary and reversible. For example, Gradient's comments note that for the subjects exposed to 0.072 ppm in Schelegle, *et al.* (2009), "lung function [was] restored to baseline conditions between one and four hours after ozone exposure ended." Gradient, Comments on the National Ambient Air Quality Standards for Ozone Proposed Rule at 6 (Mar. 16, 2015) (hereinafter "Gradient Comments"). Further, "studies have shown that acute lung

[24] Chong S. Kim, *et al.*, *Lung Function and Inflammatory Responses in Healthy Young Adults Exposed to 0.06 ppm Ozone for 6.6 Hours*, 183 AM. J. RESPIRATORY & CRITICAL CARE MED. 1215 (2011), Docket ID No. EPA-HQ-OAR-2008-0699-0195,

[25] Lawrence J. Folinsbee, *et al*., *Pulmonary Function and Symptom Responses After 6.6–Hour Exposure to 0.12 ppm Ozone with Moderate Exercise*, 38 J. AIR & WASTE MGMT. ASS'N 28 (1988), Docket ID No. EPA-HQ-OAR-2008-0699-0446.

[26] Edward S. Schelegle, *et al.*, 6.6-Hour Inhalation of Ozone Concentrations from 60 to 87 Parts per Billion in Healthy Humans, 180 AM. J. RESPIRATORY & CRITICAL CARE MED. 265, 266 (2009), Docket ID No. EPA-HQ-OAR-2008-0699-0198 (hereafter referred to as "Schelegle, *et al.* (2009)").

function decrements even after higher [O_3] exposures (~0.2 ppm) are not predictive of, or causally associated with, [O_3]-induced inflammation or subsequent lung injury (*e.g.*, Blomberg *et al.*, 1999)." *Id*. at 7. Throughout this protocol, the researchers monitor the subjects' breathing rate, pulmonary function responses, and symptoms. The Folinsbee, *et al.* (1988) protocol has been used in several studies "to examine ozone-induced responses in healthy young adults exposed to ozone concentrations ranging from 40 to 120 ppb." Schelegle, *et al.* (2009) at 265. The studies using the Folinsbee, *et al.* (1988) protocol used either 30 or 31 participants.

Although different in important ways discussed below, the alternate protocol used by Kim *et al*. (2011) is sufficiently similar to Folinsbee, *et al.* (1988) in one crucial aspect: it requires participants to engage in heavy exercise over several hours. It is important to keep this study design in mind, as it impacts the usefulness of applying these results more broadly to the U.S. population or particular subpopulations. Additionally, although Kim *et al*. (2011) used 59 participants, more than the other studies, it still focused on a relatively small group.

The Proposed Rule states that EPA is relying on the ATS guidelines and contains a discussion of these guidelines and CASAC's input on these guidelines. 79 Fed. Reg. at 75263-64. Yet this discussion is confusing because it lists several different possibilities for what constitutes an "adverse effect" and does not decisively state which definition EPA is adopting. For example, EPA notes that under the 2000 ATS guidelines, "transient, reversible loss of lung function in combination with respiratory symptoms should be considered adverse." *Id*. at 75263. But this same section of the Proposed Rule also states that sometimes decrements, by themselves, should be considered adverse. Specifically:

> [F]or children and adults with lung disease, even moderate function (*e.g.,* FEV_1 decrements ≥10% but <20%, lasting up to 24 hours) *or* symptomatic responses (*e.g.,* frequent spontaneous cough, marked discomfort on exercise or with deep breath, wheeze accompanied by shortness of breath, lasting up to 24 hours) would

> likely interfere with normal activity for many individuals, and would likely result in additional and more frequent use of medication . . . .

Id. at 75263-64; *see also id.* at 75264 ("[a]n FEV_1 decrement of ≥10% is a *scientifically relevant surrogate* for adverse health outcomes for people with asthma and lung disease") (alteration in original) (emphasis added) (internal citation and quotation marks omitted). The combination of these statements leaves commenters without clear guidance on what results EPA looks to when evaluating the adversity of O_3 effects.

The language the Administrator uses when explaining her decision on the current standard adds further to the confusion concerning what responses to O_3 the Administrator considers adverse. The Administrator states "[t]he combination of lung function decrements *and* respiratory symptoms reported to occur in healthy adults following exposures to 72 ppb O_3 or higher, while at moderate exertion, meet ATS criteria for an adverse response,"*id*. at 75288 (emphasis added), which shows that she is focused on both decrements *and* respiratory symptoms. In her summary of the health information she believes shows the current standard is not requisite to protect public health, she "specifically notes that . . . controlled human exposure studies provide support for the occurrence of adverse respiratory effects following exposures to O_3 concentrations below the level of the current standard (*i.e.*, as low as 72 ppb)," *id.* at 75291, and that she does not rely on results from exposures at 60 ppb, which did not include findings of respiratory symptoms.[27] Yet she looks to FEV_1 decrements ≥15% and ≥10%, by themselves, as

[27] The Administrator does not state that exposures at 60 ppb are adverse.She does state that concentrations at 60 ppb result in "lung function decrements large enough to be judged an abnormal response by ATS and that could be adverse in individuals with lung disease . . . ." 79 Fed. Reg. at 75288; *see also id*. at 75304-05 ("The Administrator has decreasing confidence that adverse effects will occur following exposures to O_3 concentrations below 72 ppb. . . . [S]he has less confidence that adverse effects will occur following exposures to O_3 concentrations as low as 60 ppb. . . . [S]tatistically significant increases in respiratory symptoms, combined with lung function decrements, have not been reported following exposures to 60 or 63 ppb O_3, though several studies have evaluated the potential for such effects.").

surrogates for adverse health outcomes when evaluating the HREA estimates of O_3-induced lung function decrements. *Id*. at 75290. This creates substantial confusion for commenters because the Administrator has not clearly stated her position on what kinds of effects are adverse. It also raises the possibility of a moving target, where comments focused on the Administrator's best-articulated reasoning (that only decrements accompanied by symptoms are adverse) can be ignored if she chooses to adopt a different concept of adversity for the final rule.

For the purpose of these comments, UARG relies on the Administrator's statements indicating that a 10% FEV_1 decrement, in combination with respiratory symptoms, is adverse. *Seeid*. at 75291 ("[S]he specifically notes that . . . controlled human exposure studies provide support for the occurrence of adverse respiratory effects following exposures to O_3 concentrations below the level of the current standard (*i.e.*, as low as 72 ppb) . . . ."). Therefore, UARG's comments on the health science take the view that EPA considers the combination of FEV_1 decrements >10% and respiratory symptoms as an adverse health effect, but FEV_1 decrements <10% are not adverse, and FEV_1 decrements <20% but >10% unaccompanied by symptoms are not adverse.[28]

Building on this definition of adversity, UARG concludes that the five studies that the Proposed Rule focuses on are insufficient to show that a sensitive *group* will experience a statistically significant adverse effect at an exposure level below the current standard of 75 ppb. The five studies are Adams (2002)[29], Adams (2006)[30], Schelegle *et al.* (2009), Kim, *et al*.

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[28] UARG recommends the Administrator revise her view of adversity. *See* Julie E. Goodman, *et al., Evaluation of Adverse Human Lung Function Effects in Controlled Ozone Exposure Studies,* J. APPLIED TOXICOLOGY, July 2013 (concluding that "only [O_3] exposures of at least 88 ppb should be considered to induce adverse health effects, albeit of low severity.").

[29] William C. Adams, *Comparison of Chamber and Face-Mask 6.6-Hour Exposures to Ozone on Pulmonary Function and Symptoms Responses*, 14 INHALATION TOXICOLOGY 745 (2002), Docket ID No. EPA-HQ-OAR-2008-0699-0209.

(2011), and Brown, *et al.* (2008)[31], a re-analysis of Adams (2006). Of these five studies, three found statistically significant effects at exposure levels below 75 ppb: Schelegle, *et al.* (2009), Kim, *et al*. (2011), and Brown, *et al.* (2008).[32] But even these three did not find statistically significant *group mean responses* for O_3 levels below 75 ppb that meet the EPA's determination of adversity. At 72 ppb, Schelegle, *et al.* (2009) found a statistically significant increase in respiratory symptoms and a group mean FEV_1 decrement of 5.34%,[33] but this falls below the 10% which CASAC stated could be a surrogate for adverse health effects in people with asthma or lung disease, *see* 79 Fed. Reg. at 75250, and which the Administrator appears to consider adverse. At 60 ppb, only Kim, *et al*. (2011) and Brown, *et al.* (2008) determined that their results were statistically significant, and these results also fall far below the 10% marker for adverse health effects that the Administrator noted in the Proposed Rule. As will be detailed in the next section, it is inappropriate to rely the results of specific individuals from these studies, and as such, the group mean decrements are the only relevant measure of whether these effects were adverse. None of these studies have group mean FEV_1 decrements larger than 10%, and thus, none of these studies show that O_3 levels below 75 ppb endanger public health.

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[30] William C. Adams, *Comparison of Chamber 6.6-h Exposures to 0.04-0.08 ppm Ozone via Square-Wave and Triangular Profiles on Pulmonary Responses*, 18 INHALATION TOXICOLOGY 127 (2006).

[31] James S. Brown, *et al.*, *Effects of Exposure to 0.06 ppm Ozone on FEV1 in Humans: A Secondary Analysis of Existing Data*, 116 ENVTL. HEALTH PERSP. 1023 (2008), Docket ID No. EPA-HQ-OAR-2008-0699-0220.

[32] The PA contained the following summary of the chamber study evidence: "Prolonged exposure to an average O3 concentration of 60 ppb results in group mean FEV1 decrements ranging from 1.8% to 3.6% (Adams 2002; Adams, 2006;13 Schelegle et al., 2009;14 Kim et al., 2011). Based on data from multiple studies, the weighted average group mean decrement was 2.7%. In some analyses, these group mean decrements in lung function were statistically significant (Brown et al., 2008; Kim et al., 2011), while in other analyses they were not (Adams, 2006; Schelegle et al., 2009)." PA at 3-12.

[33] *But see* Gradient Comments at 6 ("[A]n independent analysis of the Schelegle *et al.* (2009) individual data showed no correlation between symptoms (expressed as total symptom score, or TSS) and the magnitude of lung function decrements (FEV_1) in these individuals (p-value = 0.2764).").

Not only do these five studies fail to show the current standard is inadequate, they also have limited application to most, if not all, sensitive subpopulations that EPA evaluated in the Proposed Rule. All of these studies required the participants to engage in heavy exercise that is unrepresentative of the typical activity levels of the general population, let alone for the activity levels of the sensitive subpopulations on which EPA primarily focuses. In its Proposed Rule, EPA states "the factors for which the ISA concludes there is adequate evidence of increased risk for experiencing O_3-related effects were related to asthma, lifestage (children and older adults), genetic variability, dietary factors, and working outdoors." 79 Fed. Reg. at 75269. EPA contends that "[t]he controlled human exposure studies reporting these respiratory effects were conducted in healthy adults, while at-risk groups (*e.g.*, children, people with asthma) could experience larger and/or more serious effects." *Id*. at 75288. But this theory is seriously undermined by the study design, which requires moderate exercise over several hours. Asthmatics or people with respiratory problems would not be expected to exercise outside for 6.6 hours at a time. "[T]he exercise level maintained in these and other controlled [O_3] exposure studies is likely more strenuous and of a longer duration (*i.e.*, up to 6.6 hours) than most of the general [U.S.] population, including sensitive subpopulations, experiences, with the exception of some outdoor workers and athletes." Gradient Comments at 8. "The most sensitive populations have conditions that prevent them from exercising for the duration and at the intensity reached in these studies, even in the absence of [O_3]." *Id*.

The inability of sensitive populations such as asthmatics to exercise for the duration or intensity observed in these studies, is critically important because it means they would likely have a *lower* absorbed O_3 dose at the same ambient concentration as healthy people. As Gradient explained in its comments to CASAC:

> While the nominal ambient ozone [O_3] concentration in the Adams (2006) study at issue is 0.06 ppm , the subjects were exercising vigorously (V_e = ~20 L/min/m^2) over 6.6 hours, so the absorbed dose of was substantially higher than it would have been if the subjects had been at rest. Indeed, the absorbed dose can probably be safely said to be much higher than that of sensitive populations exerting even moderate physical effort. Because this is the case, Adams (2006) has a bias toward overestimating the effect on lung function response. Thus, this provides a "margin of safety" for sensitive individuals in the population.

Gradient, Response to CASAC Ozone Review Panel Regarding the Reconsideration of the 2008 NAAQS, at 2 (Feb. 28, 2011) at 2, *available at* http://yosemite.epa.gov/sab/sabproduct.nsf/F9C4D3C5EACEF0CD852578460077DDC0/$File/Goodman_O3_Response_Comments.pdf (hereinafter "Gradient Response"). Thus, the results of these human exposure studies are of limited relevance to individuals with preexisting disease. Given this, EPA's approach results in needless, duplicative levels of conservatism. Looking at any decrements ≥ 10% as a surrogate to protect sensitive populations is unnecessary when members of those populations are unlikely to ever exercise for the lengths of time and at the intensity that the clinical studies examined.

Additionally, there is insufficient evidence for EPA to conclude that it needs to apply a level of conservatism to protect children as a sensitive subgroup. Gradient has analyzed the relevant literature and concluded that "[t]he evidence for increased risks in children is also not consistently supported" and additionally, "evidence from controlled human exposure studies suggesting that children are not as responsive to the respiratory effects of ozone as adults does not support EPA's conclusion that this is a sensitive subpopulation." Gradient Comments at 11.

2. The New Human Exposure Studies Are Scientifically Insufficient to Indicate that the Current Standard Does Not Protect Public Health

A closer analysis of these studies reveals that they do not indicate that the current standard is inadequate. The design of Schelegle, *et al.* (2009) study makes it inappropriate for

EPA to use individual responses instead of the group mean; Kim, *et al*. (2011) is missing critical information and its study design makes comparison to the other studies difficult; and the Brown, *et al.* (2008) re-analysis is inappropriate and insufficient.

In the Proposed Rule, EPA looks not only at the group mean changes in lung function but also at the results of specific individuals in the study. 79 Fed. Reg. at 75249 ("[E]ven when group mean decrements in lung function are small, some individuals could experience decrements that are 'clinically meaningful' (Pellergrino et al., 2005; ATS, 1991) with respect to criteria for spirometric testing, and/or that could be considered adverse with respect to public health policy decisions . . . ."). EPA explains that it looks to the results from individuals, especially FEV_1 decrements >10%, for two reasons: 1) "[a] 10% FEV_1 decrement is accepted by the American Thoracic Society (ATS) as an abnormal response and a reasonable criterion for assessing exercise-induced bronchoconstriction," and 2) "[f]or people with lung disease, the EPA judged that moderate functional decrements (*e.g.,* FEV_1 decrements >10% but <20%, lasting up to 24 hours) would likely interfere with normal activity for many individuals, and would likely result in more frequent use of medication . . . ." *Id*. at 75250 (citing 75 Fed. Reg. 2938, 2973 (Jan. 19, 2010).[34]

It is inappropriate for EPA to use the results of select individual participants from Schelegle, *et al.* (2009) as any evidence of adverse health effects. Schelegle, *et al.* (2009) was designed to investigate the general relationship between O_3 exposure and certain responses (FEV_1 decrements and respiratory symptoms). Schelegle, *et al.* (2009) aimed to study this potential relationship by comparing different groups against each other, namely exposures to

[34] Oddly enough, EPA gives as an added reason for looking to individual results >10% was that "some individuals in the Schelegle et al. (2009) study experienced 5-10% FEV_1 decrements following exposure to filtered air." 79 Fed. Reg. at 75250. The fact that participants experienced 10% decrements after breathing filtered air should caution EPA against using decrements close to 10% as a sure sign of an adverse health effect.

different concentrations of O_3 and exposures to filtered air. The group mean FEV_1 decrements are meant to show whether there is a relationship between O_3 exposure and FEV_1 decrements instead of the results being due to random chance or variables for which that the study did not control. EPA has recognized this is the reason group mean values are reported and relied upon. 79 Fed. Reg. at 75249 ("To the extent studies report statistically significant decrements in mean lung function following O_3 exposures after controlling for other factors, these studies provide greater confidence that measured decrements are due to the O_3 exposure itself, rather than to chance alone."). Yet EPA completely ignores that this study design, combined with the fact that these studies did not control for individual variability, means that the individual results, by themselves, do not provide much relevant information. Without taking repeated measures of individuals to determine their sensitivity to O_3 and control for any random variation, individual results, by themselves, cannot be said to be due to O_3 rather than due to chance or another variable. The results of individuals are only useful when taken together in the group mean.

Similarly, Adams (2006) was designed to test groups to explore the relationship between O_3 exposure and health effects, not to test O_3 impacts on an individual level, and thus for this and other reasons, the re-analysis in Brown, *et al.* (2008) is flawed.[35] As an initial matter, UARG

[35] Gradient specifically noted it was inappropriate for Brown, *et al.*(2008) to use individual results from Adams (2006) when it was designed

> to examine whether ozone affected *groups* of people who were exposed to various concentrations differently, not whether ozone affected any particular *individual*. That it is, it was not designed to account for intra-individual variability, or how ozone affected any individual study subject. . . . Indeed, it is well-established that there is substantial inter-individual variation in FEV_1 measurements that is largely unexplained (McDonnell *et al.*, 1993, 1997), which shows that lung function, as assessed by paired filtered air *versus* test exposures, can vary appreciably due to factors unrelated to ozone. Particularly at low ozone concentrations, this variability must be carefully considered because it can lead to relatively large apparent decrements after ozone exposure that may be completely unrelated to the exposure.

Gradient Response at 1-2 (emphasis added).

disagrees with EPA's description of the discussion of this study in *Mississippi v. EPA*. When discussing EPA's re-analysis of the Adams (2006) data in the Proposed Rule, EPA states that Brown, *et al*. (2008) indicates "a pattern of response following exposures to 60 ppb O3 that was consistent with a dose-response relationship, rather than random variability." 79 Fed. Reg. at 75249 (citing *Mississippi*, 744 F.3d at 1347 as "upholding EPA's interpretation of the Adams studies")) But all the D.C. Circuit said about the Brown, *et al.* (2008) re-analysis of Adams (2006) was that "nothing in the Clean Air Act or the IQA prohibits EPA from independently analyzing the science" and that addressing Mississippi's objections to Brown, *et al.* (2008) would have "require[d] us to weigh in on what is apparently legitimate scientific debate," which was not the court's role in reviewing EPA's action. *Mississippi*, 744 F.3d at 1347. Because the D.C. Circuit viewed the Brown, *et al.* (2008) re-analysis as a subject of "legitimate scientific debate," it did not evaluate the substance of Mississippi's arguments. *Id.* This is not approval of EPA's interpretation; this is deference to the agency's technical judgments. *Id.* at 1346 ("We do not reweigh the evidence or second-guess technical judgments but are limited to determining whether EPA made a rational judgment."). In fact, the entire point of the D.C. Circuit's analysis was that it was *not* evaluating the merits of Mississippi's arguments, and therefore the D.C. Circuit could not have approved of EPA's interpretation.

Further, the D.C. Circuit's description of EPA's re-analysis of Adams (2006) is inaccurate. Brown, *et al.* (2008) did not merely use "a different statistical model," nor did it simply "disagree[] with Adams's interpretation of his data." *Id.* at 1347. Rather, the Brown, *et al.*(2008) re-analysis only achieved statistical significance because it cut out large amounts of data. Instead of comparing results from O_3 exposures throughout the protocol, the Brown, *et*

al.(2008) re-analysis used only the final response information at 6.6-hours, excluding the data taken at earlier points in the study. As Gradient noted in its comments to CASAC,

> this approach is at variance with those of other research groups that have performed prolonged ozone exposures and published their results in the scientific literature prior to the Brown reanalysis, including those by researchers at the University of Rochester (Torres *et al.*, 1997), the University of Toronto (Liu *et al.*, 1999), the University of California, Los Angeles (Gong *et al.*, 1997), and US EPA (Gong *et al.*, 2004).

Gradient Response at 3. The study author himself, William C. Adams, has critiqued EPA's approach.[36]

For similar reasons, Kim, *et al.* (2011) is also of limited value. This study used an unconventional design that reported measurements only before and at the end of the 6.6-hour exposure and compared those results to those in filtered air, thus excluding large amounts of information about how the exposure, over time, impacted lung function. The failure to analyze data from the interim rest periods is particularly confusing given that the study states that "[a]dditional spirometry measurements were performed in the chamber during 10-minute rest periods," Kim, *et al.* (2011) at 1216, which could have yielded useful information. Instead of including these measurements, the decision by Kim, *et al.* (2011) to report and analze only measurements before and after the entire 6.6-hour exposure is a significant drawback of this study. An additional issue with this study is that it does not present easily-accessible information on individual results. Instead, the results for each individual participant can be determined only by viewing the figures, but these figures are difficult to read. This hampers efforts to understand the amount of uncontrolled variation in Kim, *et al.* (2011), such as information on how many individuals experienced *improvements* in FEV_1 and further diminishes the value of Kim, *et al.*

[36] William C. Adams, Comment on EPA Memorandum: The Effects of Ozone on Lung Function at 0.06 ppm in Healthy Adults (Oct. 9, 2007), Docket ID No. EPA-HQ-OAR-2005-0172-5227.

(2011) because it is more difficult to evaluate whether the results are masking variation based on uncontrolled or unknown variables.

3. Effects in Human Exposure Studies Associated with O_3 Exposures Below the Current Standard Should Not Be Considered Adverse

The Proposed Rule's use of results from individuals, rather than the group mean, contradicts the CAA. As previously discussed, EPA has recognized that the congressional intent of CAA § 109 is to protect groups of people, not just the most sensitive individuals in any group. 79 Fed. Reg. at 75237 n.1. These studies were not designed to have individuals represent portions of any larger group, and the Administrator provides no explanation or justification for why these individuals can be viewed as representatives of a subpopulation. Thus looking to individual results contradicts the purpose of the CAA. It transforms the statute from one focused on *public* health – that is, "the health of the public," *Whitman*, 531 U.S. at 466 – to one searching for effects on a handful of individuals. Impacts on a small number of people do not implicate the health of an entire subpopulation, especially when these FEV_1 decrements are small, temporary, and reversible.

Further, EPA is inconsistent as to which individual results it utilizes, demonstrating that it looks to individual results not because it believes it is scientifically appropriate to do so, but because they provide a convenient way to support a standard below 75 ppb. As will be discussed later in these comments, EPA extrapolated the percentage of individual participants who experienced FEV_1 decrements to estimate population-wide effects, which UARG contends is scientifically inappropriate. Interestingly, EPA did not similarly extrapolate the percentage of individual participants who experienced FEV_1 *improvements*. For example, Brown, *et al.* (2008) reported that of 6 of the 30 (20%) of the participants in the Adams (2006) study, that they reanalyzed, showed an improvement in lung function after exposure to 60 ppb O_3, *see* Brown, *et*

al. (2008) at 1024 Table 1, yet EPA's risk analysis for FEV_1 decrements does not include an estimates of improved lung function following O_3 exposure. *See* 79 Fed. Reg. at 75275 Table 2. It could reasonably be argued that these improvements do not represent health benefits from O_3 but rather are the result of random variation or another source of variability for which the study did not adequately control. Yet the exact same argument applies to the individual FEV_1 decrements. The only meaningful results of the study were those showing the group mean decrements, and thus the individual results are not useful in interpreting whether the size of these decrements is due to chance or a third factor for which the study had not adequately controlled.

B. The Epidemiologic Studies Also Do Not Support a More Stringent Standard

1. The Administrator Appropriately Recognized that These Studies Should Receive Less Weight, But Failed To Discount Them Sufficiently

In the Proposed Rule, the Administrator properly acknowledges the general limitations of epidemiologic studies, as well as particular issues with many of the studies evaluated in the supporting documents. As the Proposed Rule notes, "[a]n uncertainty that applies to epidemiologic studies in general is the extent to which reported health effects are caused by exposures to O_3 itself, as opposed to other factors such as co-occurring pollutants or pollutant mixtures." *Id*. at 75282. According to the Proposed Rule, this uncertainty increases as lower concentrations of O_3 are evaluated, such that the Proposed Rule states that "there is increasing uncertainty as to whether the observed associations *remain plausibly related to exposures to ambient O_3*, rather than to the broader mix of air pollutants present in the ambient air." *Id*. at 75282 (emphasis added). Further, the Administrator gives less weight to risk estimates based on epidemiologic evidence because "of key uncertainties, including the heterogeneity in effect estimates between locations, the potential for exposure measurement errors, and uncertainty in the interpretation of the shape of concentration-response functions for O_3 concentrations in the

lower portions of ambient distributions . . . ." *Id*. at 75289 (citing HREA § 9.6). Yet the Administrator erred by continuing to rely on these studies in spite of these admitted limitations. As will be discussed in further detail below, the Administrator should reevaluate the epidemiology evidence, which is insufficient to show that the current standard is inadequate.

In justifying her decision to revise the current primary standard, the Administrator relied on "recent epidemiologic studies [that] provide support, beyond that available in the last review, for associations between short-term O_3 exposures and a wide range of adverse respiratory outcomes (including respiratory-related hospital admissions, emergency department visits, and mortality) and with total mortality." *Id*. However, as UARG has noted throughout this review process, epidemiological studies are observational by nature, not allowing for any control, and thus are inherently uncertain. Thus, the epidemiologic evidence relied on by the Administrator fails to show that the current standard is no longer requisite to protect public health with an adequate margin of safety.

The use of these studies also highlights the significance of EPA's failure to explain how it determines what levels of risk are acceptable. As noted earlier, protecting public health with an adequate margin of safety does not require "a world that is free of all risk – an impossible and undesirable objective." *Whitman*, 531 U.S. at 494 (J. Breyer, concurring) (citing *Indus. Union Dep't.*, 448 U.S. at 642 (the word "safe" does not mean "risk-free")). The epidemiologic evidence EPA relies on has significant limitations and thus is highly uncertain. Therefore, EPA should weigh this uncertainty against the severity of these affects to the health of the public, not merely the health of any given individual, given that the NAAQS are not meant to be zero-risk standards.

This balancing would also be greatly aided by the use of Integrated Uncertainty Analysis ("IUA") recommended by the National Academy of Sciences ("NAS") and specifically discussed in EPRI's Comments. NAS has critiqued the fact that EPA's risk analysis approach relegates sensitivity analyses, which deal with uncertainty, "to an ancillary status and not to the primary analysis," and EPA fails to offer any explicit judgment "as to the relative plausibility of the alternative scenarios considered in these analyses." EPRI Comments at 6 (quoting NAS (2002) at 135). IUA offers a way to address these issues because it incorporates sensitivity analyses into the primary analysis and it combines "many different sources of uncertainty together into a *probability distribution* on a predicted outcome, i.e., placing a distribution of possible values on a given variable." *Id*. at 1. This is a much more useful way of dealing with uncertainty, which not only IUA would improve EPA's decisionmaking, but also would enhance the value of the public comments EPA would receive. EPRI's analysis used the mortality estimates based on long-term exposures as an illustration of the importance of integrating sensitivities into the main analysis, but there is an ample reason to believe that IUA would be important for other kinds of evidence. *Id.* ("It is important to perform an IUA when there are multiple highly sensitive assumptions in an analysis."). For example, work by Anne Smith, Ph.D. and Garrett Glasgow, Ph.D., demonstrates that risk estimates of morbidity and mortality based on short-term exposures are highly sensitive to the presence of a threshold. Anne E. Smith & Garrett Glascow Technical Comments on the Proposed Rule to Revise the Ozone National Ambient Air Quality Standards (79 *Fed. Reg.* 75234), at 9-19 (Mar. 17, 2015) ("Smith & Glascow Comments") (Attachment 1). Because some level of risk above 0 is acceptable and there are multiple important uncertainties with the epidemiologic evidence, EPA needs a clear

framework for determining both what level of effects is sufficient to imperil the health of the public and how certain the evidence should be of those effects.

2. The Short-Term Exposure Studies Do Not Support Revising the Primary NAAQS

In considering the implications of the recent short-trm epidemiological evidence for the adequacy of the current Standard, the Administrator "places the most weight on air quality analyses in locations of single-city studies of short-term O_3 . . . ." 79 Fed. Reg. at 75289. She particularly focuses on Mar and Koenig (2009)[37], "a U.S. single-city study [that] reported associations with respiratory emergency department visits in children and adults in a location that would have likely met the current O_3 standard over the entire study period . . . ." *Id.* However, as Gradient points out in its comments, there are multiple weaknesses with this study. First, the study fails to control for many potential confounders such as aeroallergens, respiratory infections, and co-pollutants. Gradient Comments at 10. Second, many of the emergency department visits Mar and Koenig (2009) looked at occurred on the same days as elevated O_3 levels, and "associations between [emergency department] visits and same-day ozone must be interpreted cautiously." *Id*. This is because O_3 levels tend to be the highest in the early afternoon, and therefore the peak O_3 for the day may occur *after* many of the emergency department visits for that day. High O_3 concentrations that occur after an emergency department visit can obviously not be the cause of the visit, and therefore EPA should have discounted the factor of the same-day associations more than it did. It could be one of several factors "such as incorrect model specification and residual confounding, [that] might have caused false positive results." *Id*. Finally, Gradient also states in their comments that "the large number of

[37] Therese F. Mar & Jane Q. Koenig, *Relationship Between Visits to Emergency Departments for Asthma and Ozone Exposure in Greater Seattle, Washington*, 103 ANNALS ALLERGY, ASTHMA & IMMUNOLOGY 474 (2009), Docket ID No. EPA-HQ-OAR-2008-0699-0372.

comparisons explored in this analysis raise concerns about a potential 'multiple comparison problem,' in which false positive associations occur due to chance alone." *Id*.

The Administrator also relies on two additional single-city studies, Silverman and Ito (2010)[38] and Strickland *et al*. (2010)[39]. 79 Fed. Reg. at 75289 ("[E]ven in some single-city study locations where the current standard was likely not met (*i.e.*, Silverman and Ito, 2010; Strickland et al., 2010), the Administrator notes PA analyses indicating that reported concentration-response functions and available air quality data support the occurrence of O_3-health effect associations on subsets of days with ambient O_3 concentrations below the level of the current standard . . . .") (emphasis in original). Gradient has also pointed out flaws in these studies that should have reduced EPA's reliance on them in the Proposed Rule. When Silverman and Ito (2010) controlled for fine particulate matter ("$PM_{2.5}$"), the association between hospital admissions and O_3 was "attenuated . . . across all age groups." Gradient Comments at 10. Further Silverman and Ito (2010) failed to control for other confounders "such as aeroallergens and respiratory infections, which exhibit extremely strong associations with adverse respiratory outcomes, so it is unclear whether the associations observed were due to ozone exposure." *Id*. Upon closer examination, Strickland, *et al*. (2010) fares no better. As Gradient notes, this study "investigated [emergency department] visits for pediatric asthma in Atlanta and found elevated risks, but they were inconsistent across the year and lost statistical significance when co-pollutants were added to the model." *Id*. Further, "Strickland *et al*. (2010) also found that relationships with [O3] and other pollutants were generally attenuated when upper respiratory infection rates were

[38] Robert A. Silverman & Kazuhiko Ito, *Age-Related Association of Fine Particles and Ozone with Severe Acute Asthma in New York City*, 125 J. ALLERGY & CLINICAL IMMUNOLOGY 367 (2010), Docket ID No. EPA-HQ-OAR-2008-0699-0266.

[39] Matthew J. Strickland, *et al.*, *Short-Term Associations Between Ambient Air Pollutants and Pediatric Asthma Emergency Department Visits*, 182. AM. J. RESPIRATORY & CRITICAL CARE MED. 307 (2010), Docket ID No. EPA-HQ-OAR-2008-0699-0363.

considered, and they concluded that associations between air pollution and respiratory morbidity may be confounded by upper respiratory infections." *Id*.

Although the Administrator does not point to other specific studies of short-term exposures to support her conclusion that the current standard is inadequate, she does "note that O_3 associations with respiratory morbidity or mortality have been reported in several multicity studies when the majority of study locations (though not all study locations) would likely have met the current O_3 standard." 79 Fed. Reg. at 75389. Therefore, UARG comments herein to highlight the inconsistencies and uncertainties in other epidemiological studies of effects associated with short-term O_3 exposure. EPA appropriately recognized the limitations of these studies when it determined that the multi-city studies should receive lesser weight. *See, e.g.*, *id*. at 75282. (stating that because of heterogeneity in multicity studies, "there is often greater uncertainty in conclusions about the extent to which multicity effect estimates reflect associations with air quality meeting the current standard"). But EPA did not fully account for how these issues impact the helpfulness of these studies for selecting a NAAQS at the level requisite to protect public health. For example, UARG has previously noted that the results in Bell, *et al.* (2006)[40] are counterintuitive: some of the cities with the highest mortality risk estimates have the lowest O_3 levels, and some of the cities with the highest O_3 levels have lower mortality risk estimates or even negative mortality risk estimates.

Not only does heterogeneity introduce substantial uncertainty into whether O_3 is responsible for health effects observed in these studies, but also heterogeneity can obscure whether there is a threshold for health effects. The Proposed Rule repeats the ISA's conclusion

[40] Michelle L. Bell, *et al.*, *The Exposure-Response Curve for Ozone and Risk of Mortality and the Adequacy of Current Ozone Regulations*, 114 ENVTL. HEALTH PERSP. 532 (2006), Docket ID No. EPA-HQ-OAR-2008-0699-0214.

that because of the heterogeneity of multicity studies, "a national or combined analysis may not be appropriate to identify whether a threshold exists in the O_3-mortality [concentration-response] relationship . . . ." *Id*. (internal quotation marks omitted) (citing ISA at 2-33); *see also* ISA at lxix (noting several sources of variability and uncertainty in studies "may explain why the available human data at ambient concentrations for some environmental pollutants (e.g., [PM], O_3, lead [Pb], environmental tobacco smoke [ETS], radiation) do not exhibit thresholds for cancer or noncancer health effects, even though likely mechanisms include nonlinear processes for some key events."). The potential for a threshold for effects from short-term exposure becomes only more important as EPA proposes to lower the NAAQS standard even closer to background levels.

Analysis by Smith & Glasgow demonstrates how significantly the presence of a threshold can effect estimates of morbidity and mortality from short-term O_3 exposures. Smith & Glasgow Comments at 4-8 (reviewing evidence and concluding that studies support likelihood of a threshold for O_3-exposure effects). They found that the HREA's mortality estimates from short-term exposures were based on an incorrect assumption and therefore did not properly represent the sensitivity of these estimates to the possibility of a threshold at different concentrations of O_3. Their re-analysis, correcting for this problem, shows that the estimates of mortality from short-term O_3 exposure are highly sensitive to the potential for a threshold. As they state in their comments, using a threshold at 40 ppb reduces the estimates of mortality risk from short-term O_3 exposure "by 87% and 88% relative to what the HREA reports for 2007 and 2009 [O_3], respectively." *Id.* at 2. Additionally, short-term morbidity estimates are similarly sensitive, as a threshold of 40 ppb would reduce major morbidity impacts from short-term exposures just meeting the current standard "by nearly 90%." *Id*. at 17. This sensitivity:

> echoes the extreme sensitivity that the Proposed Rule notes regarding long-term mortality risk estimates, where estimated risks at the current standard of 75 ppb are reduced by 98% from those reported as the core estimate in the HREA simply by adopting the best estimate of the long-term effects threshold that is reported in the original epidemiological paper that serves as the basis for the long-term risk estimates.

Id. Therefore, it is likely that not only are the risk estimates in the HREA, that EPA relies on, are overestimated, but also that they would be greatly improved by use of the IUA method of evaluating risk.

The usefulness of the epidemiological studies is also limited by issues regarding estimates of exposure levels. Most studies determine O_3 exposure concentrations using central ambient monitoring sites. These monitors do not correspond well to personal exposures. As UARG and Gradient have noted in their comments previously, the use of monitor concentrations represents an important exposure measurement error issue. *See* Gradient, Comments on US EPA's Causality Determinations for Short-Term and Long-Term Ozone Exposures and Mortality in the Integrated Science Assessment for Ozone and Related Photochemical Oxidants (First External Review Draft) at 26 (May 5, 2011), Docket ID No. EPA-HQ-ORD-2011-0050-0009 ("During the prior O_3 review process, CASAC highlighted exposure measurement error as a key uncertainty affecting the O_3 epidemiology, concluding that central site ambient monitors that measure ozone in the ambient air are generally poor measures of actual exposure to individuals . . . .."). "[A]s observed by Henderson (2006), personal ozone exposures are typically much lower than ambient ozone levels, and more importantly, often show little or no correlation with concentrations measured at the central ambient sites." *Id*. Further complicating this issue is the fact that O_3 levels are highest in the warm season. The increased use of air conditioning has resulted in increased indoor time during warm months, thus decreasing the actual exposure of individuals during this time.

Additionally, as EPA has noted, these studies often possess significant uncertainty as to whether the effects observed are due to O_3 exposure or to other variables, such as other pollutants or temperature. UARG's comments on the first draft ISA pointed out that many studies on short-term exposure morbidity (hospital admissions and emergency department visits) have reported greater associations with pollutants *other* thanO_3.[41] Although some studies have controlled for co-pollutants, the body of evidence used in the HREA for its core estimates of morbidity and mortality risks from short-term exposures is insufficient to show that short-term exposures to concentrations of O_3 meeting the current standard, rather than exposures to co-pollutants, are causally related to observed health effects.

3. The Long-Term Exposure Studies Do Not Support Revising the Primary NAAQS

The Proposed Rule admits that none of the long-term epidemiologic evidence indicates that the current standard is inadequate:

> [T]he available U.S. and Canadian epidemiologic studies evaluating long-term ambient O_3 concentration metrics have not been conducted in locations likely to have met the current 8-hour O_3 standard during the study period, and have not reported concentration-response functions that indicate confidence in health effect associations at O_3 concentrations meeting the current standard (U.S. EPA, 2014c, section 3.1.4.3). Therefore, although these studies contribute to understanding of health effects associated with long-term or repeated exposures to ambient O_3, consideration of study area air quality *does not inform*

[41] *See* Robert E. Dales,*et al.*, *Gaseous Air Pollutants and Hospitalization for Respiratory Disease in the Neonatal Period*, 114 ENVTL. HEALTH PERSP. 1751, 1753 (2006), Docket ID No. EPA-HQ-OAR-2008-0699-0223 ("All individual pollutants were associated with increased respiratory hospitalizations, with NO_2 having the strongest effect whether or not adjusted for other gases . . . ."); Mercedes Medina-Ramón, *et al.*, *The Effect of Ozone and PM_{10} on Hospital Admissions for Pneumonia and Chronic Obstructive Pulmonary Disease: A National Multicity Study*, 163 AM. J. EPIDEMIOLOGY 579, 583 Table 2 (2006), Docket ID No. EPA-HQ-OAR-2008-0699-0226 (reporting stronger associations between PM_{10} exposure and hospital admissions than between O_3 exposure and hospital admissions); Silverman and Ito (2010) (reporting a greater association between rate of Intensive Care Unit asthma admissions and $PM_{2.5}$ than O_3 and an approximately equal association between risk of general hospitalization and each of $PM_{2.5}$ and O_3).

> consideration of the extent to which those health effects may be occurring in locations that meet the current standard.

79 Fed. Reg. at 75282 (emphasis added). The Proposed Rule also acknowledges that the HREA concluded

> that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O_3 exposures, primarily because that analysis is based on only one study, though that study is well-designed, and because of the uncertainty in that study about the existence and identification of a potential threshold in the concentration-response function . . . .

Id. at 75284 (citing HREA § 9.6).

Despite these statements, however, the Administrator still relies on long-term exposure studies, and the risk estimates based on them, in her proposed conclusions on the adequacy of the current standard:

> The Administrator further notes that evidence for adverse respiratory health effects attributable to long-term, or repeated short-term, O_3 exposures is much stronger than in previous reviews, and the ISA concludes that there is 'likely to be' a causal relationship between such O_3 exposures and adverse respiratory health effects (the second strongest causality finding).

Id. at 75288; *see also id.* at 75289 ("[T]he Administrator also considers the results of the HREA exposure and risk analyses in reaching initial conclusions regarding the adequacy of the current primary O_3 standard. . . . She places relatively less weight on epidemiologic-based risk estimates . . . ."). The Administrator should reconsider her reliance on these studies and the risk estimates based on them. Not only do these studies have important flaws, which diminish the value of the risk estimates based off of them, but also EPA's current method of estimating risk is inferior to the IUA method recommended by EPRI and the NAS. As the Smith and Glasgow re-analysis of the mortality estimates from long-term O_3 exposure and EPRI Comments demonstrate, there are important uncertainties that, when properly considered, undermine EPA's assertion that there are health effects from long-term exposure to O_3 at levels below the current standard. *See* EPRI

Comments at 23 (concluding that their IUA analysis "shifted expected risks downwards, and shown a pronounced skewness, with significant amounts of probability on the possibility of no risk at all in certain locations across the U.S., and/or of no risk reduction from a tightening of the [O_3] NAAQS.").

The Proposed Rule highlights two major categories of new long-term morbidity evidence: studies on new-onset asthma in children and studies on increases of respiratory symptoms in asthmatic individuals. *Id*. at 75247. However, as UARG noted in its comments on the ISA, these studies are insufficient to support EPA's causal determination change, from inconclusive in the 2006 Air Quality Criteria Document ("AQCD") to "likely causal" in the ISA. Additionally, as Gradient explains in their comments, EPA's causal framework is flawed and has not been applied consistently. Gradient Comments at 5 (noting that the NAAQS causation framework is less stringent than the Institute of Medicine's Weight of Evidence framework and does not sufficiently account for bias and confounding in studies); *id.* ("In the [O3] ISA . . . , all available evidence was not presented in a clear, consistent manner; positive associations were often given more weight than null associations; confounders were not always adequately considered; the lack of coherence among epidemiology, toxicology, and mechanistic data was not acknowledged; effects that were not adverse were often interpreted as such; and alternative explanations for observed effects were not always considered.").

The new-onset asthma studies investigating the protective effect of genetic variants in high- and low-O_3 communities are particularly uncertain because the actual protective effect of these genetic variants is still unknown. For example, one of the cited studies, Islam, *et al*. (2009)[42], actually notes that the particular genetic variations that it studied "has been reported to

[42] Talat Islam, *et al.*, *Glutathione-S-Transferase (GST) P1, GSTM1, Exercise, Ozone and Asthma Incidence in School Children*, 64 Thorax 197 (2009), Docket ID No. EPA-HQ-OAR-2008-0699-0283.

be both protective and a risk factor for asthma." Islam, *et al*. (2009) at 197. Indeed, Kim *et al*. (2011), discussed above, reported that glutathione S-transferase mu 1 ("GSTM1"), one of the genetic variants studied by Islam, *et al*. (2009), did not appear to play any significant role in modifying the effects of O_3exposure on lung function. *See* Kim, *et al*. (2011) at 1215. Moreover, even if all of the genetic variants, that the researchers and EPA assume are protective against asthma onset, actually have a protective effect, and that protective effect is reduced in some children living in high- O_3 communities, it is unclear what the implications for this would be for human health in the general population.

The studies on increased symptoms for asthmatics also suffer from important uncertainties which, combined with the general limitations of epidemiologic studies, greatly reduce their value such that they cannot support a "likely causal" determination. Some of these studies themselves acknowledge mixed findings concerning possible associations between respiratory health effects and chronic O_3 exposure. *See, e.g*., Shao Lin, *et al.*, *Chronic Exposure to Ambient Ozone and Asthma Hospital Admissions Among Children*, 116 ENVTL. HEALTH PERSP. 1725, 1725 (2008), Docket ID No. EPA-HQ-OAR-2008-0699-0370. Others present findings that are difficult to interpret. For example, Islam, *et al*. (2009) reported that in some (but not all) cases, they found that the combined effects of O_3exposure and a specific genetic variant differed based on participation in team sports. *See* Islam *et al*. (2009) at 197. The public health significance of such findings is highly uncertain.

The mortality estimates based on long-term exposure are even more uncertain. The Proposed Rule recognizes this but does not fully appreciate this uncertainty. The HREA based its long-term mortality estimates on a single study, Jerrett, *et al.* (2009)[43], using a model that

[43] Michael Jerrett,*et al.*, Long-Term Ozone Exposure and Mortality, 360 NEW ENG. J. MED. 1085 (2009), Docket ID No. EPA-HQ-OAR-2008-0699-0357.

assumes there is no threshold. Using this non-threshold model, the HREA estimated approximately 45,000 deaths per year. HREA at 8-7 Table 8-1; *see also* 79 Fed. Reg. at 75285 ("Based on a linear concentration-response function, the current standard is estimated to allow thousands of O_3-associated respiratory deaths per year in the urban study areas."). But as the HREA and Proposed Rule admit, Jerrett, *et al.*(2009) evaluated other models, and the best fit for the data was a model using a threshold at 56 ppb.[44] Consistent with UARG's advice in its comments on the second draft HREA to model risk using this threshold model, the final HREA included sensitivity analyses that estimated mortality using threshold models. These threshold models determined that "the number of respiratory deaths associated with long-term O_3 concentrations could potentially be *considerably lower* (*i.e.*, by more than 75% if a threshold exists at 40 ppb, and by about 98% if a threshold exists at 56 ppb) . . . ." *Id*. at 75285 (emphasis added) (citing HREA at 7-84 fig. 7-9) .

The Proposed Rule's disregard of these estimates is poorly supported. The Proposed Rule attempts to devalue these threshold estimates by stating there was only "'limited evidence' for an effect threshold at an O_3 threshold of 56 ppb (p=0.06).[45] This reasoning ignores several

[44] As EPRI noted in their comments, this measurement in Jerrett, *et al.* (2009) was the seasonal average of daily 1-hour maximum O_3, which is not the form of the primary NAAQS. The NAAQS level will always be higher than the seasonal average because the NAAQS is "tied to worst case days," and "[t]hus, a threshold of 56 ppb in this epidemiological study may be above even the current NAAQS standard of 75 ppb in many parts of the country." EPRI Comments at 8. Accordingly, for those areas, the risk of mortality due to long-term o3 exposure would be zero upon attainment of the current Standard.

[45] The Proposed Rule states:

> In communications with EPA staff [(Memorandum from Erika Sasser, Acting Dir., OAQPS, EPA, to Holly Stallworth, Designated Fed. Officer, CASAC, EPA, Regarding Request for Revised Ozone HREA Chapter 7 Appendix Tables (May 9, 2014), Docket ID No. EPA-HQ-OAR-2008-0699-0495 ("Sasser (2014)")], the study authors indicated that it is not clear whether a threshold model is a better predictor of respiratory mortality than the linear model, and that "considerable caution should be exercised in accepting any specific threshold."

Id. at 75285 n.104 (citation omitted).

important issues. First, EPA does not insist on statistically significant results throughout the NAAQS process (where $p \leq 0.05$). While UARG believes that statistical significance is critical in assessing whether a meaningful association has been shown, EPA's use of it as a critique for these results appears inconsistent with its willingness to rely on results that lack statistical significance for other conclusions in this O_3 NAAQS review and demonstrates a biased view of the health evidence. Second, although the p value for Jarrett, *et al.* (2009) was marginally larger than 0.05, a p-value of 0.06, still means had a 94% likelihood that the threshold model is actually a better fit that the non-threshold model, and there is only a 6% chance that it was a better fit due to random chance. Third, the presence of a threshold is medically plausible, and thus EPA should give more serious consideration to these results. As Gradient points out in its comments, "all identified [O_3 modes of action] have thresholds below which the body's natural defenses can prevent adverse effects." Gradient Comments at 11. The presence of health effects at higher O_3 exposures is insufficient to determine whether they are persistent at lower levels, including those below the current primary standard. EPA should therefore acknowledge that a threshold is the more scientifically supported model.

VI. The Risk and Exposure Evidence Does Not Indicate that the Current Standard is Inadequate

A. EPA's Exposure Projections Show that a More Stringent NAAQS Is Unnecessary

The HREA's exposure assessment does not demonstrate that the current standard is inadequate. The HREA used the Air Pollutants Exposure ("APEX") model to estimate exposures to certain benchmark levels of ozone. Gradient notes in their comments, however, that "the largest benefits with regard to preventing lung function decrements result from just meeting the current standard of 0.075 ppm," with "generally smaller gains" from further

decreases. Gradient Comments at 12. Further, the APEX model likely overestimates ozone exposures and lung function decrements for children. *Id*.

B. EPA's Estimates of Percentages of People Experiencing FEV_1 Decrements Are Unsupported and Should Not Be Used

In the Proposed Rule, EPA includes estimates of lung function decrements expected for the current standard and for alternative standards of 70, 65, and 60 ppb. *Id*. at 75275 Table 2. EPA's estimates of the number of FEV_1 decrements are flawed and should not be used. There is no scientific support for the proposition that these individuals are representative of the larger population. These clinical studies did not choose individuals intending them to represent segments of the population. Instead, the studies sought to determine if there is a relationship between certain concentrations of O_3 and health effects generally, not how many people are likely to experience decrements. These studies did not control for individual variability, and thus the results of individuals, by themselves, could be the result of random variation or uncontrolled variables. Given these facts, it is inappropriate for EPA to extrapolate the number of individuals who experienced decrements to the larger population.

The use of the McDonnell, *et al.* (2012)[46] model does not rectify these issues. The model suffers from a paucity of data to ascertain the relationship between FEV_1 decrements and O_3 exposures below 80 ppb. As McDonnell, *et al.* (2012) notes, the bulk of the data that they analyzed to develop an exposure/response model was from exposure of 540 males were exposed to concentrations between 0.08 ppm (80 ppb) and 0.40 ppm (400 ppb). McDonnell, *et al.* (2012) at 620. Although they did have data from exposures below 80 ppb, these are limited in number and come from the clinical studies critiqued above. Consequently, the McDonnell, *et al*. (2012)

[46] William F. McDonnell, *et al.*, *Prediction of Lung Function Response for Populations Exposed to a Wide Range of Ozone Conditions*, 24 INHALATION TOXICOLOGY 619 (2012), Docket ID No. EPA-HQ-OAR-2008-0699-0359.

model is also subject to critiques about the failure of these studies to control for variability on an individual level, given the small number of subjects being used to extrapolate into the larger population. As noted earlier in these comments, EPA specifically stated it was looking to individual results >10% because "some individuals in the Schelegle et al. (2009) study experienced 5-10% FEV_1 decrements following exposure to filtered air." 79 Fed. Reg. at 75250. This raises concerns about the level of individual variability present in the Schelegle, *et al*. (2009) study, and although McDonnell, *et al.* (2012) sought to control for this variability, the low number of subjects exposed to below 80 ppb concentrations undermines this effort. Finally, the FEV_1 decrement estimates, by themselves, are not sufficiently useful to determine the presence of adverse effects, given the Administrator's focus on decrements combined with symptoms and the inability of any present model to estimate when both coincide.

VII. CASAC's Policy-Based Recommendation for a Stricter Standard Should Be Given Little Weight

A. Because CASAC's Advice Rested Largely on Policy Judgments Concerning Adversity and Margin of Safety, Its Recommendation on a Stricter Standard Is Entitled To Less Weight

The CASAC serves as scientific advisor to the Administrator in reviewing the air quality criteria and NAAQS. UARG supports this critical role, as evidenced by its participation in the CASAC process. However, UARG comments to ensure the Administrator draws the correct line between CASAC's scientific advice and its policy-based advice. As previously noted, CASAC:

> shall complete a review of the criteria published under [CAA § 108] and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under [CAA § 108 and § 109(b)].

CAA § 109(d)(2)(B) (emphasis added).

CASAC serves primarily a scientific function. *See Mississippi*, 744 F.3d at 1354 ("Congress created CASAC in the 1977 Clean Air Act Amendments and tasked it with *providing scientific advice* to aid EPA in setting NAAQS.") (emphasis added); *id.* ("Congress expected that CASAC's central role would be one of scientific analysis, explaining that CASAC's 'main function' was 'to assess health and environmental effects of ambient air pollution.'") (quoting H. REP. NO. 95-294, at 183). Although the Administrator must provide explanations when her actions "differ[] in any important respect from" CASAC's recommendations, CAA § 307(d)(3), (6)(A), CASAC's scientific analysis is entitled to greater deference than is its policy judgment over the appropriate NAAQS. *Mississippi*, 744 F.3d at 1354-55.

EPA acknowledges that there are several integral policy choices underlying this Proposed Rule. As EPA states in its Proposed Rule,

> "the PA recognizes that the final decision to retain or revise the current primary O_3 standard is a *public health policy judgment* to be made by the Administrator and will draw upon the available scientific evidence for O_3-attributable health effects and on analyses of population exposures and health risks, including judgments about the appropriate weight to assign the range of uncertainties inherent in the evidence and analyses."

79 Fed. Reg. at 75243 (emphasis added).

After CASAC reviewed the second draft of EPA staff's "Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards" ("Second Draft PA")[47], CASAC issued its "Consensus Responses to Charge Questions on the Second Draft Policy Assessment for the Review of the National Ambient Air Quality Standards for Ozone," Docket ID No. EPA-HQ-OAR-2008-0699-0190, (hereinafter "Consensus Responses") on June 26, 2014. In its letter transmitting these responses, CASAC stated it found "scientific justification that current

[47] EPA, EPA–452/P–14–002, Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, Second External Review Draft (Jan. 2014), Docket ID No. EPA-HQ-OAR-2008-0699-0236.

evidence and the results of the exposure and risk assessment call into question the adequacy of the current standard." Letter from Dr. H. Christopher Frey, Chair, CASAC, to Hon. Gina McCarthy, Adm'r, EPA, Regarding CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards at ii (June 26, 2014) (hereinafter "Closure Letter"). The letter went on to state that "there is clear scientific support for the need to revise the standard" and that "CASAC further concludes that there is adequate scientific evidence to recommend a range of levels for a revised primary [O_3]standard from 70 ppb to 60 ppb." *Id.* Further, the letter stated that:

> The CASAC acknowledges that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act. *The CASAC advises that, based on the scientific evidence, a level of 70 ppb provides little margin of safety for the protection of public health, particularly for sensitive subpopulations.* In this regard, our advice differs from that offered by EPA staff in the Second Draft PA. At 70 ppb, there is substantial scientific evidence of adverse effects as detailed in the charge question responses, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation. Although a level of 70 ppb is more protective of public health than the current standard, *it may not meet the statutory requirement to protect public health with an adequate margin of safety*. . . . Thus, *our policy advice* is to set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account your judgment regarding the desired margin of safety to protect public health, and taking into account that lower levels will provide incrementally greater margins of safety.

Id. at ii-iii (emphases added).

As the Closure Letter shows, CASAC's advice was based on several policy determinations to which EPA need not give deference. Regarding the adequacy of the current standard, the Administrator could easily agree with CASAC that "the Second Draft PA presents scientifically sound information on the health effects evidence for each major effect category," but disagree with the policy-based conclusion that this evidence "call[s] into question the

adequacy of the current standard." *Id*. at ii. The health effects evidence here does not control the policy choice of what level of protection is requisite, that is, no higher or lower than necessary, to protect public health, because the decision on what risks to accept is a policy decision. As the D.C. Circuit stated in *Mississippi*, "[d]etermining what is 'requisite' to protect the 'public health' with an 'adequate' margin of safety may indeed require a contextual assessment of acceptable risk. . . . *Such is the nature of policy*." *Mississippi*, 744 F.3d at 1343(emphasis added) (citing *Whitman*, 531 U.S. at 494-95 (Breyer, J., concurring in part and concurring in the judgment)); *id.* at 1344 ("[T]he NAAQS review process includes EPA's public health policy judgments as well as its analysis of scientifically certain fact."). The idea that EPA could reject CASAC's advice based on differing policy choices was discussed approvingly by the D.C. Circuit, which stated that "EPA could accept CASAC's scientific analysis yet explain the policy considerations that led it to select a different level than that recommended by CASAC." *Id.* at 1355.

B. The Failure to Advise CASAC that Proximity to Background O_3 Can Be Considered Further Reduces the Weight of CASAC's Policy-Based Advice

CASAC's advice should be given less weight also due to the fact that EPA failed to advise CASAC of the role that background O_3 can play in determining the NAAQS. After CASAC reviewed the Second Draft PA, CASAC issued its Consensus Responses on June 26, 2014. In its letter to EPA submitting this information, the Chair of CASAC wrote:

> The Second Draft PA is not clear as to how background estimates might impact the primary and secondary [NAAQS] and whether these impacts may differ regionally. The Second Draft PA cites a 2002 court decision (*American Trucking Associations, Inc. v. EPA*, *283 F.3d at 379*) that allows the EPA to consider relative proximity to peak background levels when evaluating alternative standards but it also cites a case where the court said "attainability and technological feasibility are not relevant considerations in the promulgation of the NAAQS" . . . . The Second Draft PA was silent as to how the EPA intends to navigate between these two legal guidelines when considering background [O_3]in a policy and standard-setting context. This question became an important issue

> in the CASAC deliberations as we listened to public comments regarding high background levels in the intermountain Western United States.

Closure Letter at i-ii (quoting *Costle*, 655 F.2d at 1185).[48]

EPA's failure to advise CASAC fully on the relevance of background O_3 is critical because, as previously noted, background O_3 levels can be substantial, in some places causing exceedances of even the current primary NAAQS. *See* 79 Fed. Reg. at 75242 ("[T]here can be episodic events with substantial background contributions where O_3 concentrations approach or [even] exceed the level of the current NAAQS (i.e., 75 ppb)."); PA at 2-18 (reporting *seasonal* mean background levels of up to 50 ppb); Langford, *et al*., (2014) at 18 (concluding that in Clark County, Nevada, exceedances of the NAAQS generated by high background concentrations and stratospheric intrusions would have occurred on 60% of the days during LVOS, making these events the rule rather than the exception); Zhang, *et al*. (2011) at 6775 (reporting "some occurrences" of background O_3 levels above 60 ppb and noting high background O_3 concentrations in the intermountain West "suggest that special consideration may be needed in the NAAQS-setting process."). Further, EPRI's Comments demonstrate that increasing background O_3 levels are both a historical trend and an expected future trend, indicating that background levels will only become more of a problem as time goes on. Background O_3 is therefore highly relevant to the determination of the primary O_3 NAAQS level.

[48] This discussion in the Closure Letter was likely triggered by written comments by CASAC-member George Allen. Mr. Allen wrote:

> Background [O_3] is still a factor in the [Second Draft PA] however, since a 2002 court decision allows EPA to consider background levels when evaluating risk for alternative (lower) standards (section 1.3.1, page 1-26, lines 17-19). But case law also states that "that attainability and technical feasibility are not relevant consideration in the setting of a NAAQS" (section 1.2.1, page 1-4 lines 19-21, API v. Costle, 1981). It is unclear how EPA might navigate between these two legal guidelines in terms of how background [O_3] would be used in a policy and standard-setting context.

Consensus Responses app. A at A-3.

Had CASAC been properly advised of the role that background O_3 can - indeed, should – be considered in determining an appropriate level for the NAAQS, the Committee might well have offered different recommendations to EPA concerning revision of the NAAQS. EPA's failure to explain to CASAC that NAAQS cannot be set at background concentrations and that proximity to background is a relevant consideration when deciding whether to revise a NAAQS, means that CASAC's advice was not fully informed and is entitled to less weight.

C. EPA Has Ample Justification for Diverging from CASAC's Recommendation to Revise the Current Primary NAAQS

CAA § 109(d)(2)(B) charges CASAC with reviewing the NAAQS and recommending "any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate" under CAA § 108 and § 109(b); EPA, in turn, must "explain the reasons for an 'important' divergences from CASAC's recommendations." *Mississippi*, 744 F.3d at 1339-40 (quoting CAA § 307(d)(3)). As explained above, there is ample information in the record to support retention of the current Standard.

EPA can explain that it is diverging from CASAC's conclusion that revision of the NAAQS is "need[ed]," Closure Letter at ii, because, *inter alia,* the Agency has adopted a different interpretation of the strength and utility of the scientific evidence. UARG's comments have highlighted several key uncertainties in the scientific evidence that contradict the conclusion that there is "clear scientific support for the need to revise the standard." *Id*. Further, the IUA test analysis done by EPRI demonstrates that there is a scientific justification for evaluating uncertainty differently than CASAC did, and the IUA approach has been endorsed by the National Academy of Sciences, which demonstrates that there is a scientific justification for evaluating uncertainty differently than CASAC did and concluding that revision of the NAAQS would not appreciably lower health risk. EPA would be reasonable in recognizing that

comments from UARG, EPRI, and Gradient, among others, do demonstrate additional uncertainty that there are ill health effects below the current standard, let alone sufficient effects to imperil the health of the public or any relevant subpopulation. EPA therefore has a scientifically-based justification for diverging from CASAC's advice.

EPA can also retain the current standard, diverging from CASAC's recommendations for policy-based reasons. As discussed above, CASAC's advice relied on policy judgments which are EPA's role , not CASAC's. EPA must make the policy choice of what level of protection is requisite, that is, no higher or lower than necessary, to protect public health. *Mississippi*, 744 F.3d at 1358 ("The task of determining what standard is 'requisite' to protect the qualitative value of public health or what margin of safety is 'adequate' to protect sensitive subpopulations necessarily requires the exercise of policy judgment. Similarly, "EPA could . . . accept[ ] CASAC's scientific conclusion[s] and explain[ ] its view that any health effects at that level were not severe enough to be considered 'adverse.'" *Id.* at 1357 n.6.

Finally, EPA may decide to retain the current standard because it believes a lower standard would be too close to background levels. Background levels may cause exceedances of the current primary NAAQS, and as EPRI notes in its comments, background levels in large portions of the country are expected to continue to increase in the future. EPRI Comments at 4. EPA recognizes that it "may consider proximity to background levels as a factor in the decision whether and how to revise the NAAQS when considering levels within the range of reasonable values . . . ." 79 Fed. Reg. at 75242. EPA could explain that it is rejecting CASAC's recommendation to revise the current standard because any alternative standard would come too close to background levels throughout significant portions of the country.

VIII. EPA Understates the Costs of and Overstates the Quantifiable Benefits from a More Stringent NAAQS.

A. EPA Understates the Cost of a More Stringent NAAQS.

As explained in UARG's comments on EPA's RIA the Proposed Rule, a copy of which is attached hereto as Attachment 2[49], EPA has underestimated the cost of a new, more stringent, NAAQS. The Agency limited itself to estimating the costs of controls. It did not attempt to address the cost of revised standards to the economy as a whole, *see* RIA at 7-37 to 7-38, although these costs will be daunting. David Harrison, Jr. *et al.*, NERA, Economic Impacts of a 65 ppb National Ambient Air Quality Standard for Ozone at 11 (Feb. 2015), *available at* http://www.nera.com/publications/archive/2015/economic-impacts-of-a-65-ppb-national-ambient-air-quality-standa.html ("The 65 ppb [O_3] standard is projected to reduce GDP from the baseline levels by about $1.7 trillion on a present value basis from 2017 to 2040 (as of 2014 and in 2014 dollars) and by $140 billion per year on a levelized average basis over that period . . . .")

In addition, EPA made several questionable choices in how the analysis was done that reduced the estimated costs. For example, EPA conducted its analysis for the year 2025, although virtually all areas outside of California will have earlier attainment deadlines. RIA Comments at 2-3. Furthermore, EPA assumed O_3 reductions from its proposed 111(d) program, although that proposal is unlikely to be finalized as proposed. *Id.* at 4. Moreover, EPA assumed that the cost of "unknown controls," which comprise a significant portion of the controls that the Agency predicts would be required to attain a more stringent NAAQS, would be no greater per ton than the cost of controls that are known and being used. *Id.* at 4-5. This approach will almost certainly lead to underestimated costs because the least cost controls are generally used first.

[49] Comments of the Utility Air Regulatory Group on the Regulatory Impact Analysis of the Proposed Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone (Mar. 17, 2015).

Finally, EPA underestimates the magnitude of the emissions reductions likely to be required to attain a revised NAAQS. In particular, the photochemical air quality models on which EPA relies for the RIA appear to underestimate the NOx reductions that would be required to attain a more stringent O_3 NAAQS "in multiple locales within the Northeast, the Midwest, the Central region, and California." Charles L. Blanchard & George M. Hidy, Envair, Effects of Past and Projected NOx Emissions on Ozone in the Continental U.S. at 1 (Mar. 11, 2015). The underestimation of required NO_2 reductions seems to increase as the O_3 target decreases. *Id*. at 11-12. The RIA does not take into account the cost of the additional NOx reductions that would be needed to attain a revised O_3 NAAQS in the range EPA has proposed.

B. The Estimated Benefits of Any More Stringent NAAQS Are Uncertain.

At the same time that EPA is understating the cost of the revised standards that it has proposed, the Agency is overstating the benefits of such a standard. EPA simply ignores the bulk of the uncertainties in the health science for its core estimates of the benefits of a revised NAAQS. As explained above, those uncertainties are substantial, a fact that should be reflected in the RIA.

The vast majority of the health benefits that EPA attributes to reduced levels of O_3 in ambient air are related to purported reduction of premature mortality related to short-term O_3 exposures. Smith & Glasgow (2015) at 16, 25.[50] Although the ISA recognizes that a threshold may exist for any association between short-term O_3 exposure and mortality, *id*. at 4 (quoting ISA at lxix), the RIA simply ignores this evidence, which suggests a possible threshold in the range of 20 ppb to 40 ppb. *Id*. at 8. Modeling a threshold of 40 ppb finds the mortality risk

[50] EPA's calculation of short-term mortality benefits based on Zanobetti & Schwartz (2008) contains an error that led to overstating the benefits that would be estimated based on that study. *Id.* at 25-27 (citing Antonella Zanobetti & Joel Schwartz, *Mortality Displacement in the Association of Ozone with Mortality: An Analysis of 48 Cities in the United States*, 177 AM. J. RESPIRATORY & CRITICAL CARE MED. 184 (2008), Docket ID No. EPA-HQ-OAR-2008-0699-0288).

reduction upon attainment of the current NAAQS is reduced by 87% to 88%. *Id.* at 2, 15 Table 2, 16. Not surprisingly, the benefits of revised NAAQS are also reduced substantially – by 90% to 96%.[51]

The other categories of health benefits addressed in the RIA are also subject to uncertainties, including possible thresholds. Modeling of possible thresholds for these other categories of benefits similarly reduces the benefits of attaining the present or alternative NAAQS dramatically. For example, with a threshold of 40 ppb, the benefits of attaining the present Standard is reduced "on average by nearly 90%." *Id*. at 17; *see also id*. at 18 Table 3, 19 Table 4 , App. A. Predicted reduction of premature respiratory mortality associated with long-term O_3 exposure upon attainment of alternative Standards is also substantially reduced using the threshold model that best fits the data in the Jerrett, *et al*. (2009) paper on which the RIA relies. *Id*. at 10-12. Indeed, applying IUA to address the possibility of a threshold and other uncertainties in this study reduced the estimated benefits based on it by 70% for a 70 ppb NAAQS and 90% for a 65 ppb NAAQS. *Id.* at 12.

If failing to account for the possibility of a threshold, the RIA fails to capture the range of uncertainty concerning possible benefits. The estimated benefits derived using an exposure/response model that incorporates a threshold are certainly within the range of realistic benefits estimates. Failure to conduct and report on the effect of a threshold when the possibility of one is supported by the health effects evidence leads to an unrealistic – and overstated -- picture of the potential health benefits of revising the NAAQS.

[51] *Id*. at 15 Table 2. Modeling a possible threshold of 20 ppb also reduces substantially (by 45% to 55%) the estimated benefits – in terms of reduction of premature mortality – associated with attainment of the present NAAQS. *Id*. Benefits of alternative, more stringent NAAQS are reduced by between 47% and 55%. *Id.*

Furthermore, the majority of the benefits that the Agency attributes to a revised standard are related not to O_3, but to reduced levels of particulate matter ("PM"). RIA at 5-3 Table 5-1. EPA separately sets and implements NAAQS for PM that, by definition, protects public health from PM in ambient air, allowing an adequate margin of safety. CAA § 109(b)(1). These PM NAAQS were revised in 2013 to provide additional health protection, 78 Fed. Reg. 3086, 3120-21 (Jan. 15, 2013), and were set at levels that the Administrator found "would be requisite to protect public health with an adequate margin of safety against health effects potentially associated with long- and short-term $PM_{2.5}$ exposures." *Id*. at 3164. EPA has provided no basis for concluding that those standards do not, in fact, protect public health and provide a margin of safety in doing so. Yet, all of purported co-benefits of $PM_{2.5}$ reductions are in areas that already meet these health-protective standards. Smith & Glasgow (2015) at 3, 35-36. Thus, there is no justification for EPA now to report benefits from reductions in the level or ambient particulate matter PM beyond those reductions required to meet the PM NAAQS.[52] Taking into account both the understated costs and the overstated benefits, it is clear that the proposed O_3 NAAQS revisions are not cost-effective. Smith & Glasgow (2015) at 2-3, 30-33.

IX. EPA's Proposed Revisions to the Air Quality Index Are Inappropriate

Section 319 of the Act instructs EPA to promulgate a "uniform air quality index" on which "daily analysis and reporting of air quality" is to be based. CAA § 319(a)(1), (3). As EPA explained previously, this requirement "is independent of the statutory provisions governing establishment and revision of the NAAQS." 64 Fed. Reg. 42530, 42532 (Aug. 4, 1999). Indeed, EPA recognizes "there is no statutory requirement that the [air quality

[52] EPA also refers to other benefits of revised O_3 NAAQS that it has not quantified. RIA at 5-3. To the extent these benefits are too uncertain to be quantified, RIA at 5-5, they are too uncertain to be considered benefits of a revised O_3 NAAQS.

index("AQI")] be linked to the NAAQS." *Id*. Although EPA has historically "keyed" the AQI to the NAAQS, *id*. at 42531, 42548, the statute keys the index to air quality.

The AQI describes air quality using an index that ranges from 0 to 500, with 0 representing the cleanest air and 500 representing the worst air quality. *See* 79 Fed. Reg. at 75311 Table 6. These index values are used to characterize air quality as "Good," "Moderate," "Unhealthy for Sensitive Groups," "Unhealthy," "Very Unhealthy," and "Hazardous." *Id*. At present, as shown in Table 6, index values of 0 to 50, characterized as "Good" air quality , are associated with 8-hour O_3levels of 0 ppb to 59 ppb. *Id*. Similar air quality breakdowns are provided for the other AQI categories.[53]

Not surprisingly, in light of its past focus on keying the AQI to the NAAQS, EPA is proposing to make "conforming changes" to the AQI if it revises the NAAQS. *Id*. at 75311. Although the index values associated with "Good" air quality would remain at 0 to 50, O_3 air quality in the range of 50 ppb to 59 ppb (depending on the level of the revised NAAQS) would no longer be considered "Good." Instead, it would be labelled as "Moderate." Changes would also be made to the air quality associated with the "Moderate, "Unhealthy for Sensitive Groups," "Unhealthy," and "Very Unhealthy" categories. As a result, in many cases, the same air quality would, in the future, be placed in a different, less healthy, category than at present.[54]

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[53] Index values of 51 to 100, characterized as "Moderate" air quality, are currently associated with 8-hour O_3 concentrations of 60 ppb to 75 ppb; index values of 101 to 150, characterized as air quality that is "Unhealthy for Sensitive Groups," are associated with O_3 concentrations of 76 ppb to 95 ppb; index values of 151 to 200, characterized as "Unhealthy" air quality, are associated with O_3 concentrations of 96 ppb to 115 ppb; index values of 201 to 300, characterized as "Very Unhealthy" air quality, are associated with O_3 concentrations of 116 ppb to 375 ppb; and index values of 301 to 400, characterized as "Hazardous" air quality, are associated with O_3 concentrations of 375 ppb or greater.

[54] O_3 levels are improving in the United States. Last year, looking at air quality data for the time period through 2013, EPA recognized, "Nationally, average [O_3] levels declined in the 1980's, leveled off in the 1990's, and showed a notable decline after 2002." Ozone – Air Trends, EPA, http://www.epa.gov/airtrends/ozone.html (last updated Oct. 8, 2014).

For example, an area for which the O_3 level improved from 75 ppb to 72 ppb on its most polluted day would currently report "Moderate" air quality on that day. If the AQI were revised as EPA has proposed, however, that area would be required to report air quality on that day as "Unhealthy for Sensitive Groups." As a result, members of the public would likely erroneously conclude that air quality had degraded. Indeed, they might question whether EPA and state regulators were doing their jobs.

There is no need for the Agency to revise the AQI and to produce this misleading result. The Act does not require it. As EPA explained previously, . the Act does not tie the AQI to NAAQS. 64 Fed. Reg. at 42532.

Indeed, the purpose of § 319(a) of the Act is to provide a consistent, uniform means of gauging *air quality*. EPA's proposal to revise the AQI runs counter to such uniformity. EPA's proposal would change the *air quality* significance of a given index value and its associated AQI category. As illustrated above, the revised AQI would fail to capture *air quality* improvements and would suggest degradation in *air quality* when none has occurred.

EPA says that it uses the AQI as its "primary" means of communicating to the public information on the implications of concentrations of O_3 (and other criteria air pollutants) for health. 79 Fed. Reg. at 75310. That is not the statutory purpose of the AQI. Even if it were, however, it is wrong to revise the AQI to suggest that any time air quality is measured (or expected) to exceed the NAAQS level, air quality is unhealthy for some members of the public (i.e., sensitive groups). The NAAQS, by definition, contains "an adequate margin of safety." *Id*. at 75237. Moreover, it protects members of sensitive population groups. *Seeid*. at 75237, n.1 (citing S. REP. NO. 91-1196, at 10). Thus, even if the Administrator revises the level of the NAAQS, it is simply improper to suggest that exposure to O_3 at the level of the revised NAAQS

would be unhealthy for sensitive groups.[55] Retention of the current AQI would allow continued provision of uniform information on air quality. Furthermore, it would advise the public if O_3 levels were to rise substantially above the level that the Administrator judged protective of the health of even sensitive population groups, allowing an adequate margin of safety.[56]

X. EPA Has Properly Proposed to Retain the Form of the Current Secondary O_3 Standard but Has Not Provided Adequate Record Support for Its Proposed Revision to the Level of the Standard.

As explained above, in setting or revising a secondary Standard, section 109(b)(2) of the CAA requires EPA to "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator . . . is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." Effects on welfare include, "effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being . . . ." CAA § 302(h). The CAA does not, however, require a secondary NAAQS to address all conceivable welfare effects. The Administrator must use her expertise to make policy judgments as to which effects rise to a level to be of concern to the public welfare and which effects are sufficient in impact to be deemed adverse. *See* 79 Fed. Reg. at 75312-13.

In its Proposed Rule, EPA has proposed to revise the secondary NAAQS for O_3 to within the range of 0.065 to 0.070 ppm, equal to its proposed revision to the primary O_3 standard, to

[55] Furthermore, the proposed NAAQS would limit "the 3-year average of the annual fourth-highest daily maximum 8-hour averageO_3 concentration,"*id*. at 75310, not the single highest reported O_3 value. This form for the standard recognizes that exposure to O_3 *at the level* of the NAAQS does not constitute an unacceptable risk to health.

[56] Of course, even if the NAAQS were revised, although we do not believe that such revision is appropriate, that revision would not alter the level of public health risk associated with a given O_3 exposure.

"provide air quality, in terms of 3-year average W126 index values, at or below a range of 13–17 ppm-hours." *Id*. at 75234.

For the reasons explained below, EPA has not provided adequate support for revising the secondary O_3 NAAQS, and, therefore, should retain the current standard. The record instead supports a finding that the current secondary NAAQS is requisite to protect the public welfare, and EPA should make such a finding. EPA's proposal to retain the current form of the standard and not to adopt a W126-based NAAQS is, however, well-reasoned and appropriate, given the record EPA has developed. Further, EPA has fully explained and adequately justified its decision to depart from CASAC's advice in that regard.

A. The Science EPA Cites Does Not Support Setting a More Stringent Secondary O3 Standard.

EPA has proposed that a NAAQS set within the range of 0.065 to 0.070 ppm will provide a level of protection within the range of 13 ppm-hours to 17 ppm-hours, and that such a level of protection satisfies the CAA's requirements. *Id*. at 75237. The science on which EPA relies, however, is too inconclusive and underdeveloped to support any revision to the secondary NAAQS. As the Administrator acknowledges in the Proposed Rule, "[t]he current body of O_3 welfare effects evidence *confirms the conclusions* reached in the last review on the nature of O_3-induced welfare effects . . . ." *Id*. at 75314 (emphasis added). It does not significantly expand scientific understanding beyond that which existed during the last review and it does not, therefore support action to lower the level of the NAAQS. Indeed, EPA expressly states in the Proposed Rule that the science is too uncertain to justify a standard designed to provide protection at levels more stringent than 13 ppm-hours. *Id*. at 75349. ("Thus, in the Administrator's judgment, focus on a three-year average W126 index value below 13 ppm-hrs would not give sufficient attention to the important uncertainties and limitations inherent in the

currently available scientific evidence and in the quantitative assessments conducted for the current review.")

The science that EPA does cite to support its proposed revision of the secondary NAAQS is subject to similar limitations and uncertainties. EPA points to three main effects: 1) impacts on tree growth, productivity and carbon storage; 2) crop yield loss; and 3) visible foliar injury. *Id*. at 75315. As discussed below, the science addressing these effects does not support a revision of the existing secondary O_3 Standard.

1. Biomass Loss in Trees

The Proposed Rule states that the Administrator has "taken particular note of" the science and impacts associated with relative biomass loss ("RBL") in trees. *Id*. at 75335. Indeed, as explained in the section of the Proposed Rule describing the "Administrator's Proposed Conclusions, *id*. at 75346-51, RBL effects in trees are the focus of the secondary O_3 NAAQS review and the driving force behind the Administrator's proposed decision. The science addressing tree species RBL is, however, inadequate to support the Administrator's proposed action.

As with the body of science on O_3 welfare effects generally, EPA acknowledges that "research published since the 2006 AQCD *substantiates prior conclusions* regarding O_3-related effects on forest tree growth, productivity and carbon storage." *Id*. at 75317 (emphasis added). That being the case, EPA should affirm the result of that review and retain the current secondary Standard.

The centerpiece of EPA's RBL science is a set of E–R functions for tree RBL in 11 species. As EPA acknowledges, these E–R functions were available during the last review. *Id.* Just as importantly, there are serious limitations to this information. First, the small number of species studied—just 0.8% of the 1,497 native tree species in the contiguous United States—

leaves significant uncertainties as to effects in the vast number of other tree species present in the nation. *Id*. at 75318. Indeed, as EPA states in the Proposed Rule, the available evidence as to even the limited number of species for which there is information shows that there is "a wide range in sensitivity across the studied species . . . ." *Id*. at 75317. The Proposed Rule notes that the technical analyses contained in EPA's WREA "recognizes uncertainty regarding the extent to which the subset of studied tree species encompass the O_3 sensitive species in the U.S. and the extent to which it represents U.S. vegetation as a whole . . . ." *Id*. at 73526 (citations omitted). The uncertainty is so significant that "[t]he WREA characterizes the direction of potential influence of E–R function uncertainty as unknown, yet its magnitude as high, concluding that further studies are needed to determine how accurately the assessed species reflect the larger suite of O_3-sensitive tree species in the U.S. . . ." *Id*.. The Administrator's proposed reliance on these E–R functions cannot be squared with these statements. Accordingly, extrapolating results from this small body of science to other species is not reasonable and this lack of reliable information undermines any case for revising the secondary standard.

Second, seedling E–R functions, regardless of the level of their reliability as to seedlings, cannot be used to discern RBL effects at other stages of tree development. Effects at other stages may be greatly reduced or disappear entirely. The Proposed Rule notes this fact, stating that "there are uncertainties inherent in these E–R functions, including the extrapolation of relative biomass loss rates from tree seedlings to adult trees and information regarding within-species variability." *Id*.; *see also id*. at 75339 ("The PA also recognizes uncertainty regarding the extent to which tree seedling E–R functions can be used to represent mature trees since seedling sensitivity has been shown in some cases to not reflect mature tree O_3 sensitivity in the same species and uncertainty in the relationship of O_3 effects on tree seedlings (*e.g.*, relative biomass

loss) in one or a few growing seasons to effects that might be expected to accrue over the life of the trees extending into adulthood . . . .") (emphasis in original) (citations omitted). The Proposed Rule and the Administrator's proposed revision to the secondary NAAQS do not, however, adequately reflect this important limitation.

Finally, the E–R functions for even the few species that have been studied are of limited reliability. Some of those functions are based on as little as a single study, and none are based on more than a handful of them. This limited body of science is not sufficiently developed to support a revision to the secondary NAAQS. Indeed, EPA appears to recognize some of these limitations in the Proposed Rule, although the Agency does not go far enough in that regard. EPA is correct, for instance, to refrain from relying on the E–R function derived for eastern cottonwood and to characterize it as less than robust. As the Proposed Rule notes, that E–R function was derived from a single field study in which controls for O_3 and climate conditions were inadequate for and further notes that the study's results were extreme. *Id*. at 75318, 75319 n. 189. Other E–R functions were also derived from single studies. S*ee, e.g.*, *id*. at 75318 (noting that the red maple E-R function is based on a single study). Nevertheless, the Proposed Rule inappropriately continues to categorize these E–R functions as robust.

In addition to the E–R functions themselves, the Proposed Rule points to two analyses in the WREA as a basis for considering a revision to the secondary O_3 standard. Each of those analyses, however, is critically flawed. First, the WREA's national RBL assessment relies on a 2% biomass loss benchmark as a threshold for identifying adverse effects. *Id*. at 75324. In this proposal, however, EPA has acknowledged that there is not a clear basis for such a benchmark, as described further below in section XIV.A., and the Agency has instead decided to look to a 5% benchmark as a more reasonable alternative. Moreover, even setting aside the arbitrary

nature of using a 2% biomass loss benchmark, the WREA's analysis shows that under conditions meeting the existing secondary NAAQS, only 0.2% of the country would exceed a 2% RBL. *Id*. Further, going below the current standard, according to the WREA, would have virtually no effect on the percentage of the nation with an RBL above 2%. *Id*. Similarly, there would be no change in the number of Class I areas with RBL over 2% at air quality conditions meeting the current Standard and possible W126 Standards of 15 ppm-hours and 11 ppm-hours, the latter below the 13 ppm-hour lower limit that the Administrator has identified as the most stringent option that can be supported by the science. *Id*. This analysis does not, therefore, support revising the secondary O_3 Standard.

The Proposed Rule also points to the WREA's county analysis as support for the proposed revision of the secondary NAAQS. In the county analysis, the WREA estimated the number of U.S. counties in which any of the studied tree species is estimated to experience more than 2% RBL, the number of species affected, and the number of counties for which the median of the species-specific functions exceeds 2% RBL. *Id*. Again, this study relies on the discredited 2% biomass loss benchmark and, therefore, its results are therefore cast in doubt. Moreover, in addition to an analysis of the 11 species for which EPA has data, the Agency also conducted an assessment without black cherry because "[t]he county RBL estimates are appreciably influenced by black cherry, a very sensitive species that is widespread in the Eastern U.S." *Id*. EPA's analysis shows that, even in terms of the specious 2% biomass loss benchmark, the vast majority of effects at that level were for the single, sensitive black cherry species. *Id*. Again, this assessment does not provide support for a secondary NAAQS revision.

In the absence of a reasoned basis for a 2% biomass loss benchmark by which to measure adverse effects in trees, a secondary O_3 NAAQS revision that relies on this area of science as

justification would need to identify some other metric for making an adverse determination and for identifying a "requisite" level of protection from that effect that the standard will be designed to achieve. The Proposed Rule does not do this and the record in fact supports a finding that RBL in trees does not warrant a NAAQS revision as a matter of public policy.

For instance, the Proposed Rule identifies commercial timber losses as a possible adverse impact against which a NAAQS could be intended to protect. It goes on to conclude, correctly, that:

> Because demand for most forestry and agricultural commodities is not highly responsive to changes in price, producer surplus (i.e., producer gains) often declines. These declines can be more than offset by changes in consumer surplus gains from lower prices, but, in some cases, lower prices reduce producer gains more than can be offset by consumer surplus . . . .

Id. at 75325 (citation omitted). The Proposed Rule also identifies urban pollutant removal by trees (citing five urban case study areas) as a possible impact that could be used to identify adversity. The results of those studies, however, show that the biggest benefit for pollutant removal will occur at air conditions just meeting the current standard. *Id*. EPA goes on to state that "[t]he results for the 15 ppm-hrs scenario were very similar to those for meeting the current standard. For the 11 and 7 ppm-hrs scenarios, all five case study areas indicate smaller additional increases in air pollutant removal beyond moving from current conditions to the current standard . . . ." *Id*. (citation omitted). Similar results have been reported with respect to carbon storage.[57] Accordingly, these effects do not provide support for a revision to the current standard.

[57] As the Proposed Rule notes, increased carbon storage in forests and urban trees at each of the modeled W126 levels is "relatively small" or "just slightly greater" than carbon storage estimated for air quality that meets the current standard. *Id*. Such a minimal welfare impact does not justify any revision to the secondary O_3 NAAQS. Similarly, the Proposed Rule states that changes in tropospheric O_3 concentrations affect climate, but correctly concludes that the science in this area is subject to "'large

Finally, the Proposed Rule mentions ecosystem productivity, forest composition, and a litany of other broader possible effects (many speculative and bordering on the absurd) that might be linked to O_3 and RBL. The Proposed Rule does not provide much specific information about these possible impacts, but does note that these sorts of effects and their magnitude:

> can vary among plant communities based on several factors including: the type of stand or community in which the sensitive species occurs (*e.g.*, single species versus mixed canopy), the role or position of the species in the stand (*e.g.*, dominant, sub-dominant, canopy, understory), the sensitivity of co-occurring species and environmental factors (*e.g.*, drought and other factors).

79 Fed. Reg. at 75318. The lack of specific information in the record on these effects and the extreme variability of these types of impacts based on factors unrelated to O_3 concentrations suggest that such effects would be poorly addressed through a secondary NAAQS and, at the very least, that there is no basis for attempting to make a NAAQS revision based on these impacts given the currently limited understanding of the issues.

In sum, the body of science addressing RBL in trees has not changed appreciably since the conclusion of the last O_3 NAAQS review. It remains subject to considerable uncertainties that do not allow EPA to make a reasoned decision on revising the secondary O_3 NAAQS to protect against RBL in trees. Further, there is no basis on which the Administrator can

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uncertainties'" and too limited to support a revision to the secondary O_3 standard. *Id*. at 75315 (quoting the ISA); *see also id*. at 75335. The Proposed Rule also relies on EPA's 2009 Interim Assessment, which asserts that future O_3 concentrations will be affected by climate change and that those effects could result in "higher peak pollution episodes in the summer, if offsetting emissions reductions are not made." *Id*. at 75,242 (citing EPA, EPA/600/R-07/094F, Assessment of the Impacts of Global Change on Regional U.S. Air Quality: A Synthesis of Climate Change Impacts on Ground-Level Ozone, An Interim Report of the U.S. EPA Global Change Research Program (Apr. 2009), Docket ID No. EPA-HQ-OAR-2008-0699-0232). As UARG demonstrated in extensive comments on EPA's Interim Assessment, the effect of climate change on O_3 concentrations is highly uncertain and EPA's Interim Assessment is not sufficiently reliable to be used as a basis for any air quality management decisions. Comments of the Utility Air Regulatory Group on EPA's "Assessment of the Impacts of Global Climate Change on Regional U.S. Air Quality: A Preliminary Synthesis of Climate Change Impacts on Ground-Level Ozone" (March 2008) (Aug. 25, 2008), Docket ID No. EPA-HQ-ORD-2007-0983-0006.

reasonably assess the adversity of the limited effects the science has identified. The 2% biomass loss benchmark has been discredited and the other impacts EPA assesses are minimal, are virtually unaffected by O_3 concentrations below the level of the current standard or are otherwise barely understood at all. The science of RBL in trees does not, accordingly, support a revision of the secondary O_3 NAAQS.

2. Crop Yield Loss

As with the other areas of welfare science EPA addresses in the Proposed Rule, nothing of significance has changed in our understanding of O_3-related crop yield loss. As EPA explains:

> On the whole, the newly available evidence supports previous conclusions that exposure to O_3 decreases growth and yield of crops. . . . The findings of the newly available studies do not change the basic understanding of O_3-related crop yield loss since the last review and little additional information is available in this review on factors that influence associations between O_3 levels and crop yield loss . . . .

See id. at 75319. This area of science provides no basis for a NAAQS revision for this reason alone.

As with tree RBL, the science addressing O_3 effects on crop yield is limited. Crop yield effects are estimated using E–R functions derived from only 10 crops. *Id*. For the reasons similar to those described above, there is no reason to assume that E–R functions across various crop species will be the same and EPA cannot properly extrapolate from one species to another.

Further, the available science suggests that no revision of the secondary NAAQS is needed to provide adequate protection. As noted in the Proposed Rule, CASAC identified a 5% yield loss benchmark by which to measure adverse impacts to crops, a policy determination that is outside of the scope of CASAC's expertise and statutory role. Moreover, as with the CASAC-identified 2% benchmark for RBL, the 5% benchmark is arbitrary and the record provides no

basis for relying on it.[58] Nevertheless, assuming for the sake of argument that a 5% benchmark were relevant – which it is not – analysis contained in EPA's WREA establishes that "[t]he largest reduction in O_3-induced crop yield loss and yield changes occurs when moving from the recent conditions scenario to the current standard scenario . . . ." *Id*. at 75326. Further, "[i]n the current standard scenario, no counties have RYL [relative yield loss] estimates at or above 5% . . . ." *Id*.

Moreover, as EPA acknowledges in the Proposed Rule, there are substantial policy reasons not to design an ambient air quality standard to protect commercial crops. Most importantly, as the Administrator explains, "maintenance of adequate agricultural crop yields is extremely important to the public welfare and is currently achieved through the application of intensive management practices." *Id*. at 75348. Those management practices make it "particularly difficult" to reach determinations as to the adversity of any O_3-related effect. *Id*. Further, "changes in yield of commercial crops and timber may affect producers and consumers differently, further complicating the question of assessing overall public welfare impacts." *Id*. For these reasons the Administrator has properly concluded

> that agricultural crops do not have [the] same need for additional protection from the NAAQS as forested ecosystems and, while research on agricultural crop species remains useful in illuminating mechanisms of action and physiological processes, information from this sector on O_3-induced effects is considered less useful in informing judgments on what level(s) would be sufficient but not more than necessary to protect the public welfare.

Id.[59]

[58] Because of the role EPA relegated the science related to crop yield loss in this review, the Administrator does not take a position on the 5% yield loss benchmark, and none is necessary so long as EPA's final rule is consistent with its proposal in this respect.

[59] This conclusion would appear to be borne out of the results of Betzelberger, *et al*. (2010), whose finding was, the Proposed Rule states, that O_3 E–R functions across 10 soybean cultivars were similar to the E-R functions derived from earlier studies conducted in the 1980s. *Id*. at 75319 (citing Amy M. Betzelberger, *et al*., *Effects of Chronic Elevated Ozone Concentration on Antioxidant Capacity,*

In sum, there have been no significant developments in this area of the science since the last O_3 NAAQS review. The science that does exist is limited and EPA's own analysis supports a finding that the current NAAQS is "requisite" to protect this public welfare value. Even so, EPA has correctly concluded that crop yield loss is ill-suited to being remedied by a secondary NAAQS and that this effect does not rise to the importance of an adverse public welfare effect under the CAA.

3. Visible Foliar Injury

The science related to visible foliar injury is old and has not changed in any significant respect since the last O_3 NAAQS review. *Id*. at 75316 ("Visible foliar injury resulting from exposure to O_3 has been well characterized and documented over several decades . . . . Recent research is consistent with previous conclusions . . . ."). This area of the science provides no basis for a secondary NAAQS revision.

The science that is available suggests the current secondary O_3 NAAQS is "requisite" to protect the public welfare. The basic science remains, after decades of research, strikingly limited. There are, for instance, no "robust exposure-response functions that would allow prediction of visible foliar injury severity and incidence under varying air quality and environmental conditions . . . ." *Id*. The Proposed Rule also notes that foliar injury can be confounded by the effects of "soil moisture and other factors, [making] it . . . difficult to predictively relate a given O_3 exposure to plant response . . . ." *Id*. at 75334.

Photosynthesis and Seed Yield of 10 Soybean Cultivars, 33 PLANT, CELL & ENV'T 1569 (2010), Docket ID No. EPA-HQ-OAR-2008-0699-0377). These results suggest that O_3 impacts are either minimal or so easily offset by other management practices that selecting cultivars based on O_3 resistance has not been necessary and that revising the secondary O_3 NAAQS to protect crops would likewise not be consistent with EPA's obligation to protect the public welfare from adverse effects.

Despite these uncertainties, the analyses performed by EPA in the WREA suggest that visible foliar injury is unlikely to occur in any significant way at O_3 levels meeting the current secondary NAAQS. In EPA's national-scale screening-level assessment of 214 national parks, under the current standard scenario, "none of the 214 parks had O_3 concentrations estimated to exceed the annual benchmark of a W126 index value above 10.46 ppm-hrs . . . ." *Id*. at 75328. As with the other benchmarks identified in this rulemaking, the 10.46 ppm-hour value has no basis in the record, is arbitrary, and is an unsuitable metric by which to judge whether the secondary standard should be revised. It is also important to note that this EPA-identified benchmark is even lower than the 13 ppm-hours that the Administrator has proposed for the low end of the range to consider in this review. In addition, EPA conducted case study analyses at three National Parks. In the current NAAQS scenario for those case studies,

> the three-year average W126 index values were at or below 7 ppm-hrs in all areas of two of the three parks . . . . Three-year average W126 index values were below 7 ppm-hrs in a little more than half of the area of the third park . . . and between 7 and 11 ppm-hrs in the remainder of the park . . . .

Id. Although uncertainties remain, these analyses suggest that the current standard would provide more than adequate protection against visible foliar injury, and they certainly do not support a more stringent secondary NAAQS.

Moreover, there is credible record evidence to support a finding that visible foliar injury is not an adverse effect on the public welfare that must be addressed through a secondary O_3 Standard. The Proposed Rule notes that "it is difficult to quantitatively relate visible foliar injury symptoms to vegetation effects such as individual tree growth, or effects at population or ecosystem levels . . . ." *Id*. at 75316 (citation omitted). It further states that visible foliar injury "is not always a reliable indicator of other negative effects on vegetation . . . ." *Id*. (quoting ISA at 9-39*)* (internal quotation marks omitted). Considering the lack of evidence of any kind of

serious adverse effect, the Administrator should determine that foliar injury is not an important effect from a public welfare perspective, and is not an adverse effect under the CAA.

The Proposed Rule notes that CASAC has stated that foliar injury can impact public welfare by damaging ornamental crops, plants with cultural significance or species occurring in settings valued for the scenic beauty. *Id*. at 75334. Setting aside the fact that there is virtually nothing in the record to support such claims, these assertions are not scientific findings, which CASAC is tasked with providing EPA. They are judgments as to matters of public policy as to which CASAC has no special expertise and as to which the Administrator should not even need to respond. Nevertheless, the Proposed Rule provides ample reasons for rejecting this advice. As to ornamental crops, the Administrator correctly concludes that "there is not adequate information at this time to establish a secondary standard based specifically on impairment of these categories of vegetation . . . ." *Id*. at 75348. Indeed there is nothing in the record to establish the monetary or other impact foliar injury might have on such crops. The same is true with respect to culturally significant species and species in settings, such as national parks, valued for scenic beauty. The Proposed Rule points out the

> lack of guidance for federal land managers regarding what spatial scale or degree of severity of visible foliar injury is considered sufficient to trigger protective action for O_3 sensitive AQRVs [air quality related values]. Further, there does not appear to be any consensus in the literature in this regard, and CASAC, while identifying benchmarks to consider for percent biomass loss and yield loss for tree seedlings and commodity crops, respectively, did not provide a similar recommendation for this endpoint.

Id. at 75334; *see also id*. at 75321 ("No criteria have been established, however, regarding a level or prevalence of visible foliar injury considered to be adverse to the affected vegetation, and . . . there is not a clear relationship between visible foliar injury and other effects, such as reduced growth and productivity.").

In sum, the science addressing visible foliar injury has not changed since the previous O_3 NAAQS review. That body of science is limited but suggests that O_3 concentrations meeting the current secondary NAAQS will result in minimal foliar injury effects. Moreover, the record contains no evidence suggesting that foliar injury is truly adverse to the public welfare. Accordingly, this effect does not provide an adequate bass for revising the secondary O_3 NAAQS.

B. EPA Has Adequately Supported Its Proposed Determination That a Standard Taking a W126 Form Is Not Requisite To Protect the Public Welfare.

EPA's Proposed Rule and the record in this rulemaking establish that a secondary standard set at a level equivalent to the proposed primary standard (i.e., 0.065 ppm to 0.070 ppm) would assure air quality equally as protective as a standard taking a W126 form set within the range of 13 ppm-hours to 17 ppm-hours that EPA has identified as "requisite" to protect the public welfare. *Id*. at 75237. Indeed, evidence in the record supports the conclusion that the existing secondary NAAQS, set at 0.075 ppm, provides protection equivalent to the 13 ppm-hours to 17 ppm-hours range EPA has identified. For those reasons, EPA should make final its proposal to retain the current form and level of the secondary Standard.

EPA's analysis of the equivalency between a W126 NAAQS and a NAAQS retaining the form of the current secondary NAAQS begins with the Agency's proposed conclusion, consistent with CASAC advice, that "the W126 cumulative exposure metric [i]s the most appropriate to use to evaluate both the adequacy of the current secondary standard and the appropriateness of any potential revisions." *Id*. at 75314. Accordingly, EPA examines the protection that a Standard taking the form of the current NAAQS can provide at 0.075 ppm, 0.070 ppm, 0.065 ppm, and 0.060 ppm.

The Proposed Rule points to several analyses in the record that support its proposal to retain the current form of the secondary NAAQS: a "focus study" in the ISA; air quality analyses described in chapters 2, 5 and 6 and Appendix 2b of the PA, and a more recently prepared analysis – Memorandum from Benjamin Wells, OAQPS, EPA, to Ozone NAAQS Review Docket, Regarding Comparison of Ozone Metrics Considered in the Current NAAQS Review (Nov. 20, 2014), Docket ID No. EPA-HQ-OAR-2008-0699-0155 ("Wells Memorandum"). *Id*. at 75344, 75345.

Of this material, the Wells Memorandum is the most current and most significant technical support for EPA's proposed conclusion that a secondary NAAQS that takes the same form and level as the proposed primary NAAQS, *i.e.*, the annual 4th highest daily maximum 8-hour O_3 concentration, or "4th max," will provide the requisite level of protection for the public welfare. That analysis looked at air quality data from 2001 to 2003 and from 2011-2013. Wells Memorandum at 3. The Wells Memorandum demonstrates that, generally, the trends in both the 4th max and W126 values have been decreasing. *Id*. at 10. More importantly, the Wells Memorandum confirms that at all monitor sites where 4th max values are less than or equal to 0.070 ppm, *id*. at 3, the upper range of the primary standard EPA has proposed, there are no sites with W126 values greater than 17 ppm-hours, only 4 sites with W126 values over 15 ppm-hours, and only 16 sites with W126 values over 13 ppm-hours. *Id*. at 5 Table 4. This information provides clear and convincing support for EPA's proposed determination to retain the current form of the secondary NAAQS as protective against adverse effects associated with these levels of a W126 indicator. 79 Fed. Reg. at 75345. Moreover, analysis contained in the RIA supporting this Proposed Rule provides additional evidence that a standard set at 0.070 ppm would provide even greater protection than suggested by the Wells Memorandum and that the

current standard could provide adequate protection. Indeed, the modeling results presented in section 3.4.2 and in figures 3-9 and 3-10 of the RIA, which project O_3 concentrations in 2025 under a 0.070 ppm 8-hour NAAQS scenario, appear to show that only a handful of areas, all in the West, would even approach W126 levels of 13 ppm-hours. EPA failed, however, to evaluate the protection that would be provided by a 0.075 ppm standard in the RIA. The Agency must conduct such an analysis and should incorporate it in the justification for its final rule.

In addition, the record supports a finding that the current secondary O_3 NAAQS does provide protection within the range of 13 ppm-hours to 17 ppm-hours. The Proposed Rule notes that EPA's analysis in the WREA shows that O_3 concentrations that would just meet the current 0.075 ppm 8-hour secondary NAAQS would achieve W126 values that range from 18.9 ppm-hours to 2.6 ppm-hours. *Id*. at 75323. Similarly, EPA states that the analysis set forth in the Wells Memorandum shows that, at monitors just meeting the current Standard, W126 values range from "less than 3 ppm-hrs to approximately 20 ppm-hrs . . . ." *Id*. at 75345. These analyses, however, almost certainly overstate O_3 exposures in terms of W126 values. As explained in the UARG March 24, 2014 comments on the Agency's draft HREA, WREA, and PA and in an attached technical assessment prepared by Gradient,[60] when air quality data are adjusted to just meet the existing Standard, there are only 5 monitors in the U.S. with W126 values above 15 ppm-hrs, and only 17 monitors with W126 values above 11 ppm-hrs. *Id*. Attachment 2 at 3. Further, based on the limits in the scientific information identified by Gradient, it is likely that the impacts would be even less significant. Similarly, if modeling such

[60] Comments of the Utility Air Regulatory Group on the U.S. Environmental Protections Agency's Health Risk and Exposure Assessment for Ozone: Second External Review Draft (February 2014) and Welfare Risk And Exposure Assessment for Ozone: Second External Review Draft (February 2014) and Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards: Second External Review Draft (January 2014), Attachment 2 at 3-4 (Mar. 24, 2014), Docket ID No. EPA-HQ-OAR-2008-0699-0129 (hereinafter "UARG Comments").

as that described in the RIA above was conducted for air quality just meeting the current NAAQS, it is likely that such a standard would be shown to be protective of 13 ppm-hour to 17 ppm-hour levels.

In sum, EPA's analysis demonstrates that air quality at or below 0.070 ppm, there would be no site with a monitor over 17 ppm-hours and that such a NAAQS would therefore be consistent with the level of protection EPA has proposed is requisite to protect the public welfare. 79 Fed. Reg. at 75345. Additional information in the docket suggests that the current 0.075 ppm secondary NAAQS is also likely to provide such protection. EPA should therefore retain the current form of the standard. The Agency should also supplement its assessment with modeling to evaluate whether the current secondary O_3 standard will provide protection equivalent to a W126 standard set at 13 ppm-hours to 17 ppm-hours. Indeed, figure 3-9 in the RIA, described above, suggests that had EPA presented modeling results for meeting the current 0.075 ppm secondary O_3 standard, no area apart perhaps from a minimal number of sites in the West, would likely exceed 13 ppm-hours.

C. EPA's Proposed Decision To Set the Secondary O_3 Standard Equivalent to the Primary Standard Is Consistent with the Decision of the D.C. Circuit in *Mississippi v. EPA*.

In its 2008 O_3 NAAQS rulemaking, EPA revised the secondary NAAQS to be equivalent to its revised primary standard of 0.075 ppm. Both of the revised standards were challenged in *Mississippi v. EPA*, 744 F.3d 1334 (D.C. Cir. 2013). In deciding the case, the D.C. Circuit upheld the primary Standard but remanded the secondary NAAQS to EPA. *Id*. at 1339. The court explained that because EPA had failed to identify a level of air quality requisite to protect public welfare, the revised secondary Standard was inherently unlawful and EPA's comparison between the primary and secondary Standards for determining if requisite protection for public welfare was afforded by the primary standard was insufficient to sustain the Agency's decision.

Although EPA has again proposed to revise the secondary standard by setting it equal to its proposed revised primary NAAQS – a proposed action that is, for the reasons described above, unsupported by the record and not justified – such an action would not violate the D.C. Circuit's holding in *Mississippi*. Indeed, the Mississippi court did not conclude that EPA cannot revise secondary NAAQS by making them equivalent to the primary Standard or that such action was suspect. On the contrary, EPA's 2008 secondary O_3 Standard failed to satisfy CAA requirements because EPA failed to identify the level of air quality that is requisite to protect the public welfare. *Id*. at 1361. In the absence of such a finding, EPA could not reasonably conclude that the primary Standard would provide the requisite level of protection for the public welfare.

In this rulemaking, EPA has made the determinations that the D.C. Circuit found to be missing from the Agency's 2008 rule. EPA has expressly identified a range of air quality – 13 ppm-hours to 17 ppm-hours – within which public welfare is protected. Moreover, EPA's technical assessment of the equivalency between a W126 Standard and a Standard in the form of the current O_3 NAAQS demonstrates that a 0.070 ppm Standard in the O_3 NAAQS' current form will provide the level of air quality that EPA has found to be requisite. Although UARG believes a standard set at 0.075 ppm would also provide the requisite protection, EPA's equivalency analysis is sufficient to justify retention of the current form of the secondary Standard. Unlike the analysis prepared in 2008, which showed rough overlap in protection between a W126 standard and a 0.075 ppm NAAQS, the analysis supporting this rulemaking demonstrates that a standard retaining the current form of the NAAQS will provide the requisite level of protection throughout the nation. Accordingly, EPA's Proposed Rule is consistent with the D.C. Circuit's opinion in *Mississippi*.

D. EPA Has Adequately Justified Its Differences from CASAC's Advice.

CASAC is charged by the Act with completing a review of the air quality criteria for the primary and secondary NAAQS every five years, and with "recommend[ing] to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate. . . ." CAA § 109(d)(2)(B). When the Administrator either proposes or finalizes a rule promulgating or revising a NAAQS, the preamble to the rule must "set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments" by CASAC and, if the proposal or rule "differs in any important respect from any of these recommendations, [provide] an explanation of the reasons for such differences." CAA § 307(d)(3), (6)(A).

EPA's Proposed Rule differs from CASAC advice on the secondary NAAQS on several issues: (1) the adoption of a 2% benchmark for determining adversity related to RBL effects in trees; (2) the range of W126 levels to consider; (3) the use of a three-year averaging time for a W126 standard; and (4) the adoption of a secondary standard in taking a W126 form. EPA has explained CASAC's advice on these matters and offered a complete and well-reasoned basis for each of its proposed decisions that differ from CASAC's recommendation. Accordingly, EPA's proposal is consistent with the requirements of the CAA.

1. The 2% RBL Benchmark

The Proposed Rule notes that CASAC recommended adoption of a 2% benchmark for RBL in trees as a threshold for adversity. EPA explains the full consideration it gave to the 2% RBL recommendation. *See, e.g.*, 79 Fed. Reg. at 75340. The Agency also then explains its evaluation of 6% RBL, the level CASAC found to be unacceptably high, followed by an evaluation of other, higher RBL benchmark levels at 10% and 15%. *Id*. at 75340-41. Of

particular note, EPA concludes that the 2% benchmark was arbitrary and unreliable, explaining that the 2% value was taken from a 1997 workshop report and finding that:

> The workshop report provides *no explicit rationale* for the percentages identified (2% RBL and 5% or 10% RYL); nor does it describe their connection to ecosystem impacts of a specific magnitude or type and judgments on significance of the effects for public welfare, *e.g.*, taking into consideration the intended use and significance of the affected vegetation . . . .

Id. at 75321 (emphasis added) (citing W.W. Heck & E.B. Cowling, EB, The Need for a Long Term Cumulative Secondary Ozone Standard—An Ecological Perspective, 1 ENVTL. MANAGER 23 (1997), Docket ID No. EPA-HQ-OAR-2008-0699-0291). In the absence of a rationale for the 2% RBL benchmark, EPA nevertheless takes it into account in its review of the science, but chooses to give greater weight to the 6% value in conducting its assessment. *Id*. at 75348-49. This rational explanation satisfies EPA's obligations with respect to CASAC.

CASAC's advice on the 2% benchmark is also not wholly scientific. As the Proposed Rule notes, CASAC's assertion that a 2% benchmark should be adopted amounts to little more than a policy judgment, especially in light of the absence of any scientific basis for the 1997 workshop recommendation. As the D.C. Circuit has explained, EPA's policy judgments are paramount when the science does not direct a particular outcome:

> The task of determining what standard is "requisite" to protect the qualitative value of public health or what margin of safety is "adequate" to protect sensitive subpopulations necessarily requires the exercise of policy judgment. . . . Although both CASAC and EPA must exercise public health policy judgment when confronted with scientific evidence that does not *direct* it to a specific outcome, it is to EPA's judgment that we must defer.

Mississippi, 744 F.3d at 1358 (emphasis in original).[61] That is the case here, and EPA's judgments are therefore sound.

2. The Relevant Range of W126 Levels

CASAC recommended that EPA consider establishing a standard that would achieve a level of protection equivalent to a W126 value of 7 ppm-hours to 15 ppm-hours. *See* 79 Fed. Reg. at 75343. EPA acknowledged and considered CASAC's recommendation. *Id*. For a variety of valid and fully explained reasons, described below, EPA correctly proposed a different W126 range, based on uncertainties in the science and the proper application of policy-making judgments.

Indeed, the Proposed Rule explains the general considerations that went into the Administrator's proposed decision on identifying an appropriate range of protection to consider:

> In reaching a conclusion on the appropriate range of W126 index values that describe the O_3 conditions expected to provide the requisite protection of public welfare, the Administrator has given careful consideration to the following: (1) The nature and degree of effects of O_3 to the public welfare, including what constitutes an adverse effect; (2) the strengths and limitations of the evidence that is available regarding known or anticipated adverse effects from cumulative, seasonal exposures, and its usefulness in informing selection of a proposed range; and (3) CASAC's views regarding a range of W126 levels appropriate to consider, as well as on the strength of the evidence and its adequacy to inform a range of levels.

Id. at 75347.

As to the Administrator's proposed decision to curtail the lower end of the range under consideration to 13 ppm-hours, the Proposed Rule explains that "focus on a three-year average W126 index value below 13 ppm-hrs would not give sufficient attention to the important

[61] The D.C. Circuit's opinion does not specify when scientific evidence might direct EPA to a particular policy judgment. In UARG's view, such circumstances would be exceptionally rare given the nature of the policy determinations that the CAA calls on the Administrator to make.

uncertainties and limitations inherent in the currently available scientific evidence and in the quantitative assessments conducted for the current review." *Id*. at 75349. Those scientific uncertainties are discussed above in detail and provide a valid basis for disagreement with CASAC's recommendation.

With respect to the proposal to extend the high end of range under consideration from 15 ppm-hours to 17 ppm-hours, the Proposed Rule explains that CASAC relied heavily on the 2% RBL benchmark for trees and the 5% benchmark for crop yield loss. *Id*. at 75343. As described above, EPA has valid scientific and policy reasons for discounting the 2% benchmark, thus providing a scientific justification for deviating from CASAC's advice. As additional support for the consideration of a range including a W126 value of 17 ppm-hours, EPA explains that

> the number and proportion of individual species with RBL estimates at or below 2%, a benchmark given emphasis by CASAC, do not vary across W126 index values from 17 ppm-hrs down to 9 ppm-hrs . . . , providing little distinction with regard to the significance of growth impacts for exposures across this large portion of the PA range.

Id. at 75349.

Similarly, as described above, there are valid policy and scientific reasons for not relying on crop yield loss as the basis for the secondary NAAQS. As the Proposed Rule explains, CASAC identified a W126 value of 15 ppm-hours as the upper limit of its range, in part, to protect against crop yield loss. *Id*. at 75348.

Further, the Proposed Rule notes that key changes in the record that CASAC did not consider also warrant deviation from CASAC's recommended range of W126 levels. In particular, the Proposed Rule notes that CASAC's lack of support for a range extending higher than 15 ppm-hours was based in part on information presented in Table 6-1 in the Second Draft PA. *Id*. The Proposed Rule states that

> revisions to this table in the final PA, made in consideration of CASAC comments have resulted in changes to the median species RBL estimates such that the median species RBL estimate for a W126 index value of 17 ppm-hrs in this table in the final PA (5.3%) is nearly identical to the median species estimate for 15 ppm-hrs (the value corresponding to the upper end of the CASAC-identified range) in the second draft PA . . . .

Id.

3. Use of a Three-Year Averaging Time for a W126 Standard

The Proposed Rule explains that CASAC expressed a preference for a single-year evaluation period for gauging compliance with a W126 standard, but stated that if compliance were to be gauged on a three-year period, the level of such a Standard should be lowered to account for the higher O_3 concentrations that such averaging might allow. *Id*. at 75347, 75349. After considering both recommendations, EPA properly proposes to reject them both and provides valid rationales for doing so.

First, EPA states that it proposes to adopt a three-year averaging period for assessing compliance, rather than a one-year period because a three-year evaluation period "can contribute to greater public welfare protection by limiting year-to-year disruptions in ongoing control programs." *Id*. at 75338-39. The Proposed Rule further notes that "considerations of stability often receive particular weight in NAAQS reviews, such as those resulting in selection of the form for the current O_3 primary and secondary standards . . ., as well as the primary standards for nitrogen dioxide . . . and sulfur dioxide . . . ." *Id*. at 75339. Based on these reasons, the Administrator proposes to determine that there is "greater confidence in judgments related to public welfare impacts based on a three-year average metric," providing a thorough and entirely adequate rationale for rejecting CASAC's recommendation. *Id*. at 75347.

The Administrator also adequately explains her reasons for rejecting CASAC's recommendation that a three-year averaging time be accompanied by a lowering of the level

under consideration, as compared to a standard using a single-year period. The Proposed Rule, in particular,

> takes note of the uncertainty associated with drawing conclusions with regard to the extent to which small percent reductions in annual growth contribute to adverse effects on public welfare and the role of annual variability in environmental factors that affect plant responses to O_3. Moreover, as explained above, the Administrator concludes that concerns related to the possibility of a singly unusually damaging year can be addressed through use of a three-year average metric, chosen with consideration of the relevant factors.

Id. at 75349. Again, these explanations satisfy EPA's obligations with respect to CASAC.

4. Adoption of a Secondary NAAQS Taking a W126 Form

Because CASAC determined that a W126 metric is more biologically relevant to the welfare impacts of O_3 than a NAAQS taking the form of the current NAAQS, CASAC recommended that EPA adopt a standard with a W126 form. *Id*. at 75330. EPA agreed with CASAC that a W126 metric was biologically relevant to the welfare effects at issue in this NAAQS review and accordingly characterized the level of protection to be provided by the secondary Standard in W126 terms, noting CASAC's strong support. *Id*. at 75316.

EPA, however, went one step further than CASAC. Consistent with public comments on its draft WREA and PA, EPA undertook several assessments, described above, comparing the level of protection that could be achieved in terms of W126 values under 8-hour NAAQS set at 0.075 ppm, 0.070 ppm, 0.065 ppm, and 0.060 ppm. The most significant of those assessments is the Wells Memorandum, which is based on the most recent monitoring data, which was not considered by CASAC, and which demonstrates that a 0.070 ppm NAAQS will achieve levels of protection consistent with EPA's proposed W126 range of 13 ppm-hours to 17 ppm-hours.

Beyond these technical reasons for proposing a NAAQS in the form of the current standard, there are also significant policy reasons for rejecting a Standard with a W126 form. As

explained in the Gradient report attached to UARG's comments on EPA's Draft HREA, WREA, and PA, there are considerable uncertainties with respect to whether the current monitoring network is sufficient to appropriately measure and implement a W126 standard. UARG Comments, Attachment 2 at 8.

In sum, EPA's proposal is consistent with the scientific and environmental concerns CASAC identified; the Proposed Rule targets a range of levels of protection based on the ecologically relevant W126 metric. Instead of simply adopting a Standard taking a W126 form, however, EPA has provided a substantial analysis, on which CASAC had no opportunity to opine, demonstrating that the level of "requisite" protection EPA has identified can be achieved with a NAAQS taking the form of the current Standard. EPA's rationale for this proposed decision, therefore, adequately responds to CASAC's advice and justifies EPA's departure from it.

XI. The Proposed Transitional Provisions for PSD Are a Start Towards a Workable Program for New Source Permitting.

As explained in the Proposed Rule, the Act requires preconstruction permitting for new major stationary sources or major sources undergoing major modifications. 79 Fed. Reg. at 75373. The Act includes a PSD program for sources in areas designated unclassifiable or attainment, CAA § 161, and a Nonattainment New Source Review ("NNSR") program for areas designated nonattainment. CAA § 173. According to EPA:

> [T]he CAA and implementing PSD regulations . . . require that PSD permit applications must include a demonstration that new major sources and major modifications will not cause or contribute to a violation of any NAAQS that is in effect as of the date the PSD permit is issued.

79 Fed. Reg. at 75377.

Accordingly, if EPA revises the O_3 NAAQS as it has proposed, anyone planning to build a major new source or make a major modification to an existing one – even someone who has a complete permit application pending – will be required to address the new Standard before receiving a PSD permit unless the Agency takes regulatory action to grandfather certain categories of permit applications. *See Sierra Club v. EPA*, 762 F.3d 971, 973-74 (9th Cir. 2014) (vacating a permit that was issued without addressing a NAAQS promulgated after the application had been completed, but recognizing that EPA could, by rulemaking, grandfather certain permit applications).

An immediate requirement to address a new O_3 NAAQS in all preconstruction permit applications could be quite disruptive. Construction or improvement of major sources of O_3 precursors would essentially be halted until this requirement could be satisfied. Even in areas meeting the new standard, the delay could be substantial, given the complexity of the analysis that would be required.[62] Permitting of new sources that emit O_3 precursors in areas in which the revised standard is not met would grind to a halt because those seeking permits would be unable to demonstrate a lack of contribution to nonattainment. Economic growth in this country would be adversely impacted.

No doubt seeking to alleviate some of these unfortunate effects of revising the NAAQS, EPA is proposing a transition program for PSD permitting. The Agency proposes to "grandfather" (i.e., exempt from a requirement to demonstrate the activity to be permitted will not cause or contribute to a violation of the revised NAAQS) certain pending permit applications. 79 Fed Reg. at 75378. Specifically, EPA is proposing to revise its regulations to "grandfather" (1) applications concerning which the permitting Agency had provided public

[62] *See* 79 Fed. Reg. 75378 (acknowledging "the significant level of effort, resources and time involved in preparing all the information necessary for a complete permit application").

notice of a draft permit prior to the effective date of a revised NAAQS, and (2) applications that the permitting Agency had determined to be complete prior to the signature date on a revised NAAQS. *Id*. at 75378, 75404.[63] EPA is also proposing to allow states that issue permits under a SIP-approved program "discretion to allow grandfathering consistent with the grandfathering provision contained in the federal rule provisions, even in the absence of an express grandfathering provision in their state rules . . . ." *Id*. at 75378.

These provisions make sense. They recognize the effort that has gone into permit applications prepared in advance of the effective date of a revised NAAQS and they help to alleviate concerns about an effective moratorium on permitting. They do not, of course, give applicants for permits a free pass with regard to addressing O_3. Those applicants will still have to address compliance with the existing O_3 NAAQS and to provide for the use of Best Available Control Technology ("BACT") for O_3 precursor emissions.

Of course, not all applicants for permits for planned new or modified major sources will qualify for grandfathering. Applicants that do not qualify for grandfathering will be required to address a revised O_3 NAAQS in their permit applications. In some cases, those sources will be unable to establish that they will not cause or contribute to a violation of that NAAQS.[64] This would be the case, for example, for a source in an area in which current monitoring data indicates the revised NAAQS is not being met. Once designations are finalized for the revised

[63] The distinction between the signature date and the effective date as a trigger point for these two grandfathering provisions is not explained and is not justified. The triggering date for both of these grandfathering provisions should be the effective date of a revised NAAQS. That date is published. States and permit applicants therefore have some advance notice of it. By contrast, public notice is not necessarily provided before the signature date for a final action at the completion of a NAAQS review.

[64] The tools that would be used to demonstrate compliance with a revised O_3 NAAQS are uncertain. EPA is currently evaluating whether to designate one or more air quality models to be used for O_3 permitting. *Id*. at 75377. As a result, those seeking PSD permits may find that the tools they are to use change midway through the permitting process. EPA should address this issue proactively by providing a transitional period before any newly identify modeling requirements will apply.

NAAQS two or three years in the future, such areas may well be designated nonattainment. Sources seeking to expand or locate there would proceed under the NNSR program instead of the PSD program and would be required to obtain emission offsets instead of making an impossible demonstration that the NAAQS will not be exceeded.

The Proposed Rule offers an interim program for sources planning to locate or expand in these areas. The permit application for such a source would be allowed to "utilize offsets as part of the required PSD demonstration . . . ." *Id*. at 75379. These offsets would have to be shown by the applicant "to compensate for the source's adverse impact . . . at the location of the violation." *Id*. at 75380.

Theoretically, a program of this nature could be helpful, but the parameters of the program, however, appear not to have been adequately thought out. How would the application demonstrate that the impact at the location of the violation has been offset? How large an offset might be required? Sources locating in O_3 nonattainment areas that are classified as marginal are required to offset new emissions at a ratio of at least 1.1 to 1. CAA § 182(a)(4). Applicants for permits in areas that are not designated attainment should not be required to obtain more emission offsets than would be required in such a nonattainment area. Where will the offsets come from? States implementing a NNSR program commonly operate offset banks, but in areas currently attain the O_3 NAAQS, such banks are unlikely to exist and they take time and resources to establish. How would this be accomplished? Given that new sources everywhere must already address the current O_3 NAAQS and use BACT, a more workable solution to the permitting problems posed by the new NAAQS would be to grandfather all PSD permitting applications until the parameters of this interim program can be adequately delineated. This could take significant time and resources, however. Alternatively,

consideration should be given to grandfathering all permit applications until designations for the new NAAQS are finalized.[65]

XII. EPA Is Not Planning Effective Regulatory Relief from Nonattainment Due to Background O_3.

In the Proposed Rule, EPA identifies three programs that it claims it will use to provide regulatory relief for situations in which O_3 levels "approach or exceed the concentration levels being proposed in this notice (*i.e.*, 60-70 ppb) in large part due to background sources." *Id*. at 75382. Specifically, EPA discusses use of exceptional events exclusions, rural transport areas, and international transport provisions. *Id*. at 75383-85. Each of these provisions could provide limited relief from NAAQS exceedances due to a background O_3. Each has been a part of the Act for a decade or more, however, without being used effectively. They provide little hope of relief if EPA adopts a more stringent NAAQS, that is even more likely to be exceeded as a result of background O_3.

A. EPA's Exceptional Events Program Has Not Been Successful.

Section 319(b) of the Act, which was added in 2005, required the Administrator to develop regulations to govern the review and handling of monitored air quality data influenced by exceptional events, including specification of "criteria and procedures" for states to use when petitioning for the exclusion of monitoring data "that is directly due to exceptional events" from consideration when judging NAAQS exceedances or violations. CAA § 319(b)(2)(B), (b)(3)(B)(iv). EPA's Exceptional Events Rule was published in 2007. 72 Fed. Reg. 13560 (Mar. 22, 2007) ("EER"). Although the EER was published almost eight years ago, EPA's website

[65] As discussed above, EPA's proposal to equate the secondary NAAQS to the primary NAAQS is consistent with the requirement that the Agency set a secondary standard at the level requisite to protect public welfare. If EPA should alter that approach, however, and adopt a distinct secondary NAAQS (e.g., one using a W126 indicator), UARG agrees that EPA should rely on the new source permitting program for the primary NAAQS as a surrogate for a separate permitting program for the secondary NAAQS. *See id*. at 75380.

indicates that the Agency has granted only three exceptional event determinations under it with regard to O_3, one concerning stratospheric O_3 intrusion and two related to fires. Exceptional Events - Exceptional Events Submissions Table, EPA, http://www.epa.gov/ttn/analysis/exeventstable.htm (last updated Dec. 8, 2014).

States have expressed frustration with EPA's implementation of the Act's exceptional events provision. Recently, for example, Utah's senators and representatives wrote to the EPA Administrator that:

> EPA's reliance . . . on the Exceptional Events Rule (EER) to deal with high ozone background "episodes" effectively condemns the intermountain West to "guilty until proven innocent" and incurs a high resource burden to meet the "but for" demonstration. The EER has not been effective to date in excluding background concentrations from determination of NAAQS attainment. The application process is extremely complex and time consuming, and applications by Utah for EER exclusions have routinely been denied by EPA regional officials following years of work by state and industry staff.

Letter from Hon. Orrin Hatch, Hon. Mike Lee, Hon. Rob Bishop, Hon. Jason Chaffretz & Hon. Chris Stewart, U.S. Congress, to Hon. Gina McCarthy, Adm'r, EPA, Regarding Consideration of Western Background Ozone Concentrations at 3 (Nov. 25, 2014), Docket ID No. EPA-HQ-OAR-2008-0699-0351.

They quoted testimony by the Executive Director of Utah's Department of Environmental Quality in 2013:

> Since 2008 Utah has submitted 12 exceptional-event demonstrations for [PM] that have required over 4,000 hours of technical work. None of those have been approved by [EPA] Region 8. There were many other events, *including [*O_3*] levels affected by wildfires* that we did not even attempt to demonstrate as exceptional events because the technical criteria are too difficult to meet. If the exceptional-event process doesn't work for[PM], it will not work for the complicated science behind rural background[O_3].

: Background Check: Achievability of New Ozone Standards: Hearing Before the Subcomm. on Env't of the Comm. on Sci., Space & Tech., 113th Cong. 19 (2013) (Testimony of Amanda Smith, Exec. Dir., Utah Dep't of Envtl. Quality), *available at* http://www.gpo.gov/fdsys/pkg/CHRG-113hhrg81724/pdf/CHRG-113hhrg81724.pdf (emphasis added).

Although Ms. Smith's testimony focused on the difficult technical criteria for obtaining an exceptional event determination, EPA's interpretation of the Act is also unreasonably constrained. Thus, EPA interprets the Act to exclude O_3 attributable to "natural emissions from vegetation, microbes, animals, and lightning" from exceptional event treatment. 79 Fed. Reg. at 75383 n.274. The Act, however, defines exceptional events as those affecting air quality that are "not reasonably controllable or preventable" and are due to "an event caused by human activity that is unlikely to recur at a particular location *or a natural event* . . . ." CAA § 319(b)(1)(A) (emphasis added). Elevated O_3 levels due to natural emissions would certainly appear to quality for treatment as exceptional events under this statutory definition.

EPA is also unnecessarily restrictive when it comes to exclusion of data that have a "clear causal relationship" to a NAAQS violation. CAA § 319(b)(3)(B)(ii). As alluded to in the letter from members of Utah's congressional delegation, the Agency will not exclude data affected by exceptional events unless a NAAQS violation would not have occurred "but for" that event. Days on which a violation would have occurred without the exceptional events are not excluded. 72 Fed. Reg. at 13570. By not excluding such days from the air quality data base, EPA may force a state to adopt a more stringent control strategy for an area. This outcome is not compelled by the statutory requirement of a "clear causal relationship" with a measured NAAQS

exceedance. Once again, though, EPA has made it unnecessarily difficult to take advantage of the exceptional events provision of the Act.

In short, EPA's crabbed interpretation of the exceptional events provision – in conjunction with the unreasonable technical demonstration burdens imposed by its EER – has rendered the statutory exceptional events provision virtually useless.

A. The CAA Provision Concerning Rural Transport Areas Has Not Historically Provided Effective Relief for O_3 Nonattainment Areas.

Section 182(h) of the Act permits the Administrator to determine, at her discretion, that an O_3 nonattainment area is subject only to the requirements applicable to a "marginal" area if (1) the area in question is not in or adjacent to a Metropolitan Statistical Area ("MSA") or Consolidated Metropolitan Statistical Area ("CBSA"), and (2) does not contain sources of VOC or NOx emissions that "make a significant contribution to" O_3 concentration in that or another area. CAA §182(h). EPA correctly notes in the Proposed Rule, "Historically, the EPA has recognized few nonattainment areas under this statutory provision." 79 Fed. Reg. at 75384. This is an understatement. Although EPA classified three areas as "rural transport" for the 1-hour [O_3] NAAQS,[66] no area has ever been designated a rural transport area with regard to an 8-hour NAAQS.

EPA initially planned an "interstate overwhelming transport" classification for nonattainment areas for the 1997 8-hour NAAQS that would be implemented under Subpart 1 of Part D of Title I of the Act. *See* 68 Fed. Reg. 23951, 23964 (Apr. 30, 2004). Even before the

[66] EPA mentions only Essex County, New York and Smyth County, Virginia, *id*. at 75384 n.278, the Agency's Technical Support Document for designations for the 1-hour NAAQS also identifies Door County, WI as a rural transport area for O_3. EPA, Technical Support Document for Ozone and Carbon Monoxide Designations and Classifications Under Section 107(d) of the Clean air Act Amendments of 1990 at 55 (Oct. 1991), *reprinted in* EPA, Technical Support for State and Tribal Air Quality Desigantions and Classifications, ch. 6, app. M (Apr. 2004), *available at* http://www.epa.gov/airquality/ozonepollution/designations/1997standards/tech.htm.

Agency's plan to use Subpart 1 to implement the NAAQS was rejected by the court,[67] however, EPA was backing away from such a classification. The Agency had agreed to reconsider it. 71 Fed. Reg. 15098, 15098 (Mar. 27, 2006).[68] For nonattainment areas that EPA planned to implement under Subpart 2 of Part D of Title I of the Act, the Agency indicated it did "not believe [that] there are any 8-hour nonattainment areas covered under subpart 2 that are 'rural' and therefore eligible for consideration for coverage under section 182(h)." 70 Fed. Reg. 71612, 71623 n.12 (Nov. 29, 2005). More recently, EPA acknowledged the existence of CAA § 182(h) in its rule establishing requirements for areas designation nonattainment for the 2008 O_3 NAAQS, but noted it "did not identify any nonattainment areas as rural transport areas" when it designated and classified areas for that NAAQS. 80 Fed. Reg. at 12292 n.64.

Furthermore, while pointing to the rural transport provision in the Proposed Rule as a potential source for appropriate regulatory relief, EPA at the same time limits its usefulness. First, the Agency explains that it will not consider any rural area with a monitor "heavily influenced by short-range upwind contributions from a nearby urbanized area" as a candidate for a relief as a rural transport area. 79 Fed. Reg. at 75384 n.277. In doing so, EPA is administratively limiting the scope of the relief that Congress provided for rural transport areas. The statute does not preclude a rural transport designation for an area because it is downwind of an urban area. Second, in the Proposed Rule, EPA cites with approval the 2005 draft guidance, *see supra* note 76, requiring that a demonstration to support a rural transport classification include "assembling emissions, air quality, meteorological and/or photochemical grid modeling

[67] *S. Coast Air Quality Mgmt. Dist. v. EPA*, 472 F.3d 882, 892 (D.C. Cir. 2006), *clarified on denial of reh'g by* 489 F.3d 1245 (D.C. Cir. 2007).

[68] At that time, EPA sought comment on its 2005 draft guidance on "Criteria for Assessing Whether an Ozone Nonattainment Area is Affected by Overwhelming Transport," 71 Fed. Reg. at 15100, calling into question the continuing viability of that draft. Nevertheless, EPA cites that uncertain draft guidance in the Proposed Rule. 79 Fed. Reg. at 79384 & n.279.

data" and a document that "describes analyses performed, data bases used, key assumptions and outcomes of each analysis, and why a State believes that the evidence, viewed as a whole, supports a conclusion that the area is overwhelmingly affected by transport and does not significantly contribute to downwind problems."[69] This guidance would impose a substantial analytic burden on a state in preparing its designations that must be submitted to EPA within a year after the Agency's promulgation of a revised NAAQS and likely discourage states from seeking the rural transport classification for an area within its boundaries that might otherwise qualify for it.

In short, no O_3 nonattainment area has been classified as a rural transport area for almost fourteen years, despite increasingly stringent standards issued during that period. While citing the rural transport classification as a potential source of regulatory relief for areas facing nonattainment designations as a result of air quality attributable to background O_3, EPA now seeks to limit the applicability of that classification further and to impose substantial burdens on states that might seek to use it. As a result, it is questionable that this provision will provide effective relief should EPA, now, adopt an even more stringent NAAQS.

B. The Act Provides Only Limited Relief for Areas that Would Not Meet a More Stringent O_3 NAAQS Due to International Transport of O_3 and O_3 Precursors.

Section 179B of the Act, titled International border areas, requires EPA to approve a SIP submittal for a nonattainment area if (1) the submittal meets all the applicable requirements except "a requirement that such plan or revision demonstrate attainment and maintenance of the relevant [NAAQS]" by the applicable attainment date, and (2) the state demonstrates that the SIP "would be adequate to attain and maintain the relevant [NAAQS]" by that date "but for

[69] EPA, Criteria for Assessing Whether an Ozone Nonattainment Area is Affected by Overwhelming Transport, Draft at 3 (June 29, 2005), *available at* www.epa.gov/scram001/guidance/guide/owt_guidance_07-13-05.pdf.

emissions emanating from outside of the United States." CAA § 179B(a). For O_3 specifically, the Act provides exemptions from §§ 181(a)(2) (establishing a severe area - classification with the attainment period of 17 years),[70] 181(a)(5) (providing for two possible 1-year extension of the attainment date), and 185 (concerning failure of severe and extreme nonattainment areas to achieve timely attainment). *Id*. § 179B(b).

As recognized in the Proposed Rule, this provision cannot be used to avoid a nonattainment designation or as the basis for a lower classification for a nonattainment area, but only to avoid "adverse consequence" for failing to attain by the applicable deadline. 79 Fed. Reg. at 75384. In other words, states to which this provision is applicable get only limited regulatory relief. They must still adopt a SIP addressing the control requirements associated with the initial classification for the area (e.g., reasonable further progress plans and nonattainment new source review provisions that utilize a more stringent definition of a major source). *See* CAA § 182(a)-(d).

It is not clear what will be required for a state to establish that an area qualifies for even this limited regulatory relief because of the impact of background O_3 attributable to international transport. EPA has repeatedly indicated that it will review requests for relief under Section 179B on a case-by-case basis. *See* 78 Fed. Reg. at 34205; 70 Fed. Reg. at 71624. Although the Proposed Rule refers to the 1991 guidance document of "Criteria for Assessing the Role of Transported Ozone/Precursors in Ozone Nonattainment Areas" for use in 179B demonstrations, 79 Fed. Reg. at 75384 & n.280, EPA previously "retracted" that guidance.[71] Thus, states face

[70] EPA has suggested that this statutory reference is intended to be to Section 181(b)(2) of the Act, which concerns reclassification upon failure to attain, instead of to Section 181(a)(2). 68 Fed. Reg. 32802, 32829 n.38 (June 2, 2003). This suggestion is sensible, but the Agency has provided no support for it.

[71] *See* 69 Fed. Reg. at 23965 (retracting an EPA guidance document for determining the contribution of sources to overwhelming transport that had been referenced in a 2003 proposed implementation rule

an undefined – but potentially heavy – burden in qualifying for the limited relief provided by this provision of the Act. It is therefore not surprising that the Proposed Rule identifies only one instance in which EPA relied on 179B to approve an O_3 SIP and none within the past decade.[72]

In short, none of the options that EPA has identified as providing future regulatory relief when background O_3 leads to exceedances of a revised NAAQS has consistently provided such relief in the past. Indeed, EPA has previously unnecessarily limited the applicability of these provisions and continues to do so in the Proposed Rule. These tools cannot excuse EPA's proposal to reduce the level of the O_3 NAAQS to one that is below background levels in much of the U.S.

XIII. EPA Should Provide Necessary Tools, Guidance, and Regulations To Implement any Revised NAAQS at the Time the NAAQS Is Promulgated.

The Act imposes strict timelines after a NAAQS is promulgated for the NAAQS to be implemented. According to EPA applicants for PSD permits must address a new NAAQS as soon as the NAAQS becomes effective. Memorandum for Stephen D. Page, Dir., OAQPS, EPA, to Air Div. Dirs. & Deputies, Regions I-X, EPA, Regarding Applicability of the Federal Prevention of Significant Deterioration Permit Requirements to New and Revised National Ambient Air Quality Standards at 2 (Apr. 1, 2010), Docket ID No. EPA-HQ-OAR-2008-0699-0305 ("EPA generally interprets the CAA and EPA's PSD permitting program regulations to require that each final PSD permit decision reflect consideration of any NAAQS that is in effect

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for the 1997 NAAQS); 68 Fed. Reg. at 32814 & n.15 (referencing EPA's 1991 guidance document "Criteria for Assessing the Role of Transport of Ozone/Precursors in Ozone Nonattainment Areas" in the context of an "overwhelming transport" classification).

[72] 79 Fed. Reg. at 75835. In that instance, which concerned the 1-hour O_3 NAAQS, EPA approved the demonstration only after the area had already attained the NAAQS, as shown through air quality monitoring, 69 Fed. Reg. 32450, 32451-52 (June 10, 2004), so the role of § 179B is unclear. Nevertheless, EPA indicated that "all section 179B approvals should be on a contingency basis" and are "valid only as long as the area's modeling data continue to show . . . attainment, but for emissions from outside the United States." *Id*. at 32452.

at the time the permitting authority issues a final permit."). Other aspects of implementation are mandated to follow shortly thereafter. States must submit to EPA designations of areas within their borders as "attainment," "nonattainment," or "unclassifiable" no more than a year after promulgation of a revised standard and EPA must finalize the designations no more than a year later, classifying nonattainment areas as "marginal," "moderate," "serious," "severe," or "extreme."[73] Infrastructure SIPs for all areas are due within three years of NAAQS promulgation (or less at EPA's discretion). CAA § 110(a). State submission of various aspects of SIPs for nonattainment areas is required as soon as six months after a nonattainment designation. *See Id*. § 182(a)(2)(A) (plans providing for reasonably available control technology in marginal nonattainment areas). States have some additional time to submit aspects of plans for areas in higher nonattainment classifications. *See, e.g.*, *Id*. § 182(b)(1) (three-year deadline for plans that provide for reasonable further progress in areas classified as a moderate nonattainment); *id*. § 182(c)(2) (four-year deadline for an attainment demonstration using photochemical grid modeling for areas classified as a serious nonattainment).

States have the primary responsibility for these implementation steps, *id*. § 107(a), and EPA is charged with reviewing and approving (or disapproving) the states' actions. *Id*. § 110(k). If EPA is not satisfied with the states' implementation of their responsibilities, EPA may demand changes, *id*. § 110(k)(5), or, ultimately, take over implementation responsibilities from the states, *id*. § 110(c)(1).

EPA has historically issued rules and guidance that explain how states are to fulfill their responsibilities.[74] In the Proposed Rule, EPA indicates that it plans to issue rules and guidance

[73] CAA §§ 107(d)(1), 181(a)-(b). A one-year delay of the final designations and classifications is allowed under certain circumstances. *Id*. § 107(d)(1)(B)(i).

[74] *See, e.g.*, Clean Air Fine Particle Implementation Rule, 72 Fed. Reg. 20586 (Apr. 25, 2007); Final Rule To Implement the 8-Hour Ozone National Ambient Air Quality Standard-Phase 2, 70 Fed. Reg.

to address implementation of any revised O_3 NAAQS. It has not yet done so, however. Instead, it has provided a timetable that it plans to follow for issuing these rules and guidance. Thus, "EPA intends to issue guidance concerning the designations process within 4 months of promulgation of the NAAQS, or approximately 8 months before state recommendations are due." 79 Fed. Reg. at 75372. EPA also intends "to develop and propose a new SIP Requirements Rule" that will be proposed "within 1 year after" promulgation of a revised NAAQS and will be finalized "no later than the time the area designations process is finalized . . . ." *Id*. at 75374. Similarly, the Agency "anticipates finalizing" guidance on emissions inventory development, attainment demonstrations, and conformity demonstrations "by the time areas are designated nonattainment." *Id*. at 75373.

Unfortunately, EPA has a history of failing to issue guidance and rules governing implementation in a timely manner. Implementation rules for NAAQS published in 1997 were not finalized until as late as 2007. EPA only published its rule on "Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plans" March 6, 2015, with an effective date of April 6, 2015, 80 Fed. Reg. at 12264, although designations of certain areas as nonattainment for that standard were published in May 2012, with an effective date of July 20, 2012,[75] meaning that several statutory deadlines for implementation of that rule have already passed. Similarly, EPA has yet to publish even a *proposed* rule concerning implementation of the revised annual NAAQS for $PM_{2.5}$ although in promulgating that NAAQS, the Agency stated its intention to "*finalize* the implementation rule around the time the initial

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71612 (Nov. 29, 2005); Final Rule To Implement the 8-Hour Ozone National Ambient Air Quality Standard – Phase 1, 69 Fed. Reg. 23951 (Apr. 30, 2004).

[75] Air Quality Designations for the 2008 Ozone National Ambient Air Quality Standards, 77 Fed. Reg. 30088 (May 21, 2012).

area designations process is finalized," 78 Fed. Reg. at 3251 (emphasis added), and the initial designations were published on January 15, 2015, 80 Fed. Reg. 2206.

EPA acknowledges that it has been asked by "a variety of states and other organizations" for more timely guidance. 79 Fed. Reg. at 75372. EPA's response to these requests is, first, to say that the Act "does not require" the Agency to "promulgate new implementing regulations every time that a NAAQS is revised," *Id*. at 75369, and, second, to suggest that existing regulations and guidance "may be sufficient in many cases to enable the EPA and the states to begin the process of implementing a revised NAAQS." *Id*. Even assuming that these statements are true as a general matter, in this instance, EPA has announced its intention to issue additional implementation rules and guidance as noted above. States and those they regulate will reasonably be reluctant to proceed with implementation under existing regulations when they have been told that new regulations will be forthcoming. EPA's promise to provide new implementation rules and guidance – together with the Agency's history of significant delays in providing such materials in the past – calls into question the states' ability to meet their statutory NAAQS implementation deadlines. To the extent that EPA's regulatory actions (and inactions or delayed actions) would effectively preclude the states from meeting their statutory responsibilities, EPA's actions would be an abuse of discretion and unlawful.[76]

To reduce the likelihood it will put states in the untenable position of being required to act prior to receiving instruction on the standards by which the adequacy of their action will be judged, EPA should, at a minimum allow the maximum possible time under the statutory

[76] EPA cites *National Association of Manufacturers v. EPA*, 750 F.3d 921, 926-97 (D.C. Cir. 2014) for the proposition that "issuance of [implementation] rules and guidance is not a part of the NAAQS review process . . . ." 79 Fed. Reg. at 75372. The claim here, however, is not that such rules and guidance are part of the NAAQS process, but rather that – having indicated that it intends to issue such rules and guidance – EPA has an obligation to do so in a manner that does not impede states' ability to fulfill their obligations under the Act.

timeline for implementation of any revised NAAQS. Although, as noted above, the statute in some instances allows EPA to require states to act sooner than by the default statutory deadline, the Agency should not impose earlier deadlines. Indeed, the Agency should consider an extended effective date for the rule to allow time for it to finalize implementation and guidance before the statutory timeline for implementation is triggered. Furthermore, EPA should not start the timeline running before the effective date of the revised NAAQS. Thus, EPA should recognize that the effective date, not the date of signature, is the promulgation date for a NAAQS.[77]

XIV. Conclusion

In summary, for the foregoing reasons, EPA should not adopt the revisions to the primary and secondary O_3 NAAQS that it has proposed. The Agency should, instead, recognize that the existing Standards continue to provide the requisite protection of public health and welfare. Accordingly, they should be retained and the states should be given an opportunity to implement them in accordance with EPA's recently issued implementation regulations.

[77] The version of the EPA rule signed by the Administrator is not the official version and may change before its publication. Indeed, the copies that EPA releases of a rule that have been signed note that it is not official For example, the signed version of the recent rule revising the NAAQS for PM, Attachment 3, states, "This document is a prepublication version, signed by EPA Administrator, Lisa P. Jackson on 12/14/2012. We have taken steps to ensure the accuracy of this version, but it is not the official version."

ATTACHMENT 1

Technical Comments on the Proposed Rule to Revise the Ozone National Ambient Air Quality Standards (79 *Fed. Reg.* 75234)

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Prepared on behalf of the Utility Air Regulatory Group

On December 17, 2015, the U.S. Environmental Protection Agency (EPA) released a Proposed Rule to revise the National Ambient Air Quality Standards (NAAQS) for ozone (79 *Fed. Reg*. 75234). This paper presents our comments on technical issues associated with epidemiologically-based health risk estimates that the Proposed Rule indicates may play a role in the Administrator's ozone NAAQS determination. The health risk estimates described in the Proposed Rule are documented in EPA's Heath Risk and Exposure Assessment (HREA) document (EPA, 2014a); we comment here on how the Proposed Rule is interpreting certain of those HREA estimates. The Proposed Rule also references EPA's Regulatory Impact Analysis (RIA) document (EPA, 2014b), and this paper comments on inconsistencies between the RIA's representation of the Proposed Rule's potential health benefits and the way that the Proposed Rule is being justified.

These comments address only the epidemiologically-based risks that are relied on in the Proposed Rule. While we do not address how the Proposed Rule is interpreting the clinically-based estimates of ozone-related risks, that does not imply that we consider those aspects of the Proposed Rule without concern.[2]

I. Summary of Key Points in Our Comments

Key points that we explain more fully in the later sections of this document are:

- The available scientific evidence on ozone health impacts cannot determine whether a threshold exists in the epidemiology-based short-term mortality and morbidity.

[1] The authors acknowledge and thank Reshma Patel, Sebastian Mankowski, and Julia Greenberger for their assistance in preparing the quantitative analyses used in these comments, and Dr. David Harrison for his helpful comments on drafts of the report. The authors are responsible for any remaining errors or omissions.

[2] We have prepared technical comments on the lung function risk estimates that are also relied on in the Proposed Rule in a separate report that is also being submitted to the docket at this time (NERA, 2015c).

  - EPA's Integrated Science Assessment (ISA) document (EPA, 2013) is clear on the possibility that undetected effects thresholds may exist in the short-term epidemiological associations, yet the HREA dismissed this possibility when making the quantitative estimates that the Proposed Rule is relying on.

  - Our own review of the short-term epidemiological papers that are cited in the Proposed Rule finds that the potential remains that there could be a short-term effects threshold at about 40 ppb (for daily 8-hour maxima).

- All of the epidemiology-based risk estimates that the Proposed Rule uses assume no threshold at all. Evaluation of the need for tightening the ozone NAAQS needs to be informed by additional risk estimates that explore the impact of alternative potential thresholds up to at least 40 ppb.

- The Proposed Rule provides a table that incorrectly draws on HREA data to identify the effect of alternative possible thresholds.[3] The HREA risk estimates for mortality and morbidity are all extremely sensitive to alternative assumptions on the possible level of a threshold. When the calculations of that table are corrected, they show a much larger sensitivity:

  - Short-term mortality risk estimates at the current standard of 75 ppb are reduced by 87% and 88% relative to what the HREA reports for 2007 and 2009 ozone, respectively, if a threshold at 40 ppb for daily 8-hour maximum is assumed.

  - Short-term morbidity estimates (hospitalizations and emergency room visits) are reduced by percentages similar to those for the short-term mortality estimates under alternative threshold assumptions.

- The sensitivity in the short-term epidemiological risk estimates to potential thresholds echoes the extreme sensitivity that the Proposed Rule notes regarding long-term mortality risk estimates, where estimated risks at the current standard of 75 ppb are reduced by 98% from those reported as the core estimate in the HREA simply by adopting the best estimate of the long-term effects threshold that is reported in the original epidemiological paper that serves as the basis for the long-term risk estimates.

- Even assuming that there is no threshold, the RIA finds that ozone-related benefits from tightening the current standard are less than the estimated cost of

[3] 79 *Fed. Reg*. 75234, December 17, 2014, Table 3 at 75277.

the rule, and that shortfall is made larger when potential thresholds are considered.

  - The gap is widened yet more when lack of realism in the RIA's estimates of the cost of alternative NAAQS standards is also accounted for.

- EPA's press release statements that the benefits of the rule outweigh its costs by "more than three to one" are based on a padding of the ozone-related benefits with "co-benefits" from projected coincidental ambient $PM_{2.5}$ reductions. All of those $PM_{2.5}$ changes are projected to occur in locations where $PM_{2.5}$ levels are low enough to be protective of the public health with an adequate margin of safety, but the assumptions used to estimate co-benefits do not account for this fact. As a result, the RIA's co-benefits estimates are all vastly overstated, and may be zero.

II. The Scientific Evidence Does Not Support an Assumption of No Threshold

The EPA explicitly recognizes that there is considerable uncertainty about the existence and location of a possible threshold for short-term ozone exposure in the concentration-response (C-R) function. The ISA states:

> *Various sources of variability and uncertainty, such as low data density in the lower concentration range, possible influence of exposure measurement error, and variability between individuals in susceptibility to air pollution health effects, tend to smooth and "linearize" the concentration-response function, and thus can obscure the existence of a threshold or nonlinear relationship [2006 O_3 AQCD (U.S. EPA, 2006b)]. Since individual thresholds vary from person to person due to individual differences such as genetic level susceptibility or pre-existing disease conditions (and even can vary from one time to another for a given person), it can be difficult to demonstrate that a threshold exists in a population study. These sources of variability and uncertainty may explain why the available human data at ambient concentrations for some environmental pollutants (e.g., particulate matter [PM], O_3, lead [Pb], environmental tobacco smoke [ETS], radiation) do not exhibit thresholds for cancer or noncancer health effects, even though likely mechanisms include nonlinear processes for some key events.*[4]

This statement of uncertainty is also present in the HREA, which states:

> *[E]valuation of evidence for a threshold in the C-R function is complicated by the high degree of heterogeneity between cities in the C-R functions and by the sparse data available at lower ambient O_3 concentrations (U.S. EPA, 2013b, sections 2.5.4.4 and 2.5.4.5).*[5]

Despite this uncertainty, the HREA focuses almost exclusively on linear C-R functions without a threshold. The EPA justifies this decision based on the relationship between ozone concentrations and mortality at currently observed levels, stating:

> *In conclusion, the evaluation of the O_3-mortality C-R relationship did not find any evidence that supports a threshold in the relationship between short-term exposure to O_3 and mortality within the range of O_3 concentrations observed in the United States. Additionally, recent*

[4] EPA, 2013, p. 1xix.

[5] EPA, 2014a, p. 2-14.

> *evidence suggests that the shape of the O_3-mortality C-R curve remains linear across the full range of O_3 concentrations.*[6]

Given the uncertainties described above, we cannot have much confidence in the extrapolation of a linear relationship from currently observed ozone concentrations all the way down to an ozone concentration of zero.

The EPA does admit there is considerable uncertainty in extrapolating a linear C-R function below 20 ppb,[7][8] but in fact there are numerous clues in the scientific literature that a threshold may exist for short-term ozone exposure at a higher concentration.

Bell *et al.* (2006) test the relationship between ozone and mortality in 98 US urban communities, and conclude that the relationship between ozone and mortality is linear, with a "safe" O_3 level for daily average ozone falling below 10 ppb, which corresponds roughly to 15-19 ppb for the 8 hour standard.[9] Although this paper is commonly cited as evidence of no threshold, Bell *et al*. did conduct tests of models that assume thresholds for daily ozone level between 5 and 60 ppb, and in some cases these models show an improvement in fit over the model that assumes no threshold. However, Bell *et al*. dismiss these models because the threshold models only provide a minimal improvement in the model AIC[10] when compared to the no-threshold model.[11]

Stylianou and Nicolich (2009) directly address the findings of Bell *et al*., and examine a variety of models that relate ozone exposure to mortality across a set of nine U.S. cities.[12] They find the relationship between ozone and risk is non-linear, and exhibits a great deal of heterogeneity across geographic regions, meaning that testing for a threshold by pooling data across cities (as Bell *et al*. did) could mask threshold effects (see also Smith *et al*. 2009). Stylianou and Nicolich also point out that Bell *et al*.'s dismissal of the threshold models based on a minimal improvement in model AIC is problematic, since adding the statistically significant PM_{10} or ozone variables to a basic model of mortality also does not significantly improve the AIC. They demonstrate that

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[6] EPA, 2013, p. 6-257.

[7] *Ibid.*, p. 1-15.

[8] EPA, 2014a, p. 7-3.

[9] Bell *et al.*, 2006, p. 535.

[10] AIC stands for Akaike Information Criterion, which is a commonly used measure of statistical model quality. The AIC is based both on how well the model fits the data and the complexity of the model. A lower AIC indicates a higher quality model.

[11] Bell *et al*., 2006, p. 535.

[12] Note that both Stylianou and Nicolich and Bell *et al*. use the NMMAPS data, and the cities examined by Stylianou and Nicolich are a subset of those examined by Bell *et al*.

for most cities a model with an ozone threshold at 30 ppb fits the data better than a linear ozone model without a threshold.[13] Stylianou and Nicolich conclude that "the use of a linear nonthreshold pollutant model is inconsistent with the observed data."[14] They find that most of their models exhibited an ozone threshold for a three-day weighted mean exposure that ranged between 10 and 45 ppb, with an average threshold around 32 ppb.[15] Stylianou and Nicolich note that we would expect the maximum 8-hour average ozone level to be higher than the three day weighted mean.[16]

Similarly, in a study of 12 Canadian cities, Katsouyanni *et al.* (2009) also find significant heterogeneity in the relationship between ozone and mortality, with some cities providing evidence of a threshold, while others do not. Models for four large cities (Edmonton, Montreal, Toronto, and Vancouver) produce the lowest (best) AIC for thresholds at a daily average of ozone between 20 and 40 ppb.[17] A pooled analysis of these cities suggested an overall threshold between 30 and 35 ppb for daily average ozone, although this finding was not statistically distinguishable from a model without a threshold.[18] The ISA interpreted this evidence as "no evidence of a threshold in the Canadian data (i.e., the pattern of AIC values for each increment of a potential threshold value varied across cities, most of which showed no local minima),"[19] but this is not accurate, as there was evidence of local minima in 6 out of 12 cities.[20]

Finally, Xia and Tong (2006) examine data from four cities (Hong Kong, Chicago, Pittsburgh, and El Paso), and conclude "there is evidence of a threshold effect, at which the effect starts to increase, for O_3 at about 25 ppb across the board."[21] For the city of Hong Kong the authors conclude that an 8-hour standard of 25 ppb is a "safe level" for both respiratory disease sufferers and circulatory disease sufferers, and for people with serious cardiovascular diseases in the US.[22]

Another finding that points to a possible threshold emerges from those epidemiological studies that have found a seasonal relationship between ozone and health, with a

[13] Stylianou and Nicolich, 2009, pp. 2220-1.

[14] *Ibid.*, p. 2223.

[15] *Ibid*., p. 2218.

[16] *Ibid*., p. 2220.

[17] Katsouyanni *et al.*, 2009, p. 56.

[18] *Ibid*., p. 57.

[19] EPA, 2013, p. 6-256.

[20] Katsouyanni *et al*., 2009, p. 56

[21] Xia and Tong, 2006, p. 3557.

[22] *Ibid*., p. 3558.

positive association in the warm season and no association in the cold season (e.g., Dales *et al.* 2006, Ito *et al.* 2007, EPA 2013,[23] Medina-Ramón *et al.* 2006, Stieb *et al.* 2009, Strickland *et al.* 2010, Villeneuve *et al.* 2007, Zanobetti and Schwartz 2006).

One possible explanation for this seasonal effect is that there is a threshold for ozone, and the lower concentration levels in the cold months tend not to rise above that threshold. An alternative explanation that is commonly advanced in the literature is that (1) ozone has higher concentration levels in the warmer months, and (2) individuals tend to spend more time outdoors during these months. This means that average exposure to ozone will be higher in the warm months, leading to greater health effects. There is almost no research that would allow us to distinguish between these alternative explanations.

One way in which we might distinguish between these alternative explanations is to consider the relationship between ozone and health in cities that have moderate year-round temperatures, where outdoor activity levels would be expected to be relatively constant throughout the year. Any seasonal variation we observe in these cities would be more likely due to a threshold, since activity levels are roughly constant.

We are unaware of any research that compares seasonal variation across cities with different winter activity levels. Cold season ozone measurements are not available for many cities, and many multi-city studies do not report results for individual cities (e.g., Bell *et al*. 2006, Medina-Ramón *et al*. 2006). However, Smith *et al.* (2009) find that California and Florida have low all-year ozone-mortality coefficients when compared to the North East and industrial Midwest, which suggests there is a weak or nonexistent relationship in these temperate areas in the winter.[24]

If no association between ozone and health in the cold season is found in cities with relatively constant outdoor activity patterns, the ozone concentrations observed in these cities may represent a lower bound on a threshold. Medina-Ramón *et al*. report the cold season daily 8-hour ozone concentrations for several cities generally regarded as having mild winters, including Los Angeles (31.4 ppb), San Francisco (19.3 ppb), San Diego (40.4 ppb), and Palm Beach (33.7 ppb).[25] These ozone concentrations are similar to those suggested as a possible threshold in the short-term ozone exposure literature.

[23] EPA, 2013, p. 3-134.

[24] Smith *et al*., 2009. p. 48.

[25] Medina- Ramón *et al.*, 2006, Table 1, p. 582.

In sum, existing research on the possibility of a threshold for short-term ozone exposure finds:

- There is considerable heterogeneity across cities in the relationship between ozone and mortality.
- There is evidence that the relationship between short-term ozone exposure and mortality is nonlinear.
- This heterogeneity and nonlinearity may disguise the existence of a threshold in tests that pool data across cities.
- In several cases models that assume a threshold provide a better fit to the data than a linear ozone model without a threshold, although the improvement is minimal.
- When evidence of a possible threshold is detected, it generally falls between 20 and 40 ppb.
- The lack of association between ozone exposure and health in the winter may indicate a threshold, which could be tested through an examination of cities with temperate climates. However, these tests have not been conducted.

III. Estimates of Mortality and Morbidity Risk Are Highly Sensitive to the Possibility that a Threshold Exists, Even If at Low Levels

The Proposed Rule notes that the Administrator intends to assign relatively less confidence to epidemiology-based risk estimates, due to their greater uncertainties; for example:

> *Compared to the weight given to the evidence from controlled human exposure studies, and to HREA estimates of exposures of concern and lung function risks, she places relatively less weight on epidemiology-based risk estimates. … [T]his is based on the greater uncertainties associated with mortality and morbidity risk estimates, including the heterogeneity in effect estimates between locations, the potential for exposure measurement errors, and uncertainty in the interpretation of the shape of concentration-response functions at lower O_3 concentrations*.[26] [Emphasis added.]

As this quote indicates, it is clear that the uncertainty about possible thresholds that we have described in the prior section is a known concern regarding the reliability of the epidemiology-based risk estimates. In fact, the Proposed Rule goes on to specifically note the especially low confidence associated with long-term mortality risk estimates because of the HREA's evidence of sensitivity to a potential threshold in those estimates:

> *The Administrator further notes the HREA conclusion that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O_3 exposures, primarily because that analysis is based on only one study (even though that study is well-designed) and because of the uncertainty in that study regarding the existence and identification of a potential threshold in the concentration response function (U.S. EPA, 2014a, section 9.6).*[27] [Emphasis added.]

However, the Proposed Rule continues to rely on risk estimates from the HREA that all assume there is no threshold at all. This is exacerbated by a misinterpretation in the Proposed Rule of the HREA's evidence regarding short-term mortality, as we will explain in this section.

The Administrator recognizes that information on uncertainties is important in determining how much weight to assign to any particular element of the scientific

[26] 79 *Fed. Reg*. 75234, December 17, 2014, at 75308.

[27] *Ibid*.

evidence. That is, she notes that selection of a primary NAAQS consistent with the requirements of the Clean Air Act:

> *…requires judgments based on an interpretation of the scientific evidence and exposure/risk information that neither overstates nor understates the strengths and limitations of that evidence and information, nor the appropriate inferences to be drawn therefrom.*[28]

To support such judgments, this section provides quantitative information not available in the HREA regarding the impact of alternative possible threshold values on the short-term mortality and morbidity risk estimates that are described in the Proposed Rule.

This section starts by re-capping the quantitative evidence on the uncertainty in the long-term mortality risk estimates that is noted in the previous quote from the Proposed Rule. It then turns to the evidence that the Proposed Rule describes on short-term mortality risk estimates. It describes a misunderstanding in the Proposed Rule of how potential threshold levels at 20 ppb, 40 ppb, and 60 ppb affect those short-term mortality risk estimates, and provides correct estimates of the impacts of alternative potential thresholds. The section then concludes with quantitative sensitivity analyses on the effects of potential thresholds on the HREA's risk estimates for major morbidity endpoints such as hospitalizations and emergency room visits.

Sensitivity of Long-Term Respiratory Mortality Risk Estimates to Threshold Assumptions

In response to comments on the second draft of the HREA (*e.g.*, Smith, 2014), the final HREA included a sensitivity analysis on a range of threshold levels that had been estimated in the original epidemiology paper (Jerrett *et al.*, 2009) that the HREA adopted as a basis for making long-term mortality risk estimates. This sensitivity analysis was motivated by the fact that the original paper found that the best-fit threshold was not zero, but was in fact at 56 ppb of the seasonal average of daily 1-hour maximum ozone.[29] Figure 1 graphs estimates of national long-term mortality risk under alternative threshold assumptions, with the value at 56 ppb being the best-fit assumption. It shows that estimates using every one of the alternative threshold assumptions that provide better fits than the no-threshold assumption are *less than* the

[28] *Ibid*., at 75303-4.

[29] Note that the units for the threshold are 1-hour daily maxima, and these values cannot be directly compared to the level of the standard, which is the 3-year average of each year's fourth highest daily 8-hour average. Thus, a 56 ppb standard in this study is often at a level well below the levels actually being experienced in the U.S., even in areas not already attaining the current 75 ppb ozone NAAQS.

lower bound of the 95% statistical errors that the HREA had reported for its no-threshold assumption.

Figure 1. Summary of the Sensitivity of the National Estimates of Long-Term Respiratory Mortality Risk Reported in the HREA for Recent (2006-2008) Ozone Levels
Source: NERA analysis of data in HREA

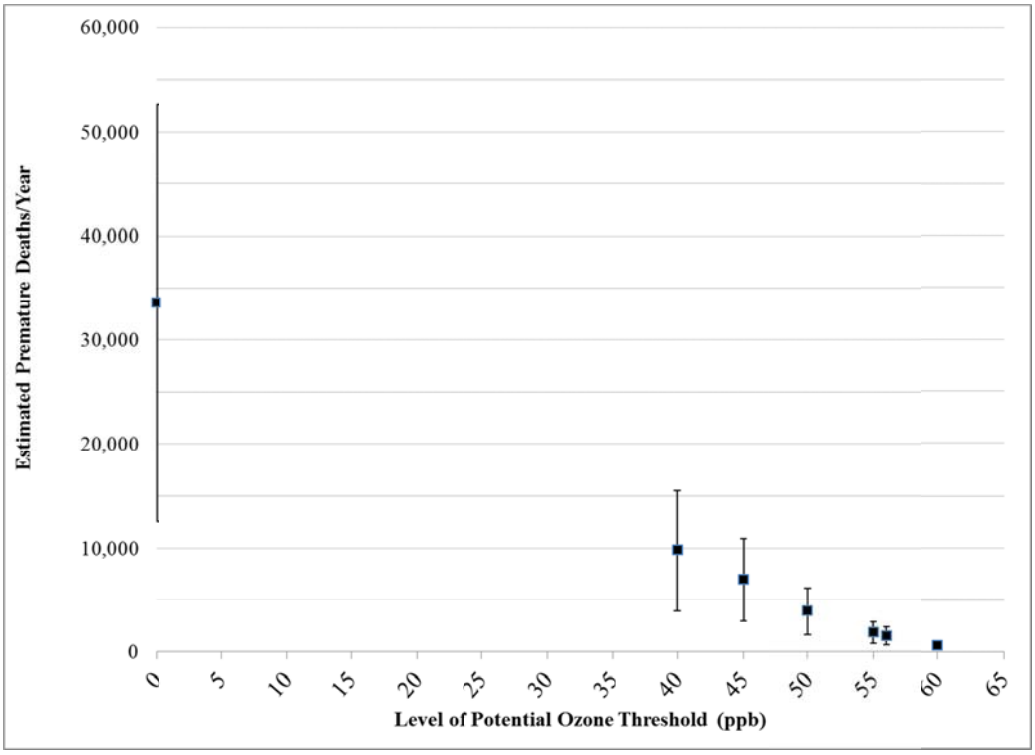


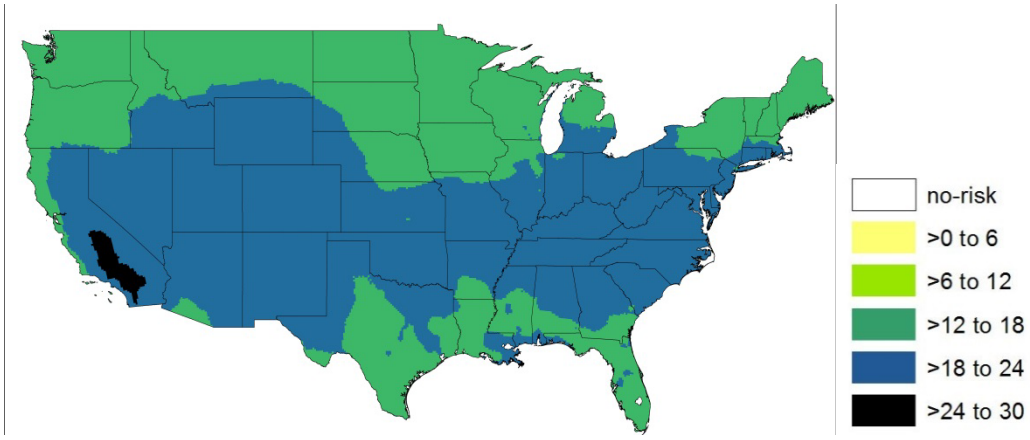
Figure 2 presents maps of the percent of respiratory mortality (A) under the no-threshold assumption and (B) under the best-fit threshold assumption. This figure reveals the reported sensitivity in the HREA's long-term mortality risk estimates in an even more striking manner. The very high percentages of total U.S. respiratory mortality that the no-threshold assumption implies are attributable to recent ozone may be viewed as implausible. The mere application of the best-fit threshold results in much lower estimates of percent of respiratory mortality attributable to ozone.

Integrated uncertainty analysis (IUA) for air pollutant risk assessments has long been called for by the National Academy of Sciences (NAS, 2002). As part of comments on this Proposed Rule, EPRI (2015) has provided an application of the IUA method to long-term respiratory mortality risk. Among other insights, the IUA in EPRI's comments indicates that the probability that there would be no long-term respiratory benefit from tightening the current standard down to even 70 ppb would be above 75% in all but two

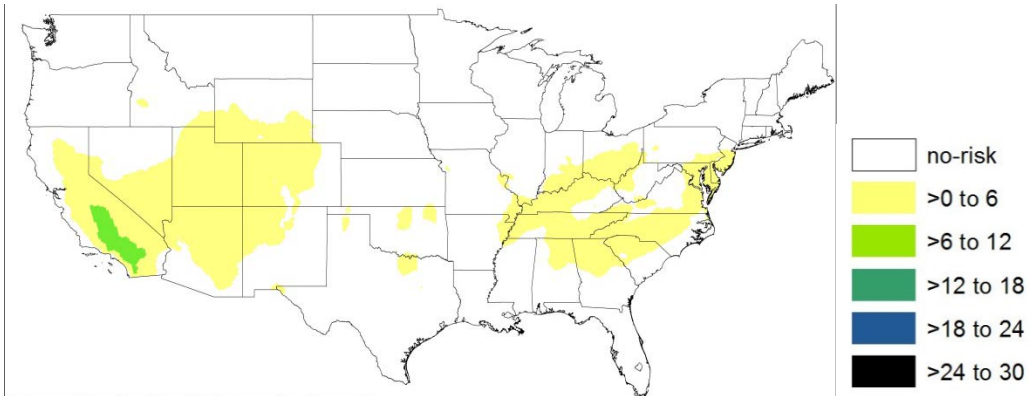
of the twelve urban study areas.[30] It finds that *expected* benefits estimated for the twelve cities to attain a 70 ppb standard are 70% less than the HREA's no-threshold estimates, 90% lower for attaining a 65 ppb standard, and 95% less for attaining a 60 ppb standard.[31]

Figure 2. Sensitivity of Long-Term Respiratory Mortality Estimates to No-Threshold and Best-Fit Threshold Assumptions in HREA (Percent of U.S. Respiratory Mortality Attributed to Ambient Ozone Levels during the Period 2006-2008)
Source: Smith (2014), based on details of calculations replicating HREA's risk estimates

A. Using Jerrett *et al.* (2009)'s 2-P No-Threshold Model:



B. Using Jerrett *et al.* (2009)'s Best-Fitting (56 ppb) Threshold Model:



[30] EPRI, 2015, Table 2, p. 21.

[31] *Ibid.,* Tables 2 to 4, pp. 21-23. (NERA calculations comparing IUA mean risk results summed over all twelve cities to those from HREA results shown in same tables).

In summary, the Proposed Rule rightfully notes that it should give very little weight to the long-term risk estimates. If the Administrator were to give any weight at all to this category of epidemiology-based risk, it should focus on IUA results such as those described in EPRI (2015).

Quantitative Sensitivity of Short-Term Mortality Risks to Potential Thresholds

The Proposed Rule notes that there is uncertainty in the shape of the concentration-response functions for short-term mortality and morbidity as well, but these epidemiological studies do not provide precise evidence to narrowly define an appropriate threshold assumption, as is possible for the long-term mortality study described above. Section II of these comments has explained in more detail the reason for the Proposed Rule to have noted this weakness in the epidemiological evidence. However, in attempting to characterize the sensitivity of the short-term mortality risks to potential alternative thresholds by summarizing information in the HREA, the Proposed Rule makes a conceptual error that greatly understates that sensitivity.

Table 3 of the Proposed Rule (copied as Figure 3 below) reports the fractions of the total estimated short-term mortality (the sum of estimated deaths in all 12 urban study areas) that is attributable to ozone above certain levels (20 ppb, 40 ppb, and 60 ppb). This table is based on data in the HREA, but has been derived specifically for the Proposed Rule, by aggregating data presented in the HREA in a different format. While the data in the table can be replicated from various tables in the HREA, the Proposed Rule incorrectly interprets those data. The Proposed Rule suggests that this table can be used to infer the sensitivity in the HREA's total short-term mortality estimates if the concentration-response function were not to continue to apply all the way to zero below each of the levels in the column headers. For example, in reference to use of its Table 3, the Proposed Rule states:

> *A focus on estimates of total risks would place greater weight on the possibility that concentration-response relationships are linear over the entire distribution of ambient O_3 concentrations, and thus on the potential for morbidity and mortality to be affected by changes in relatively low O_3 concentrations. A focus on risks associated with O_3 concentrations in the upper portions of the ambient distribution would place greater weight on the uncertainty associated with the shapes of concentration-response curves for O_3 concentrations in the lower portions of the distribution.*[32]

[32] 79 *Fed. Reg*. 75234, December 17, 2014, at 75276.

In other words, the Proposed Rule is interpreting the alternative estimates in Table 3 as if they were showing the implications of the possibility that the concentration-response relationship used is *not* "linear over the entire distribution" of ozone, which is what is meant by a threshold. This is an incorrect interpretation of what Table 3 reports; this table only reports how much of the total daily no-threshold risk estimate in the first column (which is the sum of risks calculated for each day in a season) remains if risks on some of those days (*i.e.*, days when ozone is lower than the ppb level identified in the other column headers) are excluded from the summation. For each of the other columns, the risks estimated for the days above its listed ppb level are exactly the same as in the original "total O_3" calculation. In other words, all of the numbers in each row of the Proposed Rule's Table 3 are based on a single risk model run, using the same concentration-response function. This is not how a threshold affects risk estimation. A threshold affects the "shape of the concentration-response" function, which changes the risk level for days at *every* ppb level, whether above or below the threshold.[33] Thus, estimating the sensitivity to alternative possible threshold levels requires re-estimating the total seasonal risk on every day of the season being assessed, and then summing them – not simply dropping some days from the summation based on a single (no-threshold) risk model run.

Table 1 provides the total short-term mortality risk estimates that the HREA would have reported if it had actually performed a sensitivity analysis to potential thresholds by re-running its risk model (called BenMAP) with thresholds specified at 20 ppb, 40 ppb, and 60 ppb. As can be seen by comparing the estimates in Table 1 to those in Figure 3, the short-term mortality risk estimates are much more sensitive to potential thresholds than the Proposed Rule currently recognizes. As Table 2 shows, the short-term mortality risk estimates would be reduced by essentially 100% if a threshold exists at 60 ppb. Even if a threshold were to exist at 40 ppb, the short-term mortality risk estimates at the current standard of 75 ppb would be 87% and 88% lower than the HREA has estimated (for 2007 and 2009 ozone, respectively). This is a very substantial degree of sensitivity associated with remaining uncertainties in the shape of the concentration-response functions, which echoes the sensitivity reported in the HREA for long-term respiratory mortality risk estimates.

[33] Days that fall below the threshold are assigned zero risk, as Table 3 is doing, while days above the threshold are assigned a risk that is based on the level of its concentration *relative* to the threshold. (This is what the BenMAP model that EPA has used for its HREA and RIA calculations does if its user chooses to specify a threshold.)

Figure 3. Copy of Table 3 from the Proposed Rule

TABLE 3—ESTIMATES OF O_3-ASSOCIATED DEATHS ATTRIBUTABLE TO THE FULL DISTRIBUTION OF 8-HOUR AREA-WIDE O_3 CONCENTRATIONS AND TO CONCENTRATIONS AT OR ABOVE 20, 40, OR 60 PPB O_3

[Deaths summed across urban case study areas] [83]

Number of O_3-associated deaths summed across urban case study areas				
Standard level	Total O_3	20+ ppb	40+ ppb	60+ ppb
2007				
75 ppb	7,500	7,500	5,400	500
70 ppb	7,200	7,200	4,900	240
65 ppb	6,500	6,500	2,800	90
60 ppb [84]	6,400	6,400	2,300	10
2009				
75 ppb	7,000	7,000	4,700	270
70 ppb	6,900	6,900	4,300	80
65 ppb	6,400	6,400	2,600	40
60 ppb	6,300	6,300	2,100	10

Table 1. Proposed Rule's Table 3 Calculated with Correct Threshold Logic: Estimates of Total O_3-Associated Deaths Using Various Alternative Assumptions on Level of Potential Threshold in the Short-Term Mortality Association

Number of O_3-associated deaths summed across urban case study areas				
Standard level	Total O_3 - No Threshold	Total O_3 - Threshold at 20 ppb	Total O3 - Threshold at 40 ppb	Total O3 - Threshold at 60 ppb
2007				
75 ppb	7,500	4,100	1,000	0
70 ppb	7,200	3,800	700	0
65 ppb	6,500	3,100	400	0
60 ppb	6,400	2,900	300	0
2009				
75 ppb	7,000	3,700	830	0
70 ppb	6,900	3,500	640	0
65 ppb	6,400	3,000	350	0
60 ppb	6,300	2,900	230	0

Table 2. Percentage Reduction in Total Short-Term Mortality Relative to the Zero-Threshold Calculations Used in the HREA under Alternative Assumptions of Level of Potential Threshold

Number of O_3-associated deaths summed across urban case study areas				
Standard level	Total O_3 - No Threshold	Total O_3 - Threshold at 20 ppb	Total O3 - Threshold at 40 ppb	Total O3 - Threshold at 60 ppb
2007				
75 ppb	0%	45%	87%	100%
70 ppb	0%	47%	90%	100%
65 ppb	0%	52%	94%	100%
60 ppb	0%	55%	95%	100%
2009				
75 ppb	0%	47%	88%	100%
70 ppb	0%	49%	91%	100%
65 ppb	0%	53%	95%	100%
60 ppb	0%	54%	96%	100%

The above analyses for short-term mortality sensitivities are based on a sum of the risk estimates across the 12 urban study areas in the HREA's Chapter 7. Chapter 8 of the HREA also reports short-term mortality risk estimates nationally. These national risk estimates are only provided for recent ozone conditions, which are higher in many areas of the country than at attainment of the current ozone NAAQS of 75 ppb. No estimates are provided for alternative tighter standards either. Unsurprisingly, however, these risk estimates are equivalently sensitive to alternative potential threshold assumptions.

Assuming no threshold in its calculation's, the HREA reports national annual acute deaths attributable to recent (2006-2008) ozone levels of 15,000 over the period May to September based on Smith *et al.* (2009)'s national average effect estimate, and of 15,000 over the period June to August, based on the Zanobetti and Schwartz (2008)'s national average effect estimate.[34] Figure 4 shows that these risk estimates both fall to essentially zero if a short-term mortality effects threshold were to exist at about 60 ppb, and they are very substantially reduced if there is a threshold in the range of 20 ppb to 40 ppb.[35] That is, when the level of the potential threshold on the x-axis of the figure is 0, the estimated premature deaths per year (reported on the y-axis) are shown to be at levels that would round to 15,000 when using two significant digits, as EPA has done. The declining lines in the figure show what those risk estimates would instead be for any alternative level of potential threshold. For example, if there is a threshold at about 40 ppb, EPA's risk estimates of 15,000 premature deaths per year would in fact be about 3,000 deaths per year.

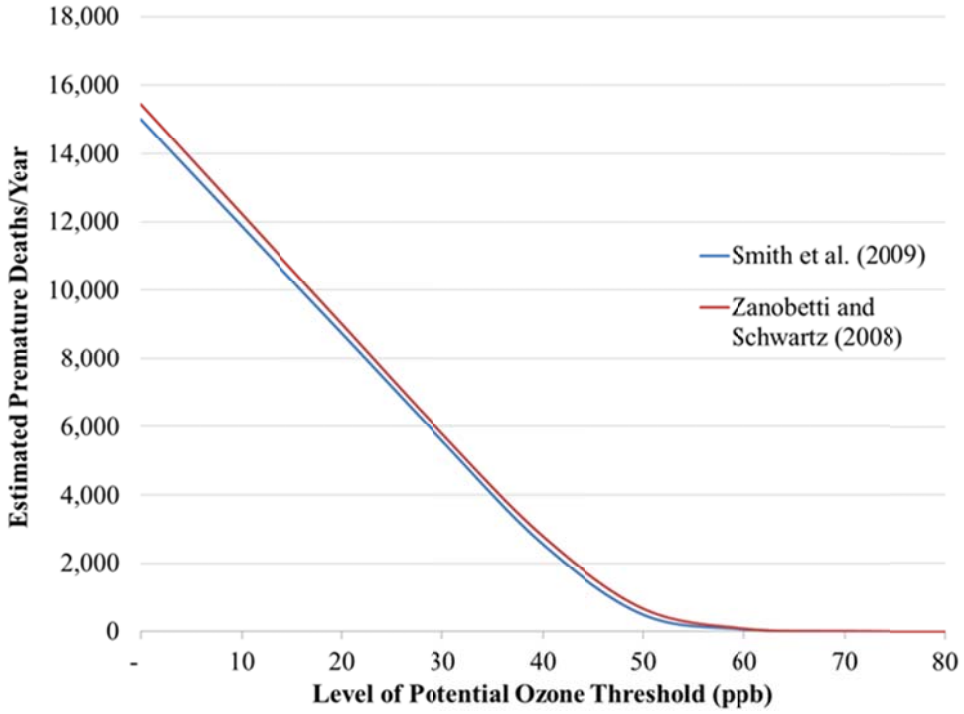
The two sensitivity curves in Figure 4 are essentially parallel, which implies that the sensitivity is nearly identical whether using the Smith *et al.* (2009) or the Zanobetti and Schwartz (2008) study, even though those respective risk estimates are calculated using different data.[36]

[34] EPA, 2014a, Table 8-1, p. 8-7. EPA has rounded these risk estimates to two significant digits. The precise results do differ for the two different studies.

[35] For the short-term mortality estimates, potential threshold levels are in units of daily 8-hour maximum concentrations. Sensitivity analyses for EPA's national-level risk estimates cannot literally apply a threshold at the daily level, as EPA used only an average of the daily ozone levels for each grid cell in the U.S. However, this does not affect the pattern of sensitivity found for the urban study areas that did use daily ozone concentrations.

[36] Each calculation uses a different national effect estimate, as reported in the HREA, and applies them to different ozone concentration metrics, as was done in the HREA. For Smith *et al.*, the ozone levels are the May to September average of the daily 8-hour maximum ozone. For Zanobetti and Schwartz, the ozone levels are the June to August average of the daily mean ozone in the hours 10 am through 6 pm. The air quality data, and the calculations of risk, are disaggregated to a 12 km by 12 km grid over the U.S. in both the HREA calculations, and in our sensitivity analyses.

Figure 4. Sensitivity of National Short-Term Ozone Mortality Risk Estimates to Alternative Threshold Assumptions
(Calculations use average ozone concentrations during 2006-2008, and national average effect estimates from Smith *et al.*, 2009, and Zanobetti and Schwartz, 2008)



Quantitative Sensitivities to Threshold Assumption of Epidemiology-Based Morbidity Risk Estimates

We have also replicated the HREA estimates for the major morbidity endpoints that the Proposed Rule describes: respiratory-related hospital admissions and emergency room visits. (These risk estimates are reported in Table 7-9 and Table 7-10 of the HREA.) We then calculated risks for those morbidity endpoints with potential thresholds assumed at 20 ppb and 40 ppb. These impacts are equivalently sensitive to potential thresholds.

The full results for every alternative standard level, and for zero, 20 ppb and 40 ppb thresholds are provided in Appendix A. Key insights of those detailed results are summarized with Table 3 and Table 4. These summary tables reveal that if a threshold in the range of 40 ppb exists, the major morbidity impacts projected to be associated with the current standard of 75 ppb are reduced on average by nearly 90%. Large reduction occurs for both simulation years, and for every concentration-response relationship, and in all locations analyzed.

The method of estimating risks for morbidity endpoints using epidemiology-based concentration-response functions is the same as the method for estimating short-term mortality risks. Thus, it is unsurprising that the various morbidity impacts reported in the HREA are equivalently sensitive to potential thresholds of effect.

Table 3. Percentage Reductions in Short-Term O_3-Attributable Morbidity at the Current Standard with a 40ppb Threshold: Respiratory-Related Hospital Admissions

Percentage Reduction for each Simulation Year	Simulation Year	
Endpoint/Study Area/Descriptor	**2007**	**2009**
HA (respiratory); Detroit (Katsouyanni et al., 2009)		
1hr max, penalized splines	76%	81%
1hr max, natural splines	76%	81%
HA (respiratory); NYC (Silverman and Ito, 2010; Lin et al.; 2008)		
HA Chronic Lung Disease (Lin)	86%	87%
HA Asthma (Silverman)	87%	87%
HA Asthma, PM2.5 (Silverman)	88%	88%
HA (respiratory); LA (Linn et al., 2000)		
1hr max, penalized splines	95%	95%
HA (COPD less asthma); all 12 study areas (Medina-Ramon, et al., 2006)		
Atlanta, GA	81%	87%
Baltimore, MD	79%	88%
Boston, MA	86%	92%
Cleveland, OH	84%	89%
Denver, OH	73%	77%
Detroit, MI	82%	87%
Houston, TX	91%	88%
Los Angeles, CA	78%	78%
New York, NY	88%	91%
Philadelphia, PA	81%	88%
Sacramento, CA	85%	85%
St. Louis, MO	80%	84%

Table 4. Percentage Reductions in Short-Term O_3-Attributable Morbidity at the Current Standard with a 40ppb Threshold: Emergency Room Visits

Percentage Reduction for each Simulation Year	Simulation Year	
Endpoint/Study Area/Descriptor	**2007**	**2009**
ER Visits (respiratory); Atlanta (Strickland et al., 2007)		
Distributed lag 0-7 days	81%	88%
Average day lag 0-2	81%	88%
ER Visits (respiratory); Atlanta (Tolbert et al., 2007, Darrow et al., 2011)		
Tolbert	82%	87%
Tolbert-CO	82%	87%
Tolbert-NO2	82%	88%
Tolbert-PM10	82%	88%
Tolbert-PM10, NO2	82%	88%
Darrow	82%	88%
ER Visits (asthma); NYC (Ito et al., 2007)		
Single Pollutant Model	88%	89%
PM2.5	88%	89%
NO2	88%	89%
CO	88%	88%
SO2	88%	89%

IV. Sensitivities and Issues with the RIA's Estimates of the Ozone-Related Benefits from Tighter Standards

The RIA reports benefits and costs of the alternative proposed NAAQS, relative to the current NAAQS of 75 ppb. The estimates of ozone-related health benefits in the RIA are derived using the same risk calculations as the HREA. The main difference is that after it reports its estimates of changes in risk for each endpoint, the RIA also translates them into monetized form, which are called "benefits." (The monetization is intended to reflect the societal value of reducing the impact from each type of endpoint, otherwise known as the population's willingness to pay to obtain those risk reductions.)

The RIA's Benefits Estimates are Inconsistent with the Proposed Rule's Assessment

Before discussing the benefits estimates in the RIA themselves, we first note that the benefit estimates in the RIA are calculated in a manner that is inconsistent with what the Proposed Rule considers to be the locus of greatest confidence in the benefits of tightening the ozone NAAQS.

The Proposed Rule emphasizes that the primary rationale for tightening the ozone NAAQS is based on clinical evidence of lung function effects, and that epidemiology-based risk estimates are too uncertain to be given as much weight in the NAAQS decision. Nevertheless, the RIA's ozone-related benefits estimates are completely dominated by estimated short-term mortality risk.[37] (Although the RIA does quantify multiple types of morbidity endpoints, including hospitalizations, emergency room visits, school absence days, and asthma attacks,[38] it finds that all of those morbidity impacts account for less than about 4% to 6% of total benefits.[39])

If the RIA *were* to have estimated lung function decrements and given them the primary emphasis, consistent with the Proposed Rule, the RIA's ozone-related health benefits would have been close to zero. This is because only a fraction of those predicted decrements might manifest themselves as actual experiences of adverse effects, and any such adverse effects are expected to be transient and reversible. The epidemiology-based estimates of asthma attacks that have been quantified in this RIA may be closest conceptually to potential benefits from lung function decrements. The RIA notes that

[37] In this RIA, each reduction of one expected premature death in 2025 is valued at $10 million stated in 2011$ (EPA, 2014b, Table 5-10, p. 5-57).

[38] EPA, 2014b, Table 5-3, p. 5-6.

[39] *Ibid*., Footnote a of Table 5-20, p. 5-79.

these benefits are "<<1%" of the total benefits,[40] which suggests a benefit of substantially less than $20 million per year.

The rest of this section explains why the upper end of the range of ozone-related benefits is overstated even under a no-threshold assumption. It then provides estimates of the sensitivity of the RIA's benefits estimates to potential thresholds, which are not included in the range of potential benefits estimates reported in the document. It concludes by showing that ozone-related benefits – under any threshold assumption – are less than the costs for each alternative potential NAAQS.

The Upper Ends of the RIA's Ozone-Related Benefits Estimates Are Incorrectly Calculated and Overstated as a Result of the Error

Table 5-19 of the RIA presents estimated reductions in short-term mortality health impacts from ozone associated with each alternative standard in 2025 (relative to the current standard of 75 ppb).[41] Table 5-20 of the RIA restates those ozone-related mortality risk reductions in the monetized form that RIAs call "benefits."[42] All of these calculations assume zero possibility of any effects threshold. Table 5-20 reports that attainment of a 70 ppb standard would produce societal ozone-related health benefits of between $2.0 billion and $3.4 billion per year compared to the current standard. The lower bound is based on national average effects estimates from Smith *et al.* (2009) and the upper bound is based on national average effects estimates from Zanobetti and Schwartz (2008).

In replicating the RIA's benefits estimates, we found that its short-term mortality estimates at the current 75 ppb NAAQS using the Zanobetti and Schwartz effect estimate (which determine the upper end of the RIA's benefits range) are larger than the same risk calculation presented for recent (2006-2008) conditions in the HREA. They should have been lower, because recent conditions were, in places, above the current standard, and also because ozone is projected to be lower by 2025 than in 2006-2008 in most parts of the U.S. This indicated an inconsistency between the RIA's benefits calculations and the risk estimates that were approved by the Clean Air Science Advisory Committee (CASAC). Checking the audit trail of the BenMAP model runs that EPA used to perform its benefits estimates, we discovered that the RIA's benefits

[40] *Ibid*.

[41] Benefits and costs estimated for 2025 exclude costs and benefits that may occur for California, which EPA assumes will not occur until after 2030. This section will discuss only the 2025 cost and benefit estimates to make its points without unnecessary complexity. Its key points are not altered if also considering the post-2025 costs and benefits reported for California.

[42] Table 3-20 also adds in some unreported quantity of benefits from estimated changes in all the morbidity endpoints that are about 4% to 6% of the total benefits (see footnote a of Table 5-20 in EPA, 2014b, p. 5-79).

estimates based on Zanobetti and Schwartz-based estimates are incorrect, with the error creating a substantial upward bias.[43] An approximate correction of that calculation produces absolute risk estimates nearly 40% lower than in the RIA analysis,[44] which are then very similar to those for the lower bound benefits estimates based on Smith *et al.* This is what one would expect, because use of those two studies resulted in similar levels of national risk estimates in the HREA' s analyses, as can be seen in Figure 4 above, or confirmed by referring to Chapter 8 of the HREA.

Thus, the high end estimates of ozone-related benefits in the RIA are not calculated in a valid manner, and should be discarded. This leaves only one set of usable ozone-related benefits estimates in the RIA, which are those based on Smith *et al.* Those ozone-related benefits estimates, which assume *no-threshold for all mortality and morbidity concentration-response functions*, project annual ozone-related benefits in 2025 of:

- $2.0 billion to attain a 70 ppb NAAQS, for a cost of $3.9 billion/year;
- $6.4 billion to attain a 65 ppb NAAQS, for a cost of $15 billion/year; and
- $12.0 billion to attain a 60 ppb NAAQS, for a cost of $39 billion/year.[45]

For the remainder of our RIA benefits discussion we will emphasize RIA calculations using the Smith *et al.* (2009) concentration-response function. Nevertheless, the sensitivities that we report below are very similar in a proportional sense for both sets of risk estimates (again, as Figure 4 makes evident).

The RIA's Ozone-Related Benefits Estimates Are Reduced When Potential Effects Thresholds Are Considered

The absolute levels of risk estimated in the RIA are just as sensitive to potential thresholds as shown for the HREA's estimates in the prior section, which is unsurprising given that the same calculation method is being applied. However, in the RIA, "benefits"

[43] Specifically, the RIA's benefits calculations apply the effect estimates from Zanobetti and Schwarz to the months of May through September, even though they are only applicable to the months of June through August.

[44] We computed this by re-running EPA's BenMAP calculations applying June through August as the applicable time period for the Zanobetti and Schwartz concentration-response function (consistent with the original epidemiology study, and consistent with how the HREA calculations were done) in place of May through September, as the RIA BenMAP runs did. A precise correction would require an air quality grid for average ozone levels during the months of June through August, which EPA has not produced, but needed to have produced in order to use Zanobetti and Schwartz in its RIA benefits calculations.

[45] EPA, 2014b (Table 5-20 for ozone-only benefits, p. 5-79, Table ES-6, p. ES-14 for costs). Although these benefits estimates include morbidity as well as mortality, the morbidity benefits account for only about 4% to 6% of the total.

are stated in terms of *differences* in estimated risk between the current ozone standard and each of the alternative standards. Our analysis below shows the sensitivity of both absolute levels of risk and differences in risks.

Although the absolute ozone-related mortality risk estimates are not reported in the RIA, we have computed them in the course of replicating the differences in them that the RIA does report. Figure 5 shows maps of the percent of all-cause mortality across the U.S. that is being assumed to be attributable to ozone at the current 75 ppb ozone NAAQS in the RIA's benefits calculations (using the Smith *et al.*, 2009, national average risk coefficients). Panel (A) shows the assumptions in the RIA that are based on no threshold, while Panel (B) shows how different those implicit risk estimates would be (again stated as percent of mortality that is attributed to ozone at the 75 ppb NAAQS) if there is a 40 ppb threshold. As was found for long-term mortality, the sensitivity of the underlying short-term mortality risk estimates also is large.

One may also question the realism of the inference that more than 2% percent of all non-accidental deaths would be attributable to acute ozone exposures over the majority of the U.S. when the current standard of 75 ppb is attained. This, however, is the implication when the no-threshold assumption is applied, as can be seen from Panel (A) of Figure 5. If a threshold in the range of 40 ppb exists in that epidemiology-based mortality risk estimate, a much lower percent of total non-accidental mortality is projected to be attributable to acute ozone exposures: 0% in many areas, and overall less than 1% except in some parts of Southern California. Information such as this provides useful context for understanding the implications of certain assumptions such as whether or not there might be a threshold at some relatively low ozone concentration.[46]

The absolute risk estimates in the RIA are just as sensitive to alternative threshold levels as the prior section has shown them to be for the HREA risk estimates. That sensitivity, stated as percentage variation under alternative threshold assumptions, is somewhat diminished when considering *differences* across standards, as is done in the RIA. The sensitivity of benefits (and changes in risk) is reported in Table 5 for an alternative threshold level of 40 ppb, compared to the no-threshold benefits estimates reported in the RIA. The table shows short-term mortality benefits only, but the 4% to 6% of total benefits due to morbidity that are not shown would respond to alternative threshold assumptions in a similar manner, as we demonstrated in the prior section of these comments when considering the sensitivity of the HREA's morbidity risk estimates. (For Table 5, we allow the incorrect calculations of Zanobetti and Schwartz to be

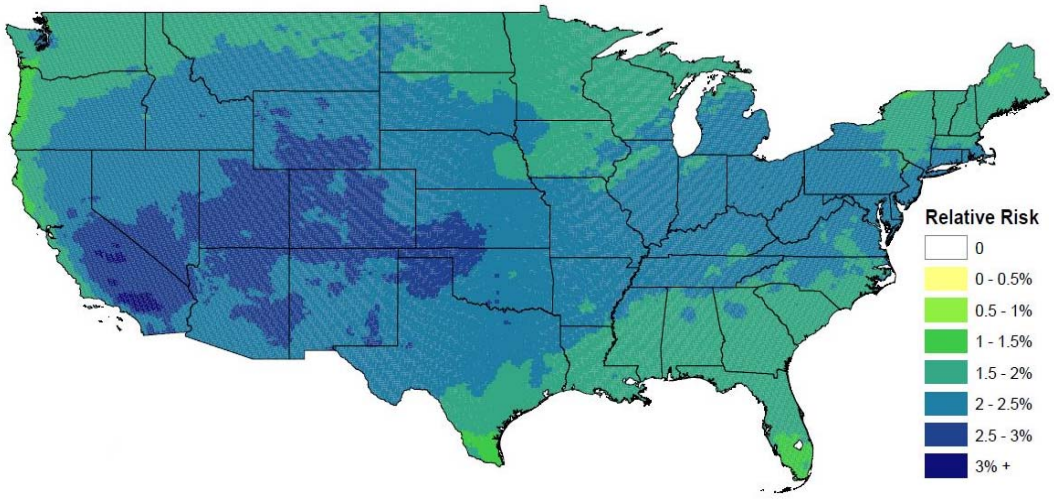
[46] The Proposed Rule cannot obtain this from the HREA because that document does not provide any estimates of ozone concentrations across the U.S. under the current 75 ppb standard.

perpetuated. If we were to present them corrected, they would be very similar in every regard to the results shown for Smith *et al*.)

Figure 5. RIA's Estimates of Percent of Short-Term Mortality Attributable to Ozone under the 75 ppb Standard in 2025 (A) with No Threshold Assumed and (B) with a 40 ppb Threshold (Using national average effect estimate of Smith *et al.*, 2009)

(These results are for the RIA's 2025 scenario, in which California does not yet attain the 75 ppb standard)

A. No Threshold



B. With a 40 ppb Threshold

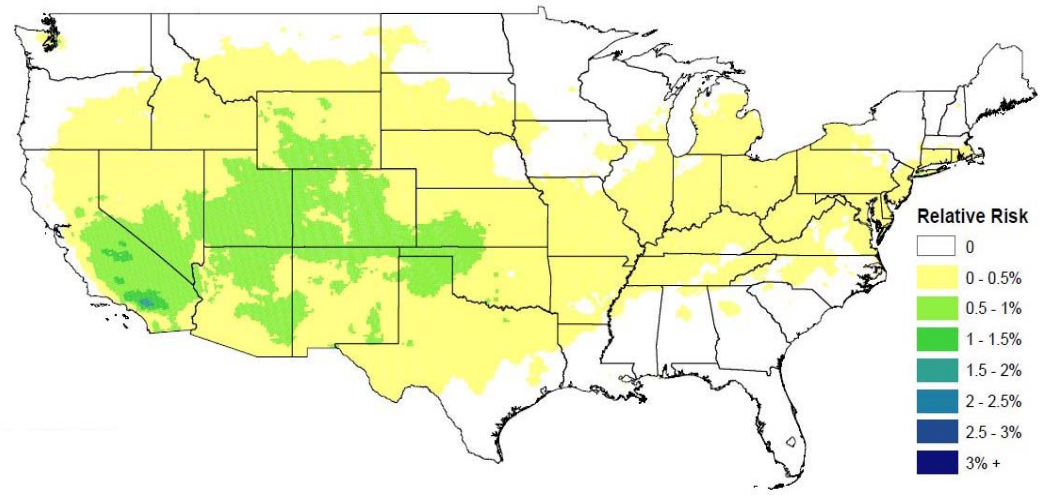


Table 5. Estimated Avoided Ozone-Related Mortality Impacts (premature deaths per year) and Benefits (millions of $2011 per year) for Alternative Annual Ozone Standards for the Year 2025 (*i.e.*, excluding post-2025 benefits in California)

(Note that calculations in this table perpetuate the RIA's error in all its Zanobetti and Schwartz-based estimates. When corrected, the results for Zanobetti and Schwartz would be very similar in magnitude to those for Smith *et al.* shown in this table.)

	Threshold	
Endpoint/Study Area/Descriptor	**None**	**40ppb**
Avoided Short-Term Mortality, Deaths, 70ppb Standard		
Zanobetti and Schwartz (2008) (all ages) - *uncorrected*	340	240
Smith et al. (2009) (all ages)	200	150
Avoided Short-Term Mortality, Deaths, 65ppb Standard		
Zanobetti and Schwartz (2008) (all ages) - *uncorrected*	1,000	720
Smith et al. (2009) (all ages)	630	430
Avoided Short-Term Mortality, Deaths, 60ppb Standard		
Zanobetti and Schwartz (2008) (all ages) - *uncorrected*	1,900	1,200
Smith et al. (2009) (all ages)	1,100	700
Avoided Short-Term Mortality, Total Monetized Benefits, 70ppb Standard		
Zanobetti and Schwartz (2008) (all ages) - *uncorrected*	$3,300	$2,400
Smith et al. (2009) (all ages)	$2,000	$1,400
Avoided Short-Term Mortality, Total Monetized Benefits, 65ppb Standard		
Zanobetti and Schwartz (2008) (all ages) - *uncorrected*	$10,000	$7,100
Smith et al. (2009) (all ages)	$6,200	$4,300
Avoided Short-Term Mortality, Total Monetized Benefits, 60ppb Standard		
Zanobetti and Schwartz (2008) (all ages) - *uncorrected*	$19,000	$12,000
Smith et al. (2009) (all ages)	$11,000	$6,900

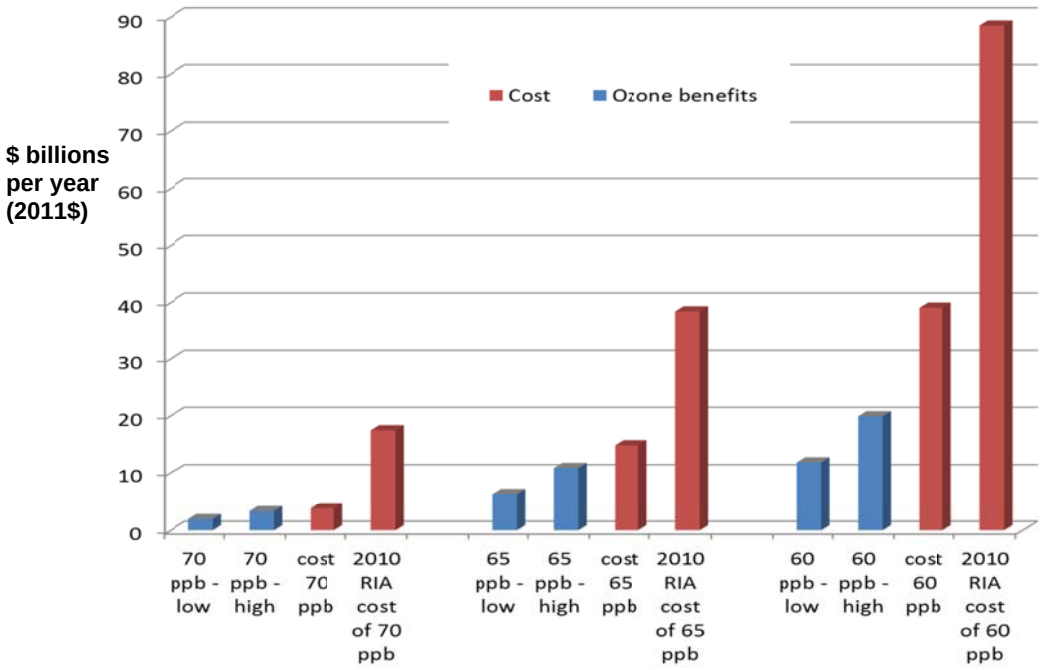
In brief, the ozone-related benefits in the RIA are reduced by 30% to 40% if a threshold in the range of 40 ppb were to be assumed for the short-term mortality-ozone relationship, whether stated as incidence (top panel of Table 5) or as monetized benefits (bottom panel of Table 5). For example, whereas the RIA has reported benefits for attaining a 70 ppb NAAQS of $2.0 to $3.4 billion per year, a threshold of 40 ppb would imply those benefits would be less than $2.5 billion. Further, if the invalid estimates based on Zanobetti and Schwartz are ignored, the benefits of the 70 ppb alternative NAAQS would be less than $1.5 billion per year.

The RIA's Own Estimates of Ozone-Related Benefits Are Less than the Estimated Costs of Each Alternative NAAQS Level

Thus, the RIA provides high and low estimates of ozone-related benefits for which the high end estimate is found to be incorrectly calculated, and when correctly calculated is very close in magnitude to the low estimates. Both estimates are overstated due to lack of consideration of potential effects thresholds. Without attempting to correct for either overstatement/error, Figure 6 compares the RIA's own ozone-related benefits range to its estimates of the cost for each alternative standard included in the RIA. The

benefits range is reflected by the two blue bars for each alternative standard in the figure.[47] This figure shows that the ozone-related benefits of each of the alternative potential rules are less than their costs. The closest these comparisons come to breakeven is for the 70 ppb NAAQS when the incorrectly-high benefits estimate is compared to the RIA's policy cost estimate. In that case, the high end of the benefits range is $3.4 billion per year, while the RIA's cost estimate is $3.9 billion per year (both stated in 2011$). However, as we have explained above, a corrected estimate of the benefit for that standard is about the level of the low estimate, or $2.0 billion per year in the case of the 70 ppb alternative. In short, the ozone-related benefits are substantially less than the costs of even the least stringent of the alternative ozone NAAQS in the Proposed Rule.

Figure 6. Comparison of Estimates of Ozone-Related Benefits and Costs for 3 Alternative Ozone NAAQS (billions of 2011$ per year in 2025, excluding California)
(Source: NERA, using data from EPA, 2014b, Tables ES-6 and 5-1, and from EPA, 2010)



At this point, it becomes important to note that the RIA's benefits estimates would be substantially lower if a potential threshold exists for ozone concentrations, even if that

[47] The lower end of the range is based on a concentration-response relationship from Smith *et al.* (2009), which EPA adopted for its core risk estimates in the HREA. The upper end of the range is based on a concentration-response function from Zanobetti and Schwartz (2008) we have found to be incorrect and too high.

threshold is somewhere below 40 ppb. This sensitivity, due to uncertainty noted in the Proposed Rule to the shape of the concentration-response function, greatly reinforces the likelihood that the ozone-related benefits will be less than the costs of a tighter ozone NAAQS, even for the least stringent option under consideration of a 70 ppb standard.

The RIA shows awareness of the weakness of the Proposed Rules' benefit-cost case. It warns the reader that "it is important to emphasize that it is not appropriate to compare the ozone-only benefits to total costs. There are additional unquantified benefits which are described in Section 5.2."[48] However, that additional discussion of unquantified ozone benefits promised in Section 5-2 consists of a table (RIA Table 5-3) which lists lung function decrements as unquantified, along with a couple of morbidity impacts that seem to be considered only suggestive of causality based on the evidence.[49] Even if these additional impacts were to be quantified and included in the analysis, they would add an inconsequential amount to the ozone-related benefits estimates. Even with multiple other, more significant morbidity endpoints that have been quantified (*i.e.*, hospital admissions for respiratory causes, emergency department visits for asthma, minor restricted activity days, and school absence days), the ozone-related benefits in the current RIA remain completely dominated by short-term mortality risk estimates. Missing unquantified ozone-related benefits cannot be considered a reason to expect that ozone-related benefits might actually exceed the ozone control costs reported in the current RIA.

We also note that the costs of the standards that are reported in this RIA are dramatically lower than EPA had estimated for the same policies in 2010. The right-most bars in the figure show what EPA estimated to be the costs of attaining these same standards in its 2010 RIA for the reconsideration of the 2008 ozone NAAQS (EPA, 2010). The very large decrease in current RIA's policy cost estimates from those in the 2010 RIA led us to question what had changed in the available information. After a careful review of the RIA's cost analyses, NERA (2015b) concludes that the current RIA's cost estimates are unrealistically low. Appendix B to this paper explains reasons why the current RIA's cost estimates should be viewed as unrealistically low.

When the understatement in the current RIA's cost estimates are accounted for, ozone-related benefits fall even further below ozone reduction costs, even for the 70 ppb alternative NAAQS.

[48] EPA, 2014b, pp. 5-2 to 5-3.

[49] *Ibid*., Table 5-3, p. 5-6.

One might then ask, why does the EPA press release for this proposed rule claim such large net benefits, as quoted below:

> *EPA estimates that the benefits of meeting the proposed standards will significantly outweigh the costs. If the standards are finalized, every dollar we invest to meet them will return up to three dollars in health benefits*.[50]

The answer is the use of estimates of "co-benefits" from another pollutant altogether, $PM_{2.5}$.[51] As Smith (2011) shows occurs in many of EPA's non-PM air rule RIAs, the ozone NAAQS RIA's benefit-cost case depends entirely on an appeal to co-benefits from $PM_{2.5}$. The role of co-benefits in both of these rules is discussed in Section V, explaining how those co-benefits are overstated by being calculated using assumptions that are inconsistent with the judgments of the EPA Administrator about where to set a NAAQS.

Long-Term Mortality Risks Should Not Be Included in RIA Benefits Estimates

The RIA for the Proposed Rule has not included any value from projected changes in risks of long-term respiratory mortality in its main benefits estimates. However, the RIA does contain calculations of such benefits, which it reports at the bottom of its final ozone-related benefits table as a "sensitivity analysis."[52] Those estimates are based on the Jerrett *et al.* (2009) model, which we discussed above in Section III. However, those "sensitivity" benefits estimates are entirely based on no-threshold models. This flies in the face of EPA's recognition in the HREA, and repeated in the Proposed Rule, that these risk estimates are highly uncertain, particularly given their sensitivity to potential thresholds that were actually detected in the original paper on which the risk calculation is based. For example, after the Proposed Rule had noted that short-term epidemiology-based risk estimates deserve lower weight than the clinical-based

[50] EPA, "EPA Proposes Smog Standards to Safeguard Americans from Air Pollution," press release, November 26, 2014. Available: http://yosemite.epa.gov/opa/admpress.nsf/596e17d7cac720848525781f0043629e/6ce92be958c8149285257d9c0049562e!OpenDocument.

[51] In response to a question from the press on this matter, an EPA spokesperson also stated that "the benefits of reducing smog-forming emissions outweigh the estimated costs" for every one of the alternative standards analyzed in the RIA (in S. Mintner, "NAM: Manufacturing Resurgence at Risk from Proposed Ozone Rule" *IndustryWeek*, February 26, 2015). This statement is misleading because the co-benefits are based on reductions in NO_x emissions, which are both a "smog-forming" emission, and a *particle-forming* emission. The benefits that outweigh the costs in this statement are not from reductions in smog (*i.e.*, ozone-related benefits) but from reductions in ambient $PM_{2.5}$ (*i.e.*, $PM_{2.5}$ co-benefits). This artful phrasing hides but does not change the fact that the ozone NAAQS RIA's ozone-related benefits are less than its ozone control cost estimates, even for the least stringent alternative of 70 ppb.

[52] See EPA, 2014b, Table 5-20, p. 5-79.

evidence in the decision on the NAAQS, it goes on to state that even lower confidence should be ascribed to the long-term mortality risk estimates:

> *The Administrator further notes the HREA conclusion that lower confidence should be placed in the results of the assessment of respiratory mortality risks associated with long-term O_3 exposures, primarily because that analysis is based on only one study (even though that study is well-designed) and because of the uncertainty in that study regarding the existence and identification of a potential threshold in the concentration-response function (U.S. EPA, 2014a, section 9.6).*[53]

EPA appears poised to include those long-term respiratory mortality benefits in its RIA for the final ozone rule. The fact that the "sensitivity analyses" of those benefits do not even include estimates that account for the likely threshold at 56 ppb (or any other level that was reported in the paper) shows little regard on the part of the authors of the RIA for the serious concerns that the HREA, CASAC, and the Administrator have raised about any risk estimates for that endpoint.

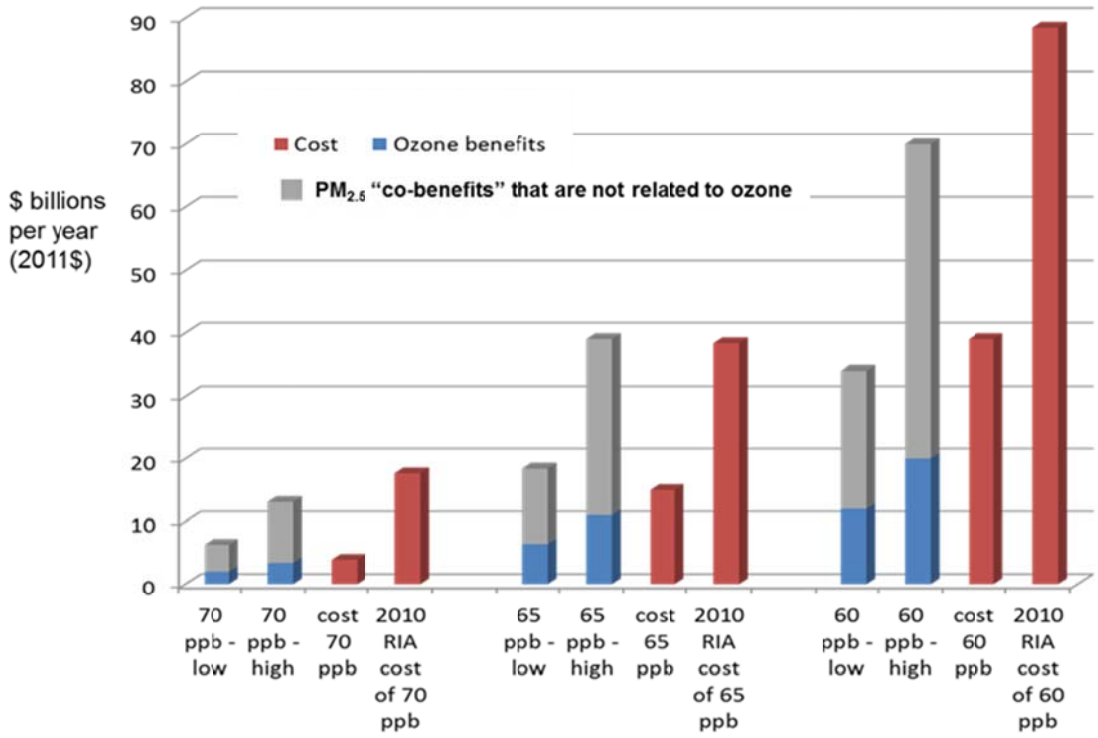
The final RIA, like the current RIA, should adhere to the judgments expressed in all those other EPA and science advisory documents that the epidemiology-based long-term respiratory ozone-mortality risk relationship is unreliable for quantification of benefits, particularly if applied using only the no-threshold model.

[53] 79 *Fed. Reg*. 75234, December 17, 2014, at 75308.

V. $PM_{2.5}$ Co-Benefits Are Overstated and Inappropriate for Inclusion in the RIA

The RIA for the proposed ozone NAAQS projects large co-benefits from coincidental reductions in ambient $PM_{2.5}$ that it projects will result when reducing NO_x emissions to reduce ozone. These co-benefits are larger than the estimates of the ozone NAAQS's actual own direct (*i.e.*, ozone-related) benefits. Figure 7 adds the ozone NAAQS RIA's estimates of co-benefits from $PM_{2.5}$ to Figure 6 (*i.e.,* co-benefits are shown as the grey shaded portions of the benefits bars, stacked on top of the blue bars from Figure 6 that show the ozone benefits). As Figure 7 shows, the co-benefits estimates in the ozone NAAQS RIA are much larger than the ozone rule's estimated ozone benefits. Only when the co-benefits are included in the analysis do the benefits of the alternative ozone NAAQS levels appear to exceed their costs.[54]

Figure 7. Comparison of Benefits and Costs in EPA's Ozone NAAQS RIA with $PM_{2.5}$ Co-Benefits Included (billions of 2011$ per year in 2025, excluding California)
(Source: NERA, using data from EPA, 2014b, Tables ES-6 and 5-1, and from EPA, 2010)



[54] If the more evidence-based costs estimates that NERA has produced (which are described in Appendix B) were to be used, none of the alternative ozone NAAQS options would have benefits exceeding their costs, *even if the $PM_{2.5}$ co-benefits are included*.

It is by comparing the height of the bars showing ozone benefits plus $PM_{2.5}$ co-benefits to the current ozone RIA's (understated) cost estimates (the left-most red bar) that the EPA press release comes up with its assertion that the Proposed Rule's benefits exceed its costs by up to three to one. In fact, that three-to-one ratio is only achieved for the 70 ppb standard, and then only when comparing the *high* end estimate of bars with co-benefits to the current ozone RIA's (understated) cost estimate.

There are many reasons to doubt the validity of these co-benefits estimates, however. As is explained next, they are all vastly overstated, and should be viewed as nearly zero on an expected value basis. That is the most important reason that these co-benefits estimates should be given no weight. However, there are also serious limitations in the method by which they have been calculated, and serious reasons why they do not belong in the ozone RIA. These are also discussed in the remainder of this section.

The Overstatement in the $PM_{2.5}$ Co-Benefits Estimates

All of the estimated health co-benefits in the current ozone RIA are attributed to a subsidiary effect of the reductions in NO_x emissions projected to occur in order to attain each alternative ozone NAAQS. While reducing ambient ozone, one can also expect some reductions in ambient nitrate, which is one of the constituents of ambient $PM_{2.5.}$ $PM_{2.5}$ is a criteria pollutant that is already subject to its own Federal health standards -- *i.e.*, its own respective NAAQS. As with the ozone NAAQS, the $PM_{2.5}$ NAAQS must be (and has been) set at a level that protects the public health from a criteria pollutant with an adequate margin of safety. The current $PM_{2.5}$ NAAQS was set in December 2012, when the annual average limit for $PM_{2.5}$ was lowered to 12 $\mu g/m^3$.

Although a health-based NAAQS is not considered to be free of any remaining health risk, it *is* considered to be stringent enough that EPA lacks confidence that further reductions in ambient concentrations will produce public health benefits. Although epidemiology-based risk estimates that simply *assume* no threshold will always continue to project benefits from emissions reductions until ambient concentrations are literally zero, the Administrator is mindful of limitations in the nature of the epidemiological evidence. The NAAQS is set at a level where those limitations are so pronounced that there is a lack of confidence that those statistical associations continue to exist at lower levels. The Administrator's articulation of this lack of confidence can be found in many parts of the preamble of the Final Rule for the current $PM_{2.5}$ NAAQS; for example, it states:

> *In reaching decisions on alternative standard levels to propose, the Administrator judged that it was most appropriate to examine where the evidence of associations observed in the epidemiological studies was*

> *strongest and, conversely, where she had appreciably less confidence in the associations observed in the epidemiological studies.*[55]

In reference to information on the ranges of $PM_{2.5}$ concentrations that were used in the epidemiological studies that were deemed part of the evidence supporting tightening the annual $PM_{2.5}$ NAAQS to 12 μg/m^3, the preamble also notes:

> *The Administrator views this information as helpful in guiding her determination as to where her confidence in the magnitude and significance of the associations is reduced to such a degree that a standard set at a lower level would not be warranted to provide requisite protection that is neither more nor less than needed to provide an adequate margin of safety.*[56]

In other words, epidemiology-based quantitative estimates of risk from concentrations below the selected NAAQS level are not credible. They are not credible because they give full weight to the assumption that those associations continue to exist, while EPA's science-based review of the evidence concludes that that assumption should be given no further weight.

"No weight" is equivalent to saying that quantitative but epidemiology-based risk estimates that are attributable to concentrations already below a NAAQS should be ignored for public health protection purposes. By extension, it also means that estimates of risk reduction (or benefits) from *changes* in concentrations that are already below a NAAQS should also be given no weight. In the parlance of risk assessment, those risks have a much lower *expected* value than what is calculated by assigning full weight to the no-threshold, linear continuation of the association to zero.

The above points are noteworthy because all of the co-benefits estimates in the ozone RIA are due to projected changes in $PM_{2.5}$ in areas already attaining that $PM_{2.5}$ NAAQS. Thus, those co-benefits estimates are vastly overstated, and may be zero.

We know those co-benefits calculations are entirely attributable to $PM_{2.5}$ that is in attainment with its NAAQS from information in the RIA for the $PM_{2.5}$ NAAQS (EPA, 2012). In that RIA, all areas of the U.S. except Southern California were projected to be in attainment with the $PM_{2.5}$ NAAQS of 12 μg/m^3 by 2020 even under baseline conditions.[57] These are the very conditions under which the Administrator has said that

[55] 78 *Fed. Reg*. 3086, January 15, 2013 at 3139.

[56] *Ibid*. at 3161.

[57] EPA, 2012, p. ES-7. The "baseline" in an RIA includes the effect of all regulations promulgated at the time of that RIA analysis. Additional regulations promulgated since 2012 would only further reduce ambient $PM_{2.5}$

confidence in the health-$PM_{2.5}$ relationships is reduced to such a degree that no tighter standard is warranted; however, all the co-benefits estimates for 2025 (shown in Figure 7) are calculated by assuming 100% certainty in the continued existence of those $PM_{2.5}$ relationships far below the level of the NAAQS. This is logical inconsistency; if the Administrator properly set the $PM_{2.5}$ NAAQS, all of those co-benefits estimates are, at best, major overstatements.

We also note that even if the co-benefits were attributable to $PM_{2.5}$ above its NAAQS, we note that all of those estimates are predicated on a presumption that the statistical ("epidemiological") associations between chronic ambient $PM_{2.5}$ concentrations and mortality risk are causal in nature, and that all $PM_{2.5}$ constituents are equally potent. In regards to the presumption of causality, even that is still subject to question, as has been demonstrated by a $PM_{2.5}$ chronic risk study published in 2011 (Greven *et al.*, 2011).[58] Uncertainty about causality means there is a possibility that there will be no benefits at all from reductions of $PM_{2.5}$, whether above or below the NAAQS, and that makes the reported numerical value of risk higher than its expected value.

An additional reason to infer that this RIA's co-benefits are overstated (even if they were attributable to $PM_{2.5}$ above its NAAQS) is the risk calculation's assumption that all $PM_{2.5}$ constituents are equally potent. Even EPA notes this as an important uncertainty.[59] It is a particularly relevant concern in the case of the ozone RIA, because all of its $PM_{2.5}$ co-benefits are tied solely to changes in just one constituent of $PM_{2.5}$, the nitrate constituent (which results, under certain atmospheric conditions) from NO_x emissions. There is no evidence that nitrates are the potent constituent within the ambient $PM_{2.5}$ mass. Indeed, in most of the U.S. where these co-benefits are being calculated, it is a minor fraction of the ambient mass. EPA has never performed any sensitivity analyses on how its benefits estimates may differ under different assumptions about the relative potency of the various $PM_{2.5}$ constituents; an analysis in Smith and Gans (2015) finds that EPA's equal potency assumption overstates the risk that might be the actual case under multiple alternative possibilities about relative potencies. In this particular case, it is a matter of simple logic: if nitrate itself does not explain the observed statistical associations between mortality and total mass of ambient, then there will be no $PM_{2.5}$-related mortality reduction from the reduction on NO_x emissions, and the co-benefits in the ozone NAAQS RIA will actually be zero.

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concentrations that would constitute the baseline conditions for the current ozone RIA. Thus, all co-incidental reductions in $PM_{2.5}$ concentrations that this ozone RIA is attributing to NO_x reductions in 2025 clearly would occur in locations that will be below the $PM_{2.5}$ NAAQS.

[58] EPA's science assessment for the $PM_{2.5}$ NAAQS, which is the source of EPA's assertion that the chronic mortality risk associations are causal, was written before the 2011 paper was published

[59] EPA, 2014b, p. 5-88.

An Overly Simplistic Calculation Method Further Undercuts the Credibility of These Co-Benefits Estimates

Besides the overstatements described in the prior section, EPA uses a very simplistic method to make its co-benefits calculations in the current RIA that further undercuts their credibility. In this RIA, EPA uses rough average "$/ton multipliers" to approximate the co-benefit from each ton of reduction in NO_x emission.

Such simplistic $/ton estimates are unable to account for the level of criteria pollutant in the areas where this RIA's tons are reduced. Instead, they were calculated by considering changes in NO_x emissions under a different ambient baseline in a different year (2016, not 2025).[60] EPA does not even develop a baseline projection of the $PM_{2.5}$ levels against which the projected 2025 coincidental precursor emission reductions are assumed to occur. Nevertheless, as noted in the prior section, we can infer from the $PM_{2.5}$ NAAQS RIA (EPA, 2012) that baseline ambient $PM_{2.5}$ in 2025 will be below the annual $PM_{2.5}$ NAAQS in all the parts of the country for which the 2025 co-benefits are being calculated.

Additional uncertainties affect the usefulness of the $/ton approach. For one, the RIA does not consider whether the formation of nitrate from a given ton of NO_x in that 2016 baseline would be higher or lower than by 2025, and under the dramatically different atmospheric chemistry associated with very tight alternative ozone NAAQS. Thus, the benefits per ton of NO_x reduction may be very different from EPA's method of deriving those multipliers.

It also cannot be known if the benefits estimated for the NO_x changes that were applied in the 2016 analysis that was used to generate the $/ton multipliers would be comparable to the NO_x changes that are projected to occur under the ozone NAAQS in 2025. The $/ton multiplier calculation reduced NO_x emissions uniformly across all facilities in the U.S. in a particular sector, calculated the $PM_{2.5}$-related benefits from those U.S.-wide reductions (which were based on locations of emitters in 2016) and divided by the tons. In the case of the ozone NAAQS RIA, EPA applies those $/ton multipliers to estimates of the tons projected to be reduced from each respective sector in 2025 as part of an ozone attainment need. The latter tons are not geographically the same as the reductions assumed to calculate the $/ton estimates.[61] We know that those NO_x reductions do not occur uniformly across the U.S. They are concentrated in states that have the most severe ozone attainment problems. Those states may not be

[60] *Ibid*., p. 5-18.

[61] *Ibid*., p. 5-19. ("The benefit-per-ton estimates used here reflect specific geographic patterns of emissions reductions and specific air quality and benefits modeling assumptions associated with the derivation of those estimates.")

representative of the U.S.-wide distribution of NO_x emissions for each respective sector. As a result, the average population-exposure impact of ambient $PM_{2.5}$ reductions under the ozone NAAQS attainment scenarios may be very different from that which was estimated when calculating the $/ton estimates.

Additionally, it is likely that the NO_X emissions that serve as the basis for the co-benefits will increase in some locations, while decreasing in others. This may happen in any sector, if productive activity in a given sector migrates to areas not facing an equivalent pressure to control ozone precursor emissions.[62] However, the RIA does not explore this possibility at all. The only changes in NO_x are the reductions projected in areas that have attainment needs. Unaccounted geographical redistribution of NO_x emissions changes would reduce the RIA's total co-benefits estimates.

These create large uncertainties in an already dubious and uncertain risk analysis process. Given that all of these co-benefits estimates occur below the current $PM_{2.5}$ NAAQS, where EPA says it has no confidence that the underlying statistical associations continue to exist, these additional sources of serious errors give further reason to ignore the co-benefits estimates in the ozone RIA.

Co-Benefits of Already-Regulated Pollutants Should Not Justify Regulations of Other Types of Pollutants

To the extent that any of the $PM_{2.5}$ co-benefits might result from exposures to baseline levels that exceed the $PM_{2.5}$ NAAQS, they will be eliminated by compliance programs to ensure attainment with that NAAQS; this portion of co-benefits (if any exist at all) should be attributed to the $PM_{2.5}$ NAAQS, because they will be enforced even without the other, non-PM regulation.

As we have noted, none of the co-benefits in the ozone NAAQS RIA fall into this category. However, even if individuals other than the EPA Administrator were to claim confidence in the continued existence of the health-pollutant relationships for $PM_{2.5}$ far below the "adequate margin of safety" that a NAAQS is supposed to provide, to let regulations for totally different types of pollution issues be justified based on such co-benefits is a recipe for an unnecessarily complex web of air regulations that can only lead to economically inefficient management of the public health.

For this reason, the co-benefits of already-regulated pollutants such as the criteria pollutants should not be included as benefits in regulations that are intended to manage

[62] Such locational shifts in emissions is a very readily observable result of policies that constrain emissions from the electricity generating system (as is the case with the ozone NAAQS). As some generating units are shut down as part of a SIP, others that do not shut down may increase their generation to make up for the lost load.

altogether different risks, such as climate change. The merits of the proposed ozone NAAQS should be evaluated based on its ozone-related benefits.

A more complete discussion of the points made in this section can be found in Smith (2011).

VI. Conclusions

These comments have focused on the uncertainties and limitations in the inferences that can be drawn from the epidemiology-based risks estimates for purposes of deciding where to set the level of the ozone NAAQS. The Proposed Rule notes the high degree of uncertainty in epidemiology-based risk estimates, including due to lack of clarity about the shape of the concentration-response functions. However, the Proposed Rule is working from risk estimates in the HREA that do not fully characterize the sensitivity of its risk estimates to that very concern.

The HREA has provided a sensitivity analysis to uncertainties in the shape of the concentration-response function for its long-term mortality risk estimates, and the Proposed Rule duly notes that those sensitivities suggest that those risk estimates should be given especially limited weight in setting the NAAQS. However, the HREA does not offer similar sensitivities for the other important epidemiology-based risk estimates, such as short-term mortality, hospitalizations and emergency room visits. Although it attempts to create such insight from details of the short-term mortality risk estimates in the HREA, the Proposed Rule misinterprets the evidence that it summarizes. In fact, the HREA simply does not contain the types of sensitivity analyses that the Administrator needs. In these comments, we have explained the degree of uncertainty in the shape of those short-term concentration-response functions, particularly for exposures below about 40 ppb (8-hour daily maximum), and we have provided quantitative summaries of the sensitivity of the short-term mortality and morbidity risk estimates to this important source of uncertainty.

We find that the short-term epidemiology-based risk estimates are almost as unreliable in the face of uncertainty about shape of concentration-response functions as are the long-term mortality risk estimates. This information has great relevance to the weight that these risk estimates should be given in the final NAAQS decision.

We also note that the benefits estimates that are provided in the RIA do not mirror the importance that the Proposed Rule places on different types of scientific evidence concerning ozone's health impacts. Whereas potential lung function responses (and the potential for adverse effects from such responses) is the central motivator of potentially tightening the ozone NAAQS in the Proposed Rule, the RIA reports estimates of benefits that are solely based on short-term mortality risks, and it gives full weight to such risk estimates, without any consideration of the uncertainties associated with their epidemiological underpinnings that are noted in the Proposed Rule.

Despite the unwarranted weight that the RIA assigns to no-threshold short-term mortality in estimating the benefits of tightening the ozone NAAQS, it does not find that the ozone-related benefits would outweigh their societal costs, even when comparing

upper bound benefits estimates to understated cost estimates. Incorporation of any possibility that a threshold may exist in those short-term mortality relationships would reduce the estimated ozone-related benefits of each alternative standard level, and widen the gap between those benefits and the cost of attaining them.

Appendix A.

Detailed Tables of Impact of Thresholds on Morbidity Counts

Table 6. Short-Term O_3-Attributable Morbidity Counts for Various Thresholds, Respiratory-Related Hospital Admissions, 2007 and 2009 Air Quality, 75ppb Standard

2007 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
HA (respiratory); Detroit (Katsouyanni et al., 2009)			
1hr max, penalized splines	190	110	45
1hr max, natural splines	180	110	43
HA (respiratory); NYC (Silverman and Ito, 2010; Lin et al.; 2008)			
HA Chronic Lung Disease (Lin)	140	80	20
HA Asthma (Silverman)	490	280	63
HA Asthma, PM2.5 (Silverman)	360	200	45
HA (respiratory); LA (Linn et al., 2000)			
1hr max, penalized splines	480	250	23
HA (COPD less asthma); all 12 study areas (Medina-Ramon, et al., 2006)			
Atlanta, GA	55	32	11
Baltimore, MD	40	24	8
Boston, MA	58	30	8
Cleveland, OH	37	21	6
Denver, OH	18	11	5
Detroit, MI	71	41	13
Houston, TX	57	28	5
Los Angeles, CA	110	67	24
New York, NY	200	110	23
Philadelphia, PA	97	56	18
Sacramento, CA	15	9	2
St. Louis, MO	43	25	9
2009 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
HA (respiratory); Detroit (Katsouyanni et al., 2009)			
1hr max, penalized splines	170	98	33
1hr max, natural splines	160	94	32
HA (respiratory); NYC (Silverman and Ito, 2010; Lin et al.; 2008)			
HA Chronic Lung Disease (Lin)	140	74	18
HA Asthma (Silverman)	470	270	61
HA Asthma, PM2.5 (Silverman)	350	190	44
HA (respiratory); LA (Linn et al., 2000)			
1hr max, penalized splines	500	260	27
HA (COPD less asthma); all 12 study areas (Medina-Ramon, et al., 2006)			
Atlanta, GA	52	27	7
Baltimore, MD	37	20	5
Boston, MA	53	25	5
Cleveland, OH	36	19	4
Denver, OH	18	11	4
Detroit, MI	64	33	8
Houston, TX	63	32	8
Los Angeles, CA	120	71	25
New York, NY	190	97	18
Philadelphia, PA	88	47	11
Sacramento, CA	16	9	2
St. Louis, MO	41	23	6

Table 7. Short-Term O_3-Attributable Morbidity Counts for Various Thresholds, Respiratory-Related Hospital Admissions, 2007 and 2009 Air Quality, 70ppb Standard

2007 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
HA (respiratory); Detroit (Katsouyanni et al., 2009)			
1hr max, penalized splines	180	100	35
1hr max, natural splines	170	100	34
HA (respiratory); NYC (Silverman and Ito, 2010; Lin et al.; 2008)			
HA Chronic Lung Disease (Lin)	140	72	13
HA Asthma (Silverman)	460	250	37
HA Asthma, PM2.5 (Silverman)	340	180	26
HA (respiratory); LA (Linn et al., 2000)			
1hr max, penalized splines	460	240	14
HA (COPD less asthma); all 12 study areas (Medina-Ramon, et al., 2006)			
Atlanta, GA	52	29	8
Baltimore, MD	38	22	7
Boston, MA	57	29	7
Cleveland, OH	36	19	5
Denver, OH	18	11	4
Detroit, MI	69	38	10
Houston, TX	56	27	4
Los Angeles, CA	110	62	19
New York, NY	190	95	14
Philadelphia, PA	93	53	15
Sacramento, CA	14	8	2
St. Louis, MO	41	23	7
2009 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
HA (respiratory); Detroit (Katsouyanni et al., 2009)			
1hr max, penalized splines	170	95	28
1hr max, natural splines	160	91	27
HA (respiratory); NYC (Silverman and Ito, 2010; Lin et al.; 2008)			
HA Chronic Lung Disease (Lin)	130	68	12
HA Asthma (Silverman)	450	240	38
HA Asthma, PM2.5 (Silverman)	330	180	27
HA (respiratory); LA (Linn et al., 2000)			
1hr max, penalized splines	490	250	19
HA (COPD less asthma); all 12 study areas (Medina-Ramon, et al., 2006)			
Atlanta, GA	50	25	4
Baltimore, MD	36	19	4
Boston, MA	53	25	4
Cleveland, OH	35	17	3
Denver, OH	18	11	4
Detroit, MI	66	35	8
Houston, TX	63	32	6
Los Angeles, CA	110	67	21
New York, NY	190	89	10
Philadelphia, PA	87	45	9
Sacramento, CA	15	8	2
St. Louis, MO	39	21	5

Table 8. Short-Term O_3-Attributable Morbidity Counts for Various Thresholds, Respiratory-Related Hospital Admissions, 2007 and 2009 Air Quality, 65ppb Standard

2007 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
HA (respiratory); Detroit (Katsouyanni et al., 2009)			
1hr max, penalized splines	170	96	27
1hr max, natural splines	160	92	26
HA (respiratory); NYC (Silverman and Ito, 2010; Lin et al.; 2008)			
HA Chronic Lung Disease (Lin)	110	46	0
HA Asthma (Silverman)	380	150	0
HA Asthma, PM2.5 (Silverman)	280	110	0
HA (respiratory); LA (Linn et al., 2000)			
1hr max, penalized splines	450	230	8
HA (COPD less asthma); all 12 study areas (Medina-Ramon, et al., 2006)			
Atlanta, GA	50	27	6
Baltimore, MD	37	21	5
Boston, MA	54	27	5
Cleveland, OH	34	17	3
Denver, OH	17	10	4
Detroit, MI	67	36	8
Houston, TX	55	26	3
Los Angeles, CA	100	58	15
New York, NY	150	50	0
Philadelphia, PA	90	49	11
Sacramento, CA	14	8	1
St. Louis, MO	38	21	5
2009 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
HA (respiratory); Detroit (Katsouyanni et al., 2009)			
1hr max, penalized splines	160	87	21
1hr max, natural splines	160	84	20
HA (respiratory); NYC (Silverman and Ito, 2010; Lin et al.; 2008)			
HA Chronic Lung Disease (Lin)	110	49	1
HA Asthma (Silverman)	390	170	0
HA Asthma, PM2.5 (Silverman)	280	120	0
HA (respiratory); LA (Linn et al., 2000)			
1hr max, penalized splines	480	240	11
HA (COPD less asthma); all 12 study areas (Medina-Ramon, et al., 2006)			
Atlanta, GA	48	23	3
Baltimore, MD	35	18	3
Boston, MA	52	24	3
Cleveland, OH	33	16	2
Denver, OH	17	10	3
Detroit, MI	65	34	7
Houston, TX	62	31	5
Los Angeles, CA	110	61	16
New York, NY	160	57	0
Philadelphia, PA	84	43	6
Sacramento, CA	15	8	2
St. Louis, MO	38	20	4

Table 9. Short-Term O_3-Attributable Morbidity Counts for Various Thresholds, Respiratory-Related Hospital Admissions, 2007 and 2009 Air Quality, 60ppb Standard
(NA: The 60 ppb standard was not attainable for New York City, and no risks are reported)

2007 Simulation Year	Threshold		
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
HA (respiratory); Detroit (Katsouyanni et al., 2009)			
1hr max, penalized splines	160	85	18
1hr max, natural splines	150	82	17
HA (respiratory); NYC (Silverman and Ito, 2010; Lin et al.; 2008)			
HA Chronic Lung Disease (Lin)	NA	NA	NA
HA Asthma (Silverman)	NA	NA	NA
HA Asthma, PM2.5 (Silverman)	NA	NA	NA
HA (respiratory); LA (Linn et al., 2000)			
1hr max, penalized splines	440	210	3
HA (COPD less asthma); all 12 study areas (Medina-Ramon, et al., 2006)			
Atlanta, GA	47	24	4
Baltimore, MD	35	19	4
Boston, MA	52	25	4
Cleveland, OH	31	14	1
Denver, OH	16	10	3
Detroit, MI	64	33	6
Houston, TX	54	25	2
Los Angeles, CA	96	52	9
New York, NY	NA	NA	NA
Philadelphia, PA	86	46	8
Sacramento, CA	13	7	1
St. Louis, MO	36	19	3
2009 Simulation Year	Threshold		
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
HA (respiratory); Detroit (Katsouyanni et al., 2009)			
1hr max, penalized splines	150	78	12
1hr max, natural splines	150	75	12
HA (respiratory); NYC (Silverman and Ito, 2010; Lin et al.; 2008)			
HA Chronic Lung Disease (Lin)	NA	NA	NA
HA Asthma (Silverman)	NA	NA	NA
HA Asthma, PM2.5 (Silverman)	NA	NA	NA
HA (respiratory); LA (Linn et al., 2000)			
1hr max, penalized splines	460	220	5
HA (COPD less asthma); all 12 study areas (Medina-Ramon, et al., 2006)			
Atlanta, GA	46	21	2
Baltimore, MD	34	17	2
Boston, MA	51	23	2
Cleveland, OH	31	14	1
Denver, OH	16	9	2
Detroit, MI	63	32	4
Houston, TX	60	29	3
Los Angeles, CA	100	56	11
New York, NY	NA	NA	NA
Philadelphia, PA	82	41	4
Sacramento, CA	14	7	1

Table 10. Short-Term O_3-Attributable Morbidity Counts for Various Thresholds, Emergency Room Visits, 2007 and 2009 Air Quality, 75ppb Standard

2007 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
ER Visits (respiratory); Atlanta (Strickland et al., 2007)			
Distributed lag 0-7 days	6,600	3,900	1,300
Average day lag 0-2	3,900	2,200	720
ER Visits (respiratory); Atlanta (Tolbert et al., 2007, Darrow et al., 2011)			
Tolbert	7,000	4,000	1,200
Tolbert-CO	6,300	3,600	1,100
Tolbert-NO2	5,700	3,200	1,000
Tolbert-PM10	4,400	2,500	780
Tolbert-PM10, NO2	4,300	2,500	750
Darrow	3,800	2,200	670
ER Visits (asthma); NYC (Ito et al., 2007)			
Single Pollutant Model	11,000	5,900	1,300
PM2.5	8,300	4,600	990
NO2	6,800	3,700	810
CO	11,000	6,200	1,400
SO2	8,500	4,700	1,000
2009 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
ER Visits (respiratory); Atlanta (Strickland et al., 2007)			
Distributed lag 0-7 days	5,900	3,100	740
Average day lag 0-2	3,500	1,800	420
ER Visits (respiratory); Atlanta (Tolbert et al., 2007, Darrow et al., 2011)			
Tolbert	6,400	3,300	810
Tolbert-CO	5,700	3,000	720
Tolbert-NO2	5,200	2,700	650
Tolbert-PM10	4,100	2,100	510
Tolbert-PM10, NO2	3,900	2,000	490
Darrow	3,500	1,800	430
ER Visits (asthma); NYC (Ito et al., 2007)			
Single Pollutant Model	10,000	5,600	1,200
PM2.5	8,100	4,300	900
NO2	6,700	3,500	740
CO	11,000	5,900	1,300
SO2	8,300	4,500	940

Table 11. Short-Term O_3-Attributable Morbidity Counts for Various Thresholds, Emergency Room Visits, 2007 and 2009 Air Quality, 70ppb Standard

2007 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
ER Visits (respiratory); Atlanta (Strickland et al., 2007)			
Distributed lag 0-7 days	6,300	3,600	950
Average day lag 0-2	3,700	2,100	540
ER Visits (respiratory); Atlanta (Tolbert et al., 2007, Darrow et al., 2011)			
Tolbert	6,700	3,700	960
Tolbert-CO	6,000	3,300	850
Tolbert-NO2	5,400	3,000	770
Tolbert-PM10	4,300	2,400	600
Tolbert-PM10, NO2	4,100	2,300	580
Darrow	3,600	2,000	510
ER Visits (asthma); NYC (Ito et al., 2007)			
Single Pollutant Model	10,000	5,300	790
PM2.5	7,900	4,100	600
NO2	6,500	3,400	490
CO	11,000	5,700	840
SO2	8,100	4,300	620
2009 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
ER Visits (respiratory); Atlanta (Strickland et al., 2007)			
Distributed lag 0-7 days	5,700	2,900	490
Average day lag 0-2	3,400	1,600	280
ER Visits (respiratory); Atlanta (Tolbert et al., 2007, Darrow et al., 2011)			
Tolbert	6,200	3,100	570
Tolbert-CO	5,500	2,800	510
Tolbert-NO2	5,000	2,500	460
Tolbert-PM10	3,900	2,000	360
Tolbert-PM10, NO2	3,800	1,900	350
Darrow	3,400	1,700	310
ER Visits (asthma); NYC (Ito et al., 2007)			
Single Pollutant Model	9,900	5,200	740
PM2.5	7,800	4,000	570
NO2	6,400	3,300	460
CO	10,000	5,500	790
SO2	8,000	4,100	590

Table 12. Short-Term O_3-Attributable Morbidity Counts for Various Thresholds, Emergency Room Visits, 2007 and 2009 Air Quality, 65ppb Standard

2007 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
ER Visits (respiratory); Atlanta (Strickland et al., 2007)			
Distributed lag 0-7 days	6,000	3,300	710
Average day lag 0-2	3,600	1,900	400
ER Visits (respiratory); Atlanta (Tolbert et al., 2007, Darrow et al., 2011)			
Tolbert	6,500	3,500	740
Tolbert-CO	5,800	3,100	650
Tolbert-NO2	5,200	2,800	590
Tolbert-PM10	4,100	2,200	460
Tolbert-PM10, NO2	4,000	2,100	440
Darrow	3,500	1,900	390
ER Visits (asthma); NYC (Ito et al., 2007)			
Single Pollutant Model	8,200	3,300	2
PM2.5	6,400	2,600	1
NO2	5,300	2,100	1
CO	8,700	3,500	2
SO2	6,600	2,600	1
2009 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
ER Visits (respiratory); Atlanta (Strickland et al., 2007)			
Distributed lag 0-7 days	5,600	2,700	310
Average day lag 0-2	3,300	1,500	170
ER Visits (respiratory); Atlanta (Tolbert et al., 2007, Darrow et al., 2011)			
Tolbert	6,000	2,900	390
Tolbert-CO	5,400	2,600	350
Tolbert-NO2	4,900	2,300	320
Tolbert-PM10	3,800	1,800	250
Tolbert-PM10, NO2	3,700	1,800	240
Darrow	3,300	1,600	210
ER Visits (asthma); NYC (Ito et al., 2007)			
Single Pollutant Model	8,500	3,600	4
PM2.5	6,700	2,800	3
NO2	5,500	2,300	3
CO	9,000	3,900	4
SO2	6,900	2,900	3

Table 13. Short-Term O_3-Attributable Morbidity Counts for Various Thresholds, Emergency Room Visits, 2007 and 2009 Air Quality, 60ppb Standard

(NA: The 60 ppb standard was not attainable for New York City, and no risks are reported)

2007 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
ER Visits (respiratory); Atlanta (Strickland et al., 2007)			
Distributed lag 0-7 days	5,700	2,900	430
Average day lag 0-2	3,400	1,700	240
ER Visits (respiratory); Atlanta (Tolbert et al., 2007, Darrow et al., 2011)			
Tolbert	6,200	3,200	470
Tolbert-CO	5,500	2,800	420
Tolbert-NO2	5,000	2,500	380
Tolbert-PM10	3,900	2,000	300
Tolbert-PM10, NO2	3,800	1,900	290
Darrow	3,300	1,700	250
ER Visits (asthma); NYC (Ito et al., 2007)			
Single Pollutant Model	NA	NA	NA
PM2.5	NA	NA	NA
NO2	NA	NA	NA
CO	NA	NA	NA
SO2	NA	NA	NA

2009 Simulation Year		Threshold	
Endpoint/Study Area/Descriptor	**None**	**20ppb**	**40ppb**
ER Visits (respiratory); Atlanta (Strickland et al., 2007)			
Distributed lag 0-7 days	5,400	2,500	170
Average day lag 0-2	3,100	1,400	99
ER Visits (respiratory); Atlanta (Tolbert et al., 2007, Darrow et al., 2011)			
Tolbert	5,900	2,700	260
Tolbert-CO	5,200	2,400	230
Tolbert-NO2	4,700	2,200	210
Tolbert-PM10	3,700	1,700	160
Tolbert-PM10, NO2	3,600	1,700	160
Darrow	3,200	1,500	140
ER Visits (asthma); NYC (Ito et al., 2007)			
Single Pollutant Model	NA	NA	NA
PM2.5	NA	NA	NA
NO2	NA	NA	NA
CO	NA	NA	NA
SO2	NA	NA	NA

Appendix B.

Reasons RIA Cost Estimates Are Probably Greatly Understated

In the main body of these comments, we have stated that the costs in the RIA should be viewed as unrealistically low. This appendix provides our basis for that statement.

This same set of alternative ozone NAAQS was considered by EPA in a rulemaking ending in 2008, and in a reconsideration that was initiated in 2010. EPA provided estimates of the cost of attaining these same alternative NAAQS in RIAs released then (EPA, 2008 and 2010). In the earlier RIAs, EPA estimated that the 60 ppb alternative could cost as much as $90 billion per year, compared to $39 billion (2011$) per year in the current ozone RIA. The costs for the 65 ppb and 70 ppb standards have similarly declined in the current RIA. Both the current and the earlier cost estimates are shown in Figure 6 (in the main body of these comments) as the left and right red bars, respectively, for each alternative NAAQS level. NERA finds that a large portion of the reduction in the costs in the current RIA, particularly for the more stringent alternative standards, can be traced to a shift in EPA's assumption about the cost per ton of NOx emissions reduction for the very large share of compliance actions that EPA calls the "unknown controls."

"Unknown controls" make up the portion of total reductions in ozone precursor emissions that the RIA has determined need to be removed for attainment to occur, but which EPA has declined to attempt to identify. Obviously, the cost for this set of actions is highly uncertain, but by leaving those control actions unidentified, it is difficult for an RIA reader to evaluate the realism of any estimate that EPA might have chosen to use in the RIA. However, there is some basic logic that can be applied to determine whether any given estimate is realistic, and we find that the current estimates are less realistic than EPA's earlier ones.

For example, the list of controls that EPA has identified (the "known" controls) is finite, but the number of tons of reduction needed to achieve each incrementally tighter standard increases; thus, the fraction of controls that EPA treats as "unknown" rises with more stringent alternative NAAQS levels. The fraction of tons to be reduced by unknown types of controls in the present RIA is 24%, 40% and 66%, respectively, for the 70 ppb, 65 ppb and 60 ppb alternative standards. It is a matter of intuition (and economic reality) that reductions that cannot even be identified in a cost analysis probably become increasingly more costly than those that can more readily be identified.

In its 2008 and 2010 RIAs, EPA made efforts to roughly approximate this increasing cost per ton; in the current RIA, however, EPA has simply assumed that all of those unknown control measures will be available at an average of only $15,000 per ton – no matter how deeply one has to cut back on total baseline emissions. If we replace the current RIA's flat $15,000 per ton for the "unknown" reductions with the same upward-sloping cost per ton assumption that EPA used in its two prior ozone RIAs, the estimated costs for the alternative rules rise. They rise the most for the 60 ppb NAAQS, nearly back to levels consistent with the estimates in the 2010 RIA.

The RIA provides no good reason to make a more simplistic assumption than it made in 2008 and in 2010 for these unknown controls' costs per ton. The higher earlier costs therefore should not be treated as outdated, but could reasonably be viewed as more realistic than those in the present RIA. In fact, NERA has completed its own analysis of EPA's data on emissions inventories, emission reductions necessary to attain a 65 ppb NAAQS, and available emissions reduction measures (NERA, 2015a). That analysis uses a more evidence-based approach for identifying the forms of controls that must comprise the "unknown" emissions reductions in EPA's RIA, and then uses that information to assess their likely costs. Whereas the current RIA reports that a 65 ppb NAAQS standard may cost about $15 billion (2011$) per year in 2025 (excluding costs for California's attainment), NERA's more evidence-based cost estimate averages over $80 billion per year (2014$) over the period 2017-2040.[63]

NERA also estimated the costs of attaining a 60 ppb NAAQS using the same evidence-based approach, but with earlier data on emissions reduction needs (NERA, 2014). That analysis estimates the cost for attaining a 60 ppb alternative standard of over $200 billion per year (2013$). The updated emissions inventory supporting the current RIA is lower, but EPA's updated attainment modeling also indicates that the emissions needed to attain a 60 ppb NAAQS are also lower; the result is that the current RIA estimates that about the same amount of emissions *reductions* will be needed as was estimated in the 2010 RIA. As a result, we can conclude that our more evidence-based estimate of the cost of attaining a 60 ppb NAAQS estimated in NERA (2014) remains a better indicator of the true costs of attaining that standard than the estimate in the present RIA of about $39 billion (2011$).

Thus, NERA concludes that the assumptions about the costs of unknown controls in the current RIA are significantly understated, and that more realistic estimates of the cost of each standard would be higher than in the current RIA for that single reason. However, NERA has identified multiple other concerns in the current RIA's cost estimation methodology that also imply further sources of understatement of the RIA's estimates

[63] NERA, 2015a, Figure S-5, p. S-11.

of attainment costs for each alternative standard level. The other concerns include consideration of emissions reduction needs only as of 2025 (rather than at the time that attainment deadlines will have to be met, in 2022 and earlier); inclusion of emissions reductions from a highly uncertain policy (*i.e.*, the Clean Power Plan) that is only in the proposal phase and for which EPA is already suggesting a delay in its targets; elimination of projected nonattainment at 26 monitors in the western states from needs for emissions reductions; assuming control strategies across multi-state regions (inconsistent with the way NAAQS SIPS can be implemented); and heavy reliance on rapid turnover of vehicle fleets by 2025. Further details of those additional sources of cost understatement are documented in NERA (2015b), which is being submitted to the ozone RIA docket simultaneously with this document as part of the joint comments of the U.S Chamber of Commerce, National Association of Manufacturers, and other parties.

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ATTACHMENT 2

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March 17, 2015

U.S. Environmental Protection Agency
EPA Docket Center (EPA/DC)
Mail Code 28221T
1200 Pennsylvania Ave., NW
Washington, DC 20460

ATTN: Docket ID No. EPA-HQ-OAR-2013-0169

Comments of the Utility Air Regulatory Group on the Regulatory Impact Analysis of the Proposed Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone

Dear Sir or Madam:

The Utility Air Regulatory Group ("UARG") submits the following comments on the Regulatory Impact Analysis of the Proposed Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone (Nov. 2014), Docket ID No. EPA-HQ-OAR-2013-0169-0013 ("RIA").[1] The RIA addresses a proposal by the Environmental Protection Agency ("EPA" or "Agency") to revise its National Ambient Air Quality Standards ("NAAQS") for ozone ("O_3"). 79 Fed. Reg. 75234 (Dec. 17, 2014) ("Proposed Rule"). These comments explain that the RIA provides an unrealistically low estimate of the costs associated with the Proposed Rule and an overstatement of its benefits. As a result, the net benefits of the

[1] UARG is a voluntary group of electric generating companies and national trade associations. The vast majority of electric energy in the United States is generated by individual members of UARG or by other members of UARG's trade association members. UARG's purpose is to participate on behalf of its members collectively in proceedings under the Clean Air Act ("CAA" or "Act"), 42 U.S.C. §§ 7401-7671q, that affect the interests of electric generators.

Proposed Rule reported in the RIA[2] are overstated. More realistic estimates of both the costs and the benefits would likely show that the Proposed Rule would not be cost-effective.

I. The Costs of the Proposed Rule Are Underestimated in the RIA.

Although it is difficult to determine how, exactly, EPA derived its estimates of the cost of a revised O_3 NAAQS,[3] it is clear that EPA's approach underestimated the cost of a new, more stringent, NAAQS. First, as EPA acknowledges, the Agency excluded certain costs from consideration in the RIA. The Agency excluded several non-complying monitors from its analysis, RIA at 3A-53 to 3A-54, and therefore the cost to bring these areas into attainment is not included in the RIA. Furthermore, the Agency limited itself to estimating the costs of controls. It did not attempt to address the cost of revised standards to the economy as a whole, *see id.* at 7-37 to 7-38, although these costs would likely be substantial. *See, e.g.*, David Harrison, Jr. *et al.*, Economic Impacts of a 65 ppb National Ambient Air Quality Standard for Ozone 11 (Feb. 26, 2015), *available at* http://www.nera.com/publications/archive/2015/economic-impacts-of-a-65-ppb-national-ambient-air-quality-standa.html ("The 65 ppb ozone standard is projected to reduce GDP from the baseline levels by about $1.7 trillion on a present value basis from 2017 to 2040 (as of 2014 and in 2014 dollars) and by $140 billion per year on a levelized average basis over that period . . . .").

In addition to simply excluding these relevant costs, EPA made several questionable choices in performing the analysis that reduced the estimated costs. First, EPA conducted its analysis for the year 2025. EPA says that it focused on that year "because most areas of the U.S. will likely be required to meet a revised ozone standard by" that date. RIA at ES-2. Although that statement is true, as EPA also recognizes, areas classified as marginal or moderate

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[2] RIA at ES-14 Table ES-6; ES-17 Table ES-10.

[3] For example, it appears that EPA used different modeling approaches to determine measures to attain the present 75 parts per billion ("ppb") O_3 NAAQS and a potential revised NAAQS. For the baseline, which involved reaching the 75 ppb NAAQS at every monitor in 2025, emissions changes (other than those attributed to 111(d) implementation) "were only applied in the areas projected to have [design values] greater than 75 ppb . . . ." *Id.* at 3-24 to 3-25. For the control strategy analyses, however, it appears that EPA "performed a national scale air quality modeling analysis" and sensitivity runs. *Id.* at 4-12. Those sensitivity runs, which focused on particular regions and emission reductions cases, *see id.* at 3-15, were used as a basis for "ozone sensitivity factors" that were used to predict emission reductions to attain alternative revised standards. *Id.* at 3-2 to 3-3. Furthermore, it is not clear what emission assumptions were used for the sensitivity runs.

nonattainment will have to attain before that time.[4] Examination of EPA's list of *Counties Violating the Primary Ground-Level Ozone Standard* that EPA released in conjunction with its announcement of the Proposed Rule finds that, using the same percent-above-the-standard approach to classifications that the Agency used for the 1997 and 2008 O_3 NAAQS,[5] all but 5 of the 358 areas that EPA identifies as violating a 70 ppb standard based on air quality data from 2011 to 2013 would be classified as marginal or moderate.[6] Thus, most of the country would be unable to rely on emission reductions (e.g., from 111(d) and Tier 3 Motor Vehicle Emission and Fuel Standards) that are projected to occur between approximately 2020-21 (for marginal areas) or 2023-24 (for moderate areas) and 2025. Instead, emissions reductions would be driven by a revised O_3 NAAQS and the costs of those emission cuts should be attributed to that standard.

A second EPA assumption that reduces the cost of a revised O_3 NAAQS is inclusion of compliance with the proposed Clean Power Plan ("Plan") into the baseline air quality for the RIA. RIA at ES-5. Essentially, EPA is assuming that the Plan, when finalized, will produce reductions in emissions of O_3 precursors prior to any reduction of such emissions being required for compliance with a revised O_3 NAAQS. Thus, costs that should realistically be attributed to a revised O_3 NAAQS are instead being attributed to a program that has not yet been finalized. Furthermore, EPA has acknowledged that the terms of the Plan (which EPA

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[4] EPA says that a moderate nonattainment area that qualifies for the two 1-year extensions provided by the Act will not have to attain until 2026. In order to take advantage of those extensions, however, the area would need to have air quality at the NAAQS level by its original attainment date (late 2023 or early 2024). CAA § 181(a)(5), 42 U.S.C. § 7511(a)(5); *see also* 69 Fed. Reg. 23951, 23968 (Apr. 30, 2004). Marginal areas would have an even earlier attainment deadline, likely late 2020 or early 2021. Thus, those areas would have to implement controls to attain a revised O_3 NAAQS well before 2025.

[5] 77 Fed. Reg. 30160, 30163 (May 21, 2012).

[6] *See Counties Violating the Primary Ground-Level Ozone Standard*, EPA, http://www.epa.gov/airquality/ozonepollution/pdfs/20141126-20112013datatable.pdf (last updated Dec. 1, 2014) (Data Table for 2011-2013 Ozone Map). Identification of those counties that would have qualified for a classification of Marginal or Moderate was based on comparison of the listed 2011-2013 Concentrations to 93 ppb, which is 15% higher than a 70 ppb standard and would be the percent-above-the-standard cutoff for a moderate classification. The five counties that had a design value of 93 ppb or higher were all in California. EPA would therefore not have included them in its 2025 modeling, anyway. RIA at ES-3. Of course, more recent air quality data will be used to classify nonattainment areas for any revised O_3 NAAQS, but given generally improving O_3 levels, it is unlikely that the number of counties qualifying for a classification above moderate would increase.

refers to elsewhere as "111(d) option 1 state"[7] will likely change before it is finalized,[8] rendering EPA's assumptions about the effect of that Plan on O_3 precursor emissions during or before 2025 even more speculative. Such evolution of a rule between proposal and promulgation is the essence of the rulemaking process and illustrates perfectly why it is inappropriate for EPA to take credit in an RIA for emission reductions that may – at some point – flow from a pending regulatory proposal.

In addition, in the sensitivity runs that EPA used to develop control scenarios, EPA assumed that the response to reductions in nitrogen oxide ("NOx") emissions was linear. RIA at 3-24. The Agency is well-aware, however, that O_3 "changes in a nonlinear fashion with the concentrations of its precursors." EPA, EPA-452/R-14-006, Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards at 2-9 (Aug. 2014), Docket ID No. EPA-HQ-OAR-2008-0699-0404. Proportionally greater reductions in NOx emissions would likely be needed to decrease O_3 concentrations from the relatively low levels now found in ambient air to the still lower levels that would be required to attain a NAAQS within EPA's proposed range. *See* Charles L. Blanchard & George M. Hidy, Envair, Effects of Past and Projected NOx Emissions on Ozone in the Continental U.S. at 12-13 (2015) (""[K]nown aspects of O_3 production and loss processes indicate that O_3 production efficiency increases as ambient concentrations of NO and NO_2 decline, thus suggesting that observed rates of O_3 decrease are more likely to decelerate, rather than accelerate, with ongoing NOx emission reductions."). Assuming that ambient O_3 concentrations will respond linearly to reductions in NOx emissions will lead to underestimates of the tons of emission reductions needed to achieve a more stringent O_3 NAAQS, *see id.* at 14, and thus, in turn, to underestimates of the costs.

Furthermore, EPA makes overly optimistic assumptions about the cost of those controls that it acknowledges will be necessary to attain a revised O_3 NAAQS. EPA identifies known controls that could be used to attain a revised NAAQS, but recognizes that those controls would not be sufficient to attain revised standards everywhere. Indeed, in California, EPA identifies no additional known controls for O_3 precursors, meaning that 100% of the required emission reductions would have to come from controls that are not known. RIA at 4-23 Table 4-11. Unknown controls would also be required elsewhere, however. Indeed, EPA indicates that even with a standard of 70 ppb, the top of the range for a proposed revised NAAQS, 23% of NOx emission reductions in the East would have to come from unknown controls. *Id.* at 4-

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[7] *See, e.g.*, RIA at 3-15 Table 3-2.

[8] *See, e.g.*, Jean Chemnick, *McCarthy Hints at Interim Target Changes in Power Plant Rule*, GREENWIRE, Feb. 17, 2015, http://www.eenews.net/greenwire/2015/02/17/stories/1060013573.

22 Table 4-10. Thus, the Agency needed to estimate costs for "unknown controls." Normally, for economic reasons, the least cost controls are implemented first. The $15,000 per ton fixed cost that EPA assigns to unknown controls is less than the cost of some known controls. *Id.* at 7-29 (only 1.18 million tons of the 1.22 million known tons available for reduction could be obtained at a cost of $15,000 per ton or less). Assuming that timely unknown controls will be available for less than the cost of known ones.

II. The Benefits of the Proposed Rule Are Overstated in the RIA.

At the same time that EPA is understating the cost of revised NAAQS, it is overstating the benefits of such standards. First, the majority of the benefits that the Agency attributes to a revised standard are related not to O_3, but to reduced levels of fine particulate matter ("$PM_{2.5}$"). *Id.* at 5-3 Table 5-1. EPA separately sets and implements NAAQS for $PM_{2.5}$ that, by definition, protect public health from particulate matter in ambient air, allowing an adequate margin of safety. CAA § 109(b)(1), 42 U.S.C. § 7409(b)(1). The $PM_{2.5}$ NAAQS were revised in 2013, and were set at levels that the Administrator found "would be requisite to protect public health with an adequate margin of safety against health effects potentially associated with long- and short-term $PM_{2.5}$ exposures." 78 Fed. Reg. 3086, 3164 (Jan. 15, 2013). In promulgating those standards, EPA took into account the very Krewski et al. (2009)[9] and Lepeule et al. (2012)[10] studies on which EPA now bases its estimates of $PM_{2.5}$-related health benefits from revised O_3 NAAQS.[11]

EPA has provided no basis for concluding that the $PM_{2.5}$ NAAQS that it promulgated in 2013 do not, in fact, protect public health and provide a margin of safety in doing so. Thus, there is no justification for EPA now to report benefits from reductions in the level of ambient $PM_{2.5}$ beyond those reductions required to meet the $PM_{2.5}$ NAAQS. Nevertheless, in the RIA, EPA claims a health benefit for each ton of $PM_{2.5}$ removed from the air, RIA at ES-11 (noting the use of a "benefit-per-ton approach" to $PM_{2.5}$ co-benefits), even when those tons are unnecessary to meet the health-protective NAAQS. Treating such $PM_{2.5}$ reductions as co-benefits is inappropriate. Nevertheless, EPA obtains "approximately two-thirds to three-quarters of the estimated benefits" of the revised O_3 NAAQS by doing so. *Id.* at ES-13.

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[9] Daniel Krewski, *et al.*, Health Effects Institute, Extended Follow-Up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality (2009), *available at* http://pubs.healtheffects.org/view.php?id=315.

[10] Johanna Lepeule, *et al.*, *Chronic Exposure to Fine Particles and Mortality: An Extended Follow-Up of the Harvard Six Cities Study from 1974 to 2009*, 120 ENVTL. HEALTH PERSP. 965 (2012), *available at* http://dash.harvard.edu/bitstream/handle/1/10436317/3404667.pdf?sequence=1.

[11] *Compare* RIA at 5-3 Table 5-1, *with* 78 Fed. Reg. at 3265 Table 4, note d.

In addition, in its Executive Summary, EPA attributes 680 (with a range of 230 to 1,100) premature deaths avoided to reductions in long-term O_3 exposure to a 70 ppb revised NAAQS. *Id.* at ES-14 Table ES-7. (Lower NAAQS are projected to reduce further O_3 - related premature mortality from long-term exposure. *Id.*) The Agency derived these estimates from a concentration-response function without a threshold. Only much later, in an appendix to Chapter 5, does EPA acknowledge that the authors of the study that is the basis of these estimates reported that a concentration-response model with a threshold at 56 "provided the best overall statistical fit to the data." *Id.* at 5B-2 to 5B-3. Sensitivity analyses using this "best-fit" function found that it reduced the estimated number of premature mortalities reduced in association with a 70 ppb NAAQS from 680 to 3.3. *Id.* at 5B-4 Table 5B-1. (The estimates associated with even lower NAAQS were similarly dramatically reduced). Indeed, a more complete integrated uncertainty analysis of the risk of mortality associated with long-term O_3 exposure found "a significant possibility that there will be *no benefit*" associated with reducing the O_3 NAAQS from 75 to 70 ppb in most locations.[12] Given that these lower estimates of benefits from a revised NAAQS are derived from a concentration-response function that better fit the data, EPA should present them as its core estimates. Estimates based on the non-threshold model should be omitted from the Executive Summary of the RIA.

EPA also refers to other benefits of revised O_3 NAAQS that it has not quantified. *Id.* at 5-3. To the extent these benefits are too uncertain to be quantified, *id.* at 5-5, they are too speculative to be considered benefits of a revised O_3 NAAQS. EPA should not refer to them (*see id.* at 5-3 Table 5-1) to imply that its quantification of benefits is an understatement.

III. The Costs of the Proposed Rule Likely Exceed Its Benefits.

Taking into account the underestimated costs and overstated benefits discussed above, it is not surprising that the costs of the proposed revision of the O_3 NAAQS would likely exceed its quantifiable benefits. Indeed, even without making allowance for the underestimated costs, a review of the "[O_3]-only Benefits" supports the conclusion that the costs of the proposed NAAQS exceed the benefits that may properly be attributed to it. Specifically, for a 70 ppb NAAQS, the estimated costs are $3.9 billion in 2011$ everywhere outside of California, *id.* at ES-14 Table ES-6, compared to quantified benefits of $2.0 to $3.4 billions in 2011 dollars.

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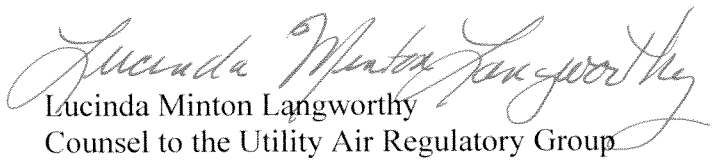
[12] Electric Power Research Institute, Comments on National Ambient Air Quality Standards for Ozone at 20 (Mar. 5, 2015), Docket ID No. EPA-HQ-OAR-2008-0699-1394 (emphasis added).

RIA at 5-3 Table 5-1.[13] The costs exceed the quantified benefits by a minimum of $0.5 billion.

IV. Conclusion.

EPA should update the RIA to reflect the actual costs and benefits of the Proposed Rule. Such an analysis would likely show that the proposed rule is not cost effective.

Sincerely,



Lucinda Minton Langworthy
Counsel to the Utility Air Regulatory Group

[13] It is impossible to make a similar comparison for California because EPA does not report California-only benefits. Indeed, EPA points out that the California and non-California estimates cannot be summed or directly compared. RIA at 5-2.

ATTACHMENT 3

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Parts 50, 51, 52, 53 and 58
[EPA-HQ-OAR-2007-0492; FRL-XXXX-X]
RIN 2060-AO47

National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Based on its review of the air quality criteria and the national ambient air quality standards (NAAQS) for particulate matter (PM), the EPA is making revisions to the suite of standards for PM to provide requisite protection of public health and welfare and to make corresponding revisions to the data handling conventions for PM and to the ambient air monitoring, reporting, and network design requirements. The EPA also is making revisions to the prevention of significant deterioration (PSD) permitting program with respect to the NAAQS revisions.

With regard to primary (health-based) standards for fine particles (generally referring to particles less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), the EPA is revising the annual $PM_{2.5}$ standard by lowering the level to 12.0 micrograms per cubic meter ($\mu g/m^3$) so as to provide increased protection against health effects associated with long- and short-term exposures (including premature mortality, increased hospital admissions and emergency department visits, and development of chronic respiratory disease), and to retain the 24-hour $PM_{2.5}$ standard at a level of 35 $\mu g/m^3$. The

EPA is revising the Air Quality Index (AQI) for $PM_{2.5}$ to be consistent with the revised primary $PM_{2.5}$ standards. With regard to the primary standard for particles generally less than or equal to 10 μm in diameter (PM_{10}), the EPA is retaining the current 24-hour PM_{10} standard to continue to provide protection against effects associated with short-term exposure to thoracic coarse particles (i.e., $PM_{10-2.5}$). With regard to the secondary (welfare-based) PM standards, the EPA is generally retaining the current suite of secondary standards (i.e., 24-hour and annual $PM_{2.5}$ standards and a 24-hour PM_{10} standard). Non-visibility welfare effects are addressed by this suite of secondary standards, and PM-related visibility impairment is addressed by the secondary 24-hour $PM_{2.5}$ standard.

DATES: The final rule is effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES: Section X.B requests comments on an information collection request regarding changes to the monitoring requirements. Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2007-0492, to the EPA by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- Email: a-and-r-Docket@epa.gov
- Fax: 202-566-9744
- Mail: Docket No. EPA-HQ-OAR-2007-0492, Environmental Protection Agency, Mail code 6102T, 1200 Pennsylvania Ave., NW, Washington, DC 20460. Please include a total of two copies.
- Hand Delivery: Docket No. EPA-HQ-OAR-2007-0492, Environmental Protection Agency, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC.