

John R. Kasich, Governor
Mary Taylor, Lt. Governor
Craig W. Butler, Director

March 17, 2015

Attention Docket No. EPA-HQ-OAR-2008-0699
Environmental Protection Agency
Mail Code 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Comments on U.S. EPA's "National Ambient Air Quality Standards for Ozone," 79 Fed. Reg. 75234 (December 17, 2014).

Dear Administrator McCarthy:

The Ohio Environmental Protection Agency thanks U.S. EPA for the opportunity to comment on the above-referenced proposed federal ozone standard.

Ohio has worked extremely hard to attain the 2008 0.075 ppm ozone standard throughout the entire state and has nearly accomplished that goal. Three areas were originally designated as nonattainment for the 2008 ozone standard. Based upon 2012 to 2014 air quality data, two of these areas are now attaining the standard and one is eligible for a one-year extension. Just as Ohio was "seeing the light at the end of the tunnel" with regard to attaining the 2008 standard, U.S. EPA proposes to adopt a significantly more stringent standard in the range of 0.065 to 0.070 ppm and agreed to accept comments for a standard as low as 0.060 ppm.

Ohio EPA recalls when the Administrator proposed the 0.060 to 0.070 ppm range for the 2010 ozone reconsideration. 75 Fed. Reg. 2938. The scientific evidence demonstrated in this proposal, like the past evidence in

2008 and 2010, does not justify the proposed range. Ohio EPA's analysis of available research and documentation reinforces that 0.075 ppm ozone is the lowest statistically justifiable standard and should not be lowered further. However, if U.S. EPA chooses to not use the larger body of evidence that supports maintaining the standard at 0.075 ppm and insists on further lowering the standard, Ohio EPA asserts that the studies do not support the 0.065 to 0.070 ppm range proposed by U.S. EPA. Ohio EPA also questions whether the very limited research conducted at 0.072 ppm justifies a lower standard. It certainly does not support the range proposed by U.S. EPA.

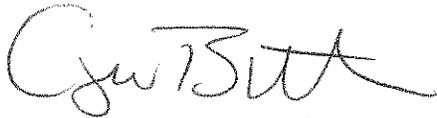
U.S. EPA is tasked with evaluating available information and recommendations as they make a discretionary policy judgment about whether to lower the standard. This decision should be designed to ensure that public health is protected sufficiently but not more than necessary, taking into account acceptable risk. As we discuss in our attached comments, Ohio EPA believes that a standard of 0.075 ppm is protective of human health and that sufficient evidence does not justify a lower standard. Ohio EPA does not believe the weight of scientific evidence supports a standard lower than 0.075 ppm.

As we will discuss in our attached comments, Ohio EPA is unaware of any new study or scientific evidence that compels a change to the existing standard. When setting the 2008 standard, U.S. EPA had before it a largely similar set of studies as are before U.S. EPA now. In 2008, the U.S. EPA considered all available information, examining the potential for setting the standard as low as 0.060 ppm, but nevertheless chose 0.075 ppm. Just as in 2008, Ohio EPA does not see a clear-cut basis for arriving at the conclusion of setting a significantly lower standard.

As indicated by U.S. EPA in both the 2008 adoption of the 0.075 ppm standard, the 2010 reconsideration of the 2008 ozone standard, and the current proposal, human studies provide the most directly applicable toxicological information for determining causality with the highest level of confidence. Ohio EPA believes these studies reviewed by U.S. EPA in 2014, indicates a standard of 0.075 ppm is protective of human health consistent with the Clean Air Act and the 0.065 to 0.070 ppm range proposed by U.S. EPA is outside the range of reliable health effects evidence and does not warrant a tightening of the standard.

Ohio EPA is dedicated to making continued improvements to Ohio's air. With that in mind, we are providing the attached detailed comments regarding this proposal. Again, Ohio EPA thanks you for this opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read "Craig W. Butler". The signature is fluid and cursive, with the first name "Craig" being the most prominent.

Craig W. Butler
Director

Cc: Robert Hodanbosi, Chief, Ohio EPA Division of Air Pollution Control

Attachment: Detailed Comments

Legal Issues

Under section 109(b)(1) of the Clean Air Act (CAA), the U.S. EPA Administrator in her judgment establishes the National Ambient Air Quality Standards (NAAQS) at a level “requisite to protect the public health” with an “adequate margin of safety.” “Requisite” means the NAAQS must be “sufficient, but not more than necessary.” *Whitman v. American Trucking Associations*, 531 U.S. 457, 473 (2001). This section “grants the Administrator considerable discretionary standard-setting authority” and “sufficient flexibility to avoid setting [NAAQS] ruinous to industry.” *Id.* at 494-95 (Breyer, J., concurring in part and concurring in the judgment).

Justice Breyer’s concurring opinion in *Whitman* is instructive of the factors that the Administrator must properly evaluate for her broad discretion to be considered reasonable. Although the U.S. Supreme Court held that cost cannot be considered in the NAAQS-setting process, the concepts of “requisite,” “public health” and “safety” must be understood in context.

We consider football equipment “safe” even if its use entails a level of risk that would make drinking water “unsafe” for consumption. And 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 of an issue. The Administrator can consider such background circumstances when deciding what risks are acceptable in the world in which we live.

Id. (Breyer, J., concurring in part and concurring in the judgment). Thus, “[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.” *Mississippi v. EPA*, 744 F.3d 1334, 1343 (D.C. Cir. 2013) (citation omitted). The CAA

authorize[s] the Administrator to consider the severity of a pollutant’s potential adverse health effects, the number of those likely to be affected, the distribution of the adverse effects, and the uncertainties surrounding each estimate. They permit the Administrator to take account of comparative health consequences. They allow her to take account of context when determining the acceptability of

small risks to health. And they give her considerable discretion when she does.

This discretion would seem sufficient to avoid the extreme results that some of the industry parties fear. After all, the EPA, in setting standards that 'protect the public health' with 'an adequate margin of safety,' retains discretionary authority to avoid regulating risks that it reasonably concludes are trivial in context.

Whitman, 531 U.S. at 495-96 (Breyer, J., concurring in part and concurring in the judgment) (citations omitted).

The D.C. Circuit Court of Appeals drew on Justice Breyer's concurrence to evaluate US EPA's exercise of discretion in setting the current ozone standard. In the *Mississippi* case, a group of petitioners challenged US EPA's decision in 2008 to set the ozone standard at 0.075 ppm. The standard had been 0.08 ppm, and some petitioners wanted the standard even lower. US EPA explained that the scientific evidence for lowering the standard below 0.075 ppm was far from certain. In such a situation, US EPA must take policy as much as science into consideration. "Where US EPA operates in the realm of uncertain science, its decision about appropriate NAAQS level must necessarily rest largely on policy judgments." *Mississippi*, 744 F.3d at 1357 (quotations omitted). The court upheld US EPA's decision not to set the 2008 ozone standard at a level below 0.075, finding that "EPA's policy judgment was informed by its view of the limitations of the scientific evidence of the existence of adverse health effects" and that US EPA had appropriately "str[uck] a balance between the increasing uncertainty associated with [its] understanding of the likelihood of such effects at lower [ozone] exposure levels and concern about the potential for health effects and their severity." *Id.*, at 1358. The court upheld US EPA's judgment to set the standard at 0.075 ppm after US EPA reasonably found "that the likelihood of obtaining benefits to public health with a standard set below 0.075 ppm [ozone] decreases, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to protect public health increases." *Id.*, at 1353.

Primary Standard

Summary

With respect to all NAAQS, the Administrator is charged with setting primary standards "the attainment and maintenance of which in the judgment of the Administrator, based on such [air quality] criteria and allowing an adequate

margin of safety, are requisite to protect the public health.” 42 U.S.C. 7409(b)(1). As described in the preamble to the proposed standard, an adequate “margin” of safety should address uncertainties in the scientific and technical information, while standards that are “requisite” to protect public health and welfare should be neither more, nor less stringent than necessary for these purposes. 79 Fed. Reg. 75237.

The current draft rule outlines a proposed standard of 0.065 to 0.070 ppm. Previously, 0.075 ppm was considered to be the level “appreciably below the concentration at which health effects had been demonstrated in controlled human exposures available at the time.” The previous standard was 0.080 ppm. Ohio EPA recognizes the need for examination by U.S. EPA to determine if there is cause for a “significant increase in protection” from human health effects.

U.S. EPA has developed a framework of examining current scientific evidence of human population health effects on a scale that categorizes the weight-of-evidence. 79 Fed. Reg. 75244. U.S. EPA divides its evidence into five categories, which span from causal relationships to no likely causal relationship, and evaluates the potential risk to populations based on a scale that ranges from adequate evidence to evidence of no effect. 79 Fed. Reg. 75244. However, the crux of the current proposal’s examination of human health effects is whether the body of scientific research has truly progressed since the 2008 Clean Air Scientific Advisory Committee (CASAC) and U.S. EPA’s conclusion, which found that the absence of any human clinical studies at ozone concentrations below 0.080 ppm did not support lowering the standard. 79 Fed. Reg. 75239.

Ohio EPA supports deliberate and reasonable regulation of ozone concentrations that are “requisite” to prevent health outcomes directly resulting from ozone exposure. However, when examining the multiple types of potential health effects, including lung function decrements, respiratory symptoms, increased school absences, hospital admissions, emergency room visits, and premature mortality, there is little to no new information available since the last revision. Furthermore, the majority of the newer information is either neutral, or does not support lowering the standard from 0.075 ppm.

Ohio EPA asserts that the current total scientific evidence cited in the *Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards* (PA) and the *Health Risk and Exposure Assessment* (HREA) does not in any way support a standard in the lower range of the proposed 0.060 to 0.075 ppm scale. This conclusion is directly linked to the variability in the direct human exposure exercise studies, which is the most relevant information to use for assessment of human health effects.

Additionally, the scientific body of information for the epidemiological studies has not significantly increased since the recent 2008 evaluation of the ozone standard. Although considered the second level, and thus, less reliable for studying human health effects from ozone exposure, the small advancement in epidemiological research has still not accounted for the numerous confounding variables to be considered in such studies. U.S. EPA itself acknowledges the lack of explanation for the irregularity in response(s) caused by other pollutants, temperature, averting behavior, and variability in responsiveness. 79 Fed. Reg. 75245. U.S. EPA lacks specific conclusions concerning defects in the epidemiological studies evaluating the NAAQS, such as particulate matter of respirable size ($PM_{2.5} - PM_{10}$), nitrogen dioxide (NO_2), and sulfur dioxide (SO_2). Variability persists within U.S. EPA's referenced materials concerning the significance of these confounding pollutants. Especially troubling is the inconsistency in results when comparing studies within the United States to those conducted in other countries. 79 Fed. Reg. 75258. These glaring inconsistencies are further evidence that lowering the current standard is not supported by the most recent scientific studies.

Undoubtedly and most importantly, the direct-exposure human health studies do not support the reduction of the ozone standard contemplated in this proposal. Large areas of uncertainty remain in the human health studies cited since the 2008 ozone evaluation. Strict interpretation of all of the results suggests U.S. EPA should not consider lowering the ozone standard from the current 0.075 ppm standard.

Direct Exposure Studies

Ohio EPA believes review of controlled exposure studies of healthy young adults exposed to various levels of ozone during moderate exercise is the most powerful tool to evaluate the effects of ozone on human health. In these studies, persons are exposed for up to 6.6 hours at various ranges of ozone concentrations, from 0.060 to 0.080 ppm, "the upper concentration at which scientists generally agree that health effects are likely to occur, to lower concentrations at which the likelihood and magnitude of the response becomes increasingly uncertain." 79 Fed. Reg. 75243.

While U.S. EPA is proposing to revise the standard from 0.075 ppm to a range between 0.065 to 0.070 ppm, even considering the standard as low as 0.060 ppm, the weight of evidence supports maintaining a standard of 0.075 ppm, with weak evidence of possible effects at 0.072 ppm, and no solid support for proposing a range of 0.065 to 0.070 ppm. U.S. EPA states in the PA "...we conclude that available controlled human exposure studies support a level no higher than 70 ppb as the upper end of the range for consideration in the current review. In reaching this conclusion, we note that 70 ppb is just below the O_3

exposure concentration reported to result in lung function decrements and respiratory symptoms in healthy adults (i.e. 72 ppb), a combination of effects that meets ATS criteria for an adverse response.” (PA, p. 315) However, U.S. EPA recognizes: “...CASAC judged that the strongest evidence comes from controlled human exposure studies of respiratory effects. The Committee specifically noted that ‘the combination of decrements in FEV₁ together with the statistically significant alterations in symptoms in human subjects exposed to 72 ppb ozone meets the American Thoracic Society’s (ATS) definition of an adverse health effect’ (Frey, 2014, p. 5).” CASAC further judged that ‘the level at which adverse effects might be observed would likely be lower for more sensitive subgroups, such as those with asthma.’ (Frey, 2014, p. 5).” (PA, p. 233-234).

Ohio EPA, CASAC and U.S. EPA agree that the direct ozone exposure clinical data are the most appropriate for setting the ozone standard. ATS defines adversity as a significant decrease in FEV₁ with a significant increase in symptoms, noting that FEV₁ decrements can vary by as much as 5% in healthy adults within a single day and by 15% or more from year to year. U.S. EPA defines a 10% FEV₁ decrement in a sensitive population as an appropriate adverse effect to protect against because it is mild and reversible. 79 Fed. Reg. 75250. U.S. EPA’s assertion that the two clinical studies (Kim *et al.* 2011 and Schelegle *et al.* 2009) justify lowering the current 0.075 ppm standard is in error. The Kim study reported statistically significant FEV₁ decrements (1.71%) in healthy young adults after 6.6 hours of 0.060 ppm ozone exposure while exercising heavily for 50 minutes out of every hour. However, these decrements are within normal variation and are not considered adverse by either the ATS criteria (because they were not statistically associated with symptoms), or by U.S. EPA’s own criteria (less than 10% FEV₁). The Schelegle study reported statistically significant FEV₁ decrements (5.34%, 7.23%, and 11.42%, respectively) associated with symptoms in healthy young adults after 6.6 hours exposure to 0.072, 0.081, and 0.088 ppm ozone, but not 0.063 ppm ozone (again, healthy young adults exercising heavily for 50 minutes out of every hour). In this study, for 0.072, 0.081 and 0.088 ppm ozone, the exposures meet the ATS criteria for adversity, but the results do not meet U.S. EPA’s criteria of adversity until 0.088 ppm, which is above the current 0.075 ppm standard.

The claim that adverse human health effects consistently result from ozone exposure at 0.060 and 0.072 ppm from the Kim and Schelegle studies is weak. U.S. EPA notes that at 0.060 ppm, three of 59 study subjects had FEV₁ decrements greater than 10%, and at 0.072 ppm five of 31 individual participants had FEV₁ decrements greater than 10%. In essence, U.S. EPA is basing their proposal on adverse human health effects occurring at concentrations lower than the current ozone standard on eight individual measurements. The same studies indicate five of 31 participants had increases in FEV₁ after 0.072 ppm ozone exposure. The remaining study subjects showed little, if any, change in FEV₁, confirming the previously stated large variability in lung function responses

between individuals. Lung function returned to baseline for all of the participants within one to four hours after cessation of exposure. U.S. EPA has not demonstrated that the human exposure science supports lowering the ozone standard from the current 0.075 ppm to within the range of 0.065 to 0.070 ppm. If anything, U.S. EPA's research citations only identify weak evidence of effects at 0.072 ppm, with considerable doubt if the standard should in fact be lowered below the current 0.075 ppm.

U.S. EPA further states: "Consistent with CASAC advice, we conclude that exposures to such O₃ concentrations are potentially important from a public health perspective given the following: The respiratory effects reported to occur in healthy young adults following exposures to O₃ concentrations of 0.060 and 0.072 ppm, while at moderate exertion, can reasonably be judged adverse based on ATS criteria and advice from CASAC." (p. 238). According to Honeycutt & Shirley: "The low concentration studies by Adams *et al.* (2002 and 2006), Schelegle *et al.* (2009), and Kim *et al.* (2011) all indicate a threshold below 70 ppb at which there are no statistically significant adverse effects associated with ozone. EPA should explain its rationale for modeling risks below 70 ppb ozone levels when controlled human exposure studies do not indicate effects at these exposure levels." (Appendix A, Honeycutt & Shirley, 2014)

Level of Significance

Further doubts about the proposed standard in light of the human health studies center on the level of significance of health effects during the chamber/exercise studies. Healthy young adults were exposed at various concentrations for 6.6 hours during the studies. Serious questions concern whether effects measured at 0.060 ppm can be considered significant. Border-line significance was measured at 0.072 ppm, with greater effect documented at 0.080 ppm or heightened exposure. Some measures of lower FEV₁ were only in the range of 5-10% difference, which is below the generally acceptable range of 10-20% considered significant. It is not specified what level of exercise for these young adults is considered "moderate", which could further confound the results of exposure below 0.072 ppm. The Schelegle *et al.* study (2009) also states that some individuals experienced 5-10% FEV₁ decrements following exposure to filtered air, further confounding the reliability of results at a range of 0.072 to 0.075 ppm ozone.

Epidemiological Studies

Significantly, epidemiological human health studies since the 2008 review do not support a radical reduction of the ozone standard. Large uncertainties remain in interpreting recent epidemiology studies for adult and childhood considering short- and long-term exposure. These irregularities supplant any basis for

lowering the current ozone standard. Even U.S. EPA cites that the literature has not advanced greatly since the last ozone health effects review, and the lack of a preponderance of evidence may not warrant a significant lowering of the standard.

Exposure Uncertainty from Monitoring

Citing the epidemiological studies as support for the reduction of the 0.075 ppm standard remains susceptible to the ever-persistent questions concerning true exposure and dose response. Uncertainty exists as to how well the ambient air monitoring network predicts true individual or population exposures. Ozone monitors are generally placed to assess macro- or meso-scale areas, reflecting county-wide average concentrations, but not necessarily the location of the greatest population. (Appendix B, Crist, 2015). Because of the nature of ozone generation and transport, which depends upon local weather conditions, measurements of high ozone concentrations are often miles away from our major metropolitan centers. Due to the nature of the creation of ozone, the highest ozone levels are frequently measured in late afternoon on warmer days after the precursors have had time to form in the atmosphere. In many of the epidemiological studies cited by U.S. EPA, the closest monitor is within 5+ miles of the studied population, but wind direction and timing of the ozone concentrations are not listed. This deficiency of information adds to the lack of certainty in defining true exposure levels for epidemiological studies.

Additionally, health assessment traditionally assumes that the exposure to the studied pollutants remain relatively constant. This is most likely inaccurate, potentially over-estimating an individual's true ozone exposure to an extreme degree. Historically, U.S. EPA guidance for acute, intermediate to long-term (chronic) health effect studies approximate exposure to air pollutant(s) for at least 24 hours a day, or for days, weeks, or even longer durations. Because ozone is primarily an outdoor pollutant (produced photochemically from the complex mixture of nitrogen oxides (NO_x) and reactive volatile organic compounds (VOCs)), indoor concentrations are lower than those measured outdoors, in some cases as low as 10%-20% of outdoor ozone concentrations. (Appendix C, Lee *et al.* 2004, Walker & Sherman 2012). For this reason, asthmatics and other sensitive sub-populations are instructed to remain indoors during periods of ozone advisories or air quality alerts. These potential exposure errors are unaccounted for in most ozone epidemiological studies to date.

Two over-estimation errors result from this fact, time spent indoors versus outdoors and, exposure consequences of avoidance or aversion behavior. A majority of Americans spend most of their hours indoors. Children and senior citizens spend on average less than 10% of their time outdoors. (ISA, page 4-31). Therefore, true average individual ozone exposure measures substantially

less than presumed by outdoor air quality monitoring. Aversion or avoidance behavior within the potentially exposed population, especially sensitive sub-groups, also factors into the over-estimation of total population ozone exposure. This could be especially significant in larger urban areas where ozone action days are widely advertised in the local media and educational systems. This fundamental over-estimation of true ozone exposure complicates the ability to discern subtle distinctions from these epidemiological studies that discount any support for a reduced ozone standard.

Lung Function Studies

Pulmonary inflammation as an indicator for long-term ozone effects remains unreliable depending on the variability and range of lung changes. While exposure can lead to temporary or long-term inflammation (leading to asthma or increased susceptibility to micro-organisms, allergens or toxins), the range of study exposures does not mimic reality. Exposures of 0.080 to 0.600 ppm provide variable levels of effect related to exercise. In one case, a level of 0.200 ppm was used to initiate a response in asthmatics. 79 Fed. Reg. 75252-75253. Considerable debate remains whether asthmatics exhibit increased response at various levels of exercise; nonetheless, the exposure scenarios do not correspond to those proposed for the potential revision of the standard.

The discussion of respiratory symptoms related to medication use further clouds the logic for a radically lowered ozone standard. Admittedly, respiratory symptoms proved significant at the 0.080 ppm exposure level (which further supports maintaining the 0.075 ppm standard). One study cited for potential effects at 0.060 ppm showed symptoms which were not even statistically significant from exposure to filtered air. The relationship of breathing filtered air on the FEV₁ necessitates further review prior to its consideration as a true baseline value. 79 Fed. Reg. 75255. Since the use of medication and the seeking of medical attention are confounded by individual subjective assessments of medical need, the studies themselves remain a source of unexplained variability; consequently, data on the use of respiratory symptoms related to medication use does not support any further reduction of the ozone standard.

While animal toxicological studies provide some evidence that exposure to 0.100 to 0.500 ppm can cause increased susceptibility to infectious diseases presumably due to alterations in the host animal's lung defense system, only one cited human study used ozone concentrations of 0.080 – 0.100 ppm for 6.6 hours of exposure during moderate exercise. 79 Fed. Reg. 75256, (Devlin et al. 1991). Once again, while perhaps adding to the basis of scientific research; human exposure studies at 0.080 ppm do not support a reduction of the current standard below 0.075 ppm.

Uncertainty in Population Studies

It remains unclear how the limited positive association linking ozone exposure to hospital admissions, emergency department visits, as well as morbidity and mortality studies support a tighter ozone standard. While some linearity of response is present as low as 0.030 ppm, the large amount of uncertainty clouds any forgone conclusion based upon these studies. For example, the positive association for respiratory mortality during summer months is moderately sensitive to PM₁₀. 79 Fed. Reg. 75258. While U.S. EPA argues that the evidence presented since the last ozone evaluation show positive correlation, the analysis presented does not account for genetic susceptibility, altered behavioral factors, and the incomplete assessment of actual environmental exposure.

The persistent issue of “harvesting” data regarding ozone-induced premature mortality remains unexplored related to true ozone exposures. Individuals near cardiac or respiratory failure may well be removed from ozone exposures due to the same reasons applicable to general population exposures discussed above. Alternatively individuals susceptible to acute ozone concentrations leading to mortality may already be removed from ambient air ozone exposure through residence indoors, perhaps with filtered air and supplemental oxygen (for those located in a health-care environment).

Studies of the onset of asthma, especially in children, do not account for the total effect confounders present in the current state of the science regarding asthma initiation and occurrence. Again, the continued lack of assessment of true exposure, indoor versus outdoor concentrations, and avoidance and aversion behavior complicates the studies mentioned above. In addition, especially in cases of childhood asthma, the studies focused little to no attention on the myriad of associated factors complicating the study of this disease. The epidemiology studies fail to adequately examine indoor allergens, such as dust mites, pet dander, the presence of cockroaches and rodents, combined with other allergens such as pollen and mold. Genetic predisposition for instance, exposure to tobacco smoke, cold air, physical exercise and excess weight, all remain critical initiation factors confounding any examination of asthma rates in children and adults. While some attention was paid to socio-economic status, geographic location, and other overall simplistic indicators of over-all health quality, the studies do not examine the details in insufficient detail to warrant a reduction in the current ozone standard.

Most importantly, the epidemiological evaluation results of asthma incidence and occurrence directly contradicts the federal and State data, which indicate asthma occurrence has been on a persistent increase during the last decade. This increase occurs in spite of a general decline of measured ambient air ozone concentrations throughout Ohio and the United States. Yet, as increasing

numbers of states have come, or are coming, into attainment status with the current ozone standard of 0.075 ppm, the occurrence of asthma remains on the rise. In a November 2012 Vital and Health Statistics report from the Center for Disease Control and Prevention, noted that "current asthma prevalence increased from 2001-2010". (Appendix D, CDC, 2012). This proves a definite lack of causality between outdoor ozone concentrations and asthma occurrence. Thus, any decision to lower the ozone standard based upon these studies is highly inappropriate and scientifically unsound.

Morbidity/ Mortality Study Uncertainty

Studies of respiratory mortality provide no discreet additional evidence supporting a tighter ozone standard. 79 Fed. Reg. 75258. While "positive associations" were reported in the literature, a variety of inconsistent factors remain unexplained. The wide range of concentrations studied show weak to no evidence at 0.033-0.104 ppm ozone levels. Again, the confounding factor of PM_{2.5} is cited as recently as in the 2011 study. Similarly, the evidence cited from cardiovascular effect studies still exhibit limited evidence from a relatively small number of animal studies, all containing high degrees of uncertainty. 79 Fed. Reg. 75261. Cardiovascular morbidity data is inconsistent because the human data studies yield very inconsistent results. Ozone animal studies, while valuable tools for ozone health effect research, also add to the uncertainty factor for assessing potential human effects. Animal studies attempting to assess potential pulmonary structure and function changes show lung effects in non-human primates exposed to unrealistically high 0.500 ppm ozone concentrations. Exposures to these concentrations are well above those experienced by humans, and as such are insignificant. For these studies to offer value, researchers must provide a more detailed assessment of the correlation between monkey lung and human tissue. Current studies exhibit mixed evidence for deficient lung growth in children resulting from ozone exposure. Any emphasis placed on these studies as evidence for a lower standard is misplaced at this time, pending many more years of rigorous research.

Likewise, additional research must be required regarding total mortality analysis as related to ozone exposure days. While some evidence supports the concept of single-day lag time increases in mortality, in general the increases follow a rather large estimation of ozone exposures (0.5-1.0% increase in mortality per 20 (24h), 30 (8h), or 40 (1h)) ppb maximum increase ozone. 79 Fed. Reg. 75262. Interestingly, some of these studies basically support the "no lower threshold" theory of ozone exposure and human health effects (from studies in the extremely low range of 0.010-0.045 ppm). It is therefore difficult to relate these low exposures to a level below the current 0.075 ppm standard.

Multiple factors were not accounted for in the assessment of asthma hospital admissions, including first-time emergency department visits. While suggesting children exposed to high ozone levels are more likely to develop asthma severe enough to be admitted to the hospital, confounding factors commonly associated with childhood asthma require further evaluation. While it appears certain socio-economic indicators were accounted for in examining the differences in this metric, Ohio EPA would propose a total examination of all factors, genetic and socio-economic, be examined prior to suggesting that ambient air pollutant concentrations of any of the NAAQS strictly influence initial admissions for medical care for asthma in children or adults.

Secondary Standard

With respect to the proposed revised secondary ozone standard, U.S. EPA has identified several detrimental effects of high concentrations of ozone on crops and trees. These effects are noted in the proposal as visible damage on leaves, reduced resistance to disease, lower reproduction and lower vegetative growth. 79 Fed. Reg. 75314. The proposal presents much information on Class I areas and the potential impacts of ozone in these Class I areas. U.S. EPA is emphasizing that at whatever level the standard is set, it must be sufficient for protection of vegetation in Class I areas. 79 Fed. Reg. 75336. How this can actually accurately be determined is questionable. Ohio does not contain any Class I areas. Therefore, protecting at a level to maintain Class I area protection should be more than adequate for Ohio's areas.

In Ohio, the potential impacts of ozone on crops would be of concern more so than Class I areas. The information presented in the proposal, examines a level of protection that would set a standard so that no more than a 5% decrease of crop production would be anticipated. Due to the various growth factors in crop production as identified in the proposal, it is difficult to quantify the exact factors that may be in play that reduces crop production. As such, the 5% value cannot be determined with precision and should be a theoretical value (with related scientific uncertainty) rather than an actual measurement.

The analysis conducted by U.S. EPA in this proposal indicates that a primary standard should also be sufficient to protect against significant secondary impacts. Ohio EPA also believes the primary standard and secondary standard should be one in the same. However, if U.S. EPA decides to promulgate a W126 standard in addition to the primary standard, then the standard should be based upon a minimum of a three-year average, if not longer, rather than the one-year average discussed. 79 Fed. Reg. 75237. Just as with the primary standard, there are wide variations in the W126 values on a year-to-year basis. A three-year average mitigates some of the year-to-year variation thus providing some

“stability” so that areas are not fluctuating in and out of the standard annually due to the natural variation of climatic conditions that have a direct impact on ozone formation.

U.S. EPA’s proposal recognizes other environmental factors that may impact plant growth and vegetation damage and the difficulty in separating out those confounding factors from ozone. 79 Fed. Reg. 75314. Also, U.S. EPA appears to set a factor of less than 2% for diminished growth as being an acceptable standard for trees and forests. 79 Fed. Reg. 75321. Based on all of the various factors that affect plant growth in addition to moisture such as amount of sunlight, temperature, nutrients, plant disease and pests, the 2% value should be considered a theoretical value, not what can actually be quantitatively determined on a large scale basis. Due to the variety of uncertainty with the factors affecting growth, Ohio EPA encourages U.S. EPA not to adopt an independent secondary standard. The primary standard should be sufficient to also protect a wide range of trees and crops from significant damage from ozone.

Ohio EPA also notes the significant decrease in ozone concentrations nationwide over the past thirty years. These improvements have surely decreased the detrimental impacts of ozone on trees and crops, so there should already be increased tree growth in the Class I areas as a result of lower ozone concentrations. As stated in the proposal, U.S. EPA is not required to set a standard at background levels or a level with no impacts, but only to minimize the impacts of the pollutant. 79 Fed. Reg. 75382. Even if U.S. EPA agrees not to tighten the current standard, there will continue to be improvements in the ozone concentrations in the ambient air. This will further reduce the detrimental effects of ozone on plants, and thus, the current standard (0.075 ppm) will meet U.S. EPA’s mandate for a secondary standard.

Background Levels

As noted above, the CAA does not require the Administrator to establish a primary NAAQS at a zero risk level or at background concentration levels. U.S. EPA goes on to recognize that “background” ozone levels, which can be significant in some areas on some days, may present a challenge to air agencies in preparing clean air plans. Ozone and ozone-forming pollution from natural and international sources could prevent ambient air from reaching attainment levels. 79 Fed. Reg. 75382. This could occur in locations where the impacts of such sources are large relative to the impact of controllable man-made sources of NO_x and VOC emissions within the United States, especially in locations with few remaining untapped opportunities for local emission reductions. 79 Fed. Reg. 75382.

The U.S. Court of Appeals for the District of Columbia Circuit authorized U.S. EPA to consider as a factor when choosing among alternative levels the proximity to peak background ozone concentrations. 79 Fed. Reg. 75239. When setting the ozone standard, U.S. EPA must be cognizant of the consequences of setting a standard low enough to encroach upon background concentrations.

U.S. EPA recognizes that background 8-hour ozone concentrations under the control of states¹ varied between 0.025 to 0.050 ppm in 2007. Infrequent events can cause even higher background occurrences. During the previous review, U.S. EPA noted that a standard set at a level of 0.070 ppm would be closer to peak background concentrations that infrequently occur in some areas due to non-anthropogenic sources of ozone precursors. 79 Fed. Reg. 75239. U.S. EPA does not directly state the peak background concentration level at this time, which reinforces that exact peak background concentration levels remain unknown. Under this review, an analysis in the PA indicates there can be episodic events with substantial background contributions where ozone concentrations approach or exceed the level of the current NAAQS (*i.e.*, 0.075 ppm). 79 Fed. Reg. 75242. U.S. EPA assumes that non-anthropogenic sources of ozone in some areas are infrequent, which may not be the case anymore and should be re-evaluated.

At the proposed levels of 0.065 to 0.070 ppm considered under this rule, background concentrations in some areas represent a significant fraction of the total ozone. According to the proposed rule: “while the majority of modeled O₃ exceedances have local and regional emissions as their primary cause, there can be events where O₃ levels approach or exceed the concentration levels being proposed in this notice (*i.e.* 0.060-0.070 ppm) in large part due to background sources.” 79 Fed. Reg. 75382. Ohio EPA does not agree that the new ozone standard should be mostly comprised of background ozone itself. As a new standard becomes closer to background levels, states have less ability to develop practical control strategies to meet the standard.

In addition, a May 19, 2014 *Draft Letter on CASAC’s Review of the EPA’s Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards* on behalf of American Chemistry Council et al., addresses similar points of concern.

‘[t]he Second Draft PA is not clear as to how background estimates might impact the primary and secondary standards and whether these impacts may differ regionally.’ EPA’s analysis indicates that the impact could be

¹ U.S. background is the ozone that would exist in the absence of any manmade emissions inside the U.S. 79 Fed. Reg. 75382 This background includes manmade emissions that may be transported into the U.S. from outside of the U.S.

quite large and, therefore, background ozone levels need to be more fully considered. The lower end of the standard that CASAC is supporting – down to 60 ppb – is very close to levels of ozone that are found naturally in some regions of the country. Also, EPA's models have shown that decreasing anthropogenic sources of ozone could actually lead to *increased* ozone in some areas (because nitrogen oxides both form and destroy ozone). By controlling human sources of ozone to achieve lower standards, many parts of the country may not be able to meet current ozone standards, partially because of naturally formed ozone. In addition, in recent years, scientists have measured increasing amounts of air pollution coming to the United States from overseas. The impacts of international emissions on ozone levels in the United States, however, have not been fully considered during the current review of the ozone NAAQS. Given these issues, EPA should calculate risks that would occur with ozone exposures above background (including impacts of international emissions), and should not set standards for which some areas will be out of attainment as a result of background ozone." (Appendix E, American Chemistry Council et al., 2014)

U.S. EPA recognizes these issues in the proposal to a limited extent and U.S. EPA cites programs that can offer regulatory relief, such as the exceptional events rule, rural transport area provisions or international transport provisions. 79 Fed. Reg. 75383. U.S. EPA also notes these options can be burdensome. However, these programs will not address all the circumstances where background ozone levels encroach upon the levels proposed in this rule. U.S. EPA must consider this factor, as authorized by the Court, which further supports maintaining a standard of 0.075 ppm.

In addition, a typical ozone exceedance in Ohio occurs during the elevated temperatures found in warmer months when atmospheric conditions are stagnant or stable. During those periods, an exceedance of 0.065 to 0.070 ppb can be highly influenced by biogenic emissions comprising background ozone. (Appendix B, Crist, 2015). It is extremely challenging, if not impossible, to develop control strategies to address these concentrations and events that are influenced by a larger biogenic impact.

AQI

The burdens associated with U.S. EPA's proposal to lower the standard at levels that may actually approach background levels for some areas is further exacerbated in the proposed changes to the air quality index (AQI). U.S. EPA acknowledges that accurate forecasting hinges on selecting breakpoints in the index values and categories that span at least a 0.015 ppm range. 79 Fed. Reg.

75311. In order to preserve the 0.015 ppm span for “moderate” and “unhealthy for sensitive groups” categories, U.S. EPA plans to set the “good” category at 0.049 to 0.054 ppm. Meaning, once the air quality reaches 0.050 to 0.055 ppm it falls out of “good” and into “moderate.” This approach implies that low-end background concentrations may no longer be considered “good.”

Breakpoints in the AQI are also a policy judgment afforded to the Administrator based on health evidence. U.S. EPA is proposing to adjust the breakpoint between “unhealthy for sensitive groups” to “unhealthy” categories from 0.095 ppm to 0.085 ppm. Essentially, U.S. EPA plans to set the “unhealthy” for everyone breakpoint at a level equivalent to the 1997 ozone standard that some areas have not attained or only recently attained. Obviously, the issues that arise with the AQI become evident as the standard becomes lower. The AQI functions to provide an important public service and U.S. EPA’s proposal may be creating a public perception of “unhealthy” air that does not exist.

Monitoring

Exceptional Events

U.S. EPA proposes changes to exceptional events criteria. An exceptional event that happened prior to this proposal would not have been considered an exceptional event under the previous ozone standard. U.S. EPA proposes to adjust the schedule for submitting exceptional event requests so these historical events can be considered exceptional if a new standard is finalized. Ohio EPA firmly believes these events should be eligible to be flagged and identified as exceptional events. 79 Fed. Reg. 75396.

However, Ohio EPA believes U.S. EPA should also adjust the exceptional events regulations to allow concentrations below the level of a standard to be submitted as an exceptional event. Exceptional events should be allowed in instances where concentrations are less than the level of any of the applicable standards. This decision should be at the discretion of a state as to whether or not they wish to declare events below a standard as exceptional. The regulation should not require only those events that result in an exceedance level to count as exceptional. One exceptional event in a state, even one below the standard, could create attainment issues later on.

Monitoring Day and Data Procedures

Changing the monitoring day to start at 7:00 A. M. is necessary in that it will avoid the overlap in hours in the rare instance of two exceedances using as many as seven mutual hours. 79 Fed Reg. 75403. Likewise, substituting 0.000

ppm for missed data is reasonable and it will eliminate issues associated with different substitution values based on an instrument model (half of the Minimum Detectable Limit). 79 Fed. Reg. 75403.

Multiple Sites

Ohio EPA believes allowing the combining of data from collocated monitors at the same site is useful and will create a more uniform system for collecting collocated data across pollutant standards. 79 Fed. Reg. 75402. The use of collocated data in the event of a primary monitor outage is already in use for particulate and lead monitoring. Having the ability to substitute approved monitoring data allows for a more accurate design value average because an actual value is used for the missing data rather than 0.000 ppm.

In addition, formalizing the procedure for combining data from successor sites which are located at a reasonable distance from an earlier site is acceptable in concept. 79 Fed. Reg. 75403. A more formalized process will allow the AQS database to document the process and to calculate design values automatically and make that data available to users and the general public more easily and in a more transparent manner. However, Ohio EPA cautions U.S. EPA not to create a regulatory burden with overly prescriptive requirements laid out in regulations, but rather ensure they maintain flexibility so this option remains a useable tool for states.

PAMS Monitoring at NCore Sites

U.S. EPA is proposing to require monitoring at NCore sites in nonattainment areas consistent with PAMS requirements (additional meteorological and hourly precursor data). 79 Fed. Reg. 75360-75362. While ozone precursor data as well as various meteorological parameters can be useful, this additional data gathering will also be a financial and resource burden for those required to maintain operation of those sites. U.S. EPA must consider increasing funding for states affected by this additional burden if finalized.

Not only will this monitoring necessitate sufficient funding, but equally important, it necessitates sufficient training. Ohio monitoring staff have little technical experience operating the PAMs equipment, and without adequate training there is concern regarding the quality of data that will be produced as site operator(s) learn the use of the equipment. U.S. EPA suggests that NCore site operators will be able to operate the equipment, but we must remind U.S. EPA that these site operators have other responsibilities and equipment to operate. Additional resources and additional training will still be needed. States cannot sacrifice data quality within our current networks while attempting to implement a new monitoring program without appropriate guidance and training. U.S. EPA must

consider a phased implementation schedule that will allow states time to adjust to this new monitoring. Other already required monitoring must not be sacrificed due to U.S. EPA's additional proposed requirements and aggressive schedule. States are already struggling with reduced funding and resources for monitoring. Because of these concerns, U.S. EPA should consider the waiver request process and initial use of canister monitoring until staff are properly trained with the equipment and data are of sufficient quality to support hourly measurements. As data are collected, it may be determined that canister sampling would be sufficient to provide the needed information and thus hourly measurements may not be needed.

Ohio EPA understands and appreciates CASAC Air Monitoring and Methods Subcommittee (AMMS) position of the importance of carbonyl monitoring. Because of the uncertainty in the current methodology, TO-11A, we encourage U.S. EPA to continue to investigate and implement changes necessary to securing more certainty in the data collected using this method. Ohio EPA recommends U.S. EPA use a phased in approach for the revised carbonyl sampling and not require sampling for carbonyls at all PAMS sites until the revisions to the method are firm. U.S. EPA should also provide sufficient training on sample set-up and retrieval. Sufficient training does not include only Standard Operating Procedures (SOPs), but also should include test samples to ensure correct interpretation of the SOP. In addition, webinars and/or videos documenting the actual step-by-step procedure for set-up, equipment operation and sample collection would be beneficial.

With regard to requiring mixing height measurements at PAMS sites, we encourage U.S. EPA's continued work with National Oceanic and Atmospheric Administration, NOAA, to enhance the ceilometers within the Automated Surface Observing System (ASOS) and for monitoring organizations to have access to this data. While the information is important for the data analysis of the species collected at the PAMS sites, it is resource intensive to require the measurement of mixing heights at all PAMS sites. It would take significant resources and training to educate monitoring staff on proper operation and maintenance of the equipment. U.S. EPA should work with NOAA on the enhancement of the ASOS by pooling resources that will provide an overall benefit to both agencies. An additional benefit of enhancing the ASOS network will be to provide the monitoring staff assigned to PAMS equipment operation more time to focus on the other required monitoring equipment resulting in better data quality and a potential for a more timely analysis of the ozone situation in their state and/or region.

In addition to the above comments, Ohio EPA also encourage U.S. EPA to consider the reduction of PAMS and/or enhanced ozone monitoring as areas

come into attainment with the standard or when there is no significant difference in species detection over a regional geographic area.

Lengthening the Ozone Season

U.S. EPA is proposing to lengthen the ozone season for several states. Specifically for Ohio, U.S. EPA is proposing to add March to the ozone season. U.S. EPA is arbitrarily proposing these changes without considering the circumstances apparent in the individual states. 79 Fed. Reg. 75410. If such a change is deemed necessary it should be based on a state-specific analysis, such as investigating which areas of a state have had a pre-determined number of historical exceedances outside of the current ozone season. Such a change should be balanced with resource considerations and the actual need for this data. In Ohio, there were no sites that have had values greater than 0.064 ppm in March 2013 or 2014. The earliest time period where Ohio realized an ozone concentration greater than 0.065 ppm occurred on April 5, 2013 (0.066 ppm). (Appendix F).

Lengthening the ozone season for regional consistency is not needed and it is not a valid reason for requiring states to operate monitors longer than necessary. It only adds a burden on states, such as Ohio, that do not need to monitor out of their current ozone season. The possible addition of March to Ohio's ozone season will add a fourth quarter to the number of audits that must be performed as well as require the site operators to operate the instruments and use time and supplies for little to no benefit. U.S. EPA must abandon this aspect of the proposal or at least limit the expansion of an ozone season to those states whose historical data truly shows a need for such an expansion.

Another consideration is that U.S. EPA's Cross State Air Pollution Rule, Clean Air Interstate Rule, and NO_x SIP Call imposes requirements on sources based on a cap and trade program during the ozone season. Under these programs the ozone season runs from May 1st to September 30th. It is imperative that any changes made under this proposal to a state's ozone season do not impact the compliance periods under these rules. State budgets and allocations are based on emissions that run from May 1st to September 30th and adjustments would be required if this period were also extended.

Additional Monitoring Costs

The U.S. EPA proposal acknowledges that the changes to monitoring will require additional expenditures by state and local agencies; however, the suggested solution is inadequate. Although U.S. EPA discusses redirecting current funds, the amount of federal dollars going to state and local agencies remains inadequate to meet U.S. EPA requirements. It remains unlikely that U.S. EPA will

obtain additional mandates being proposed by U.S. EPA. If U.S. EPA redirects existing funding to address additional monitoring under this proposal, it only means that some other state/local agency or program will have to absorb an additional shortfall. U.S. EPA must consider the increasing financial burden on states prior to requiring additional mandated air quality monitoring.

Increments for Setting Standard

In the past, U.S. EPA has chosen ozone standards in 0.005 ppm increments, such as 0.075 ppm or this proposal of a standard of between 0.065 ppm and 0.070 ppm. There is no mandate that U.S. EPA set a standard in 0.005 ppm increments. For example, the current standard of 0.075 ppm does not have to be lowered to 0.070 ppm as a result of monitoring accuracy. Monitors are capable of measuring to the individual ppm level and the accuracy of monitoring should not be used as a reason to lower the standard to 0.070 ppm.

Implementation

Ohio EPA has serious concerns regarding the proposed promulgation schedule. 79 Fed. Reg. 75354. U.S. EPA states that they are required under Court Order “to take final action no later than October 1, 2015.” States will then have up to one year (October 1, 2016) to submit initial nonattainment recommendations. State recommendations “would likely use air quality data from the years 2013 to 2015.” U. S. EPA would then have until June 2017 to notify states of any modifications to their nonattainment recommendations. U.S. EPA’s final promulgation would occur in October 2017, likely based on 2014 to 2016 air quality data, with a final effective date usually 60 days later or approximately December 1, 2017.

States will then have three years (i.e., December 1, 2020) to bring marginal nonattainment areas into attainment. In order for a state to show attainment, three full years of air quality data are needed to compute a design value. Historically, when the attainment date for a standard falls mid-year, U.S. EPA has interpreted that states must then default to showing compliance with the three calendar years preceding the attainment year. Because attainment is due in December, presumably states will not be able to use air quality data for the year 2020 due to the lack of a full year of 2020 data. This essentially causes states to not be allotted the full three years to reach attainment authorized by the CAA. States would need to use air quality data from 2017 to 2019 to show attainment instead of data from 2018 to 2020. States must be allowed to use the full three years of data to show attainment as specified by the CAA.

This is not the first instance where the promulgation of a new NAAQS has created a timing issue. Under the “Implementation of the 2008 National Ambient Air Quality Standards for Ozone: Nonattainment Area Classifications Approach, Attainment Deadlines and Revocation of the 1997 Ozone Standards for Transportation Conformity Purposes” rule (77 Fed. Reg. 30160), U.S. EPA recognized that the timeframe limited states ability to have the full time allowed by the CAA to attain the 2008 standard and attempted to rectify this matter by allowing states to have until the end of the calendar year to show attainment of the standard. However, on December 23, 2014, the United States Court of Appeals for the District of Columbia Circuit vacated the attempt to set the attainment date as December 31st of the attainment year. Therefore, consistent with the Phase 1 rule for implementation of the 1997 ozone NAAQS, attainment timeframes under the 2008 standard run from the date that area designations and nonattainment classifications (by operation of law) became effective.

Ohio EPA appreciates U.S. EPA’s effort to rectify this issue in the past; however, the method was not successful and an immediate solution must be found. Ohio EPA would like to stress that attainment schedules should be aligned so states are ensured the full time to reach attainment under the CAA. If U.S. EPA cannot align these schedules to allow the full time to reach attainment because they have found themselves in the position to be under court order to finalize a review of the standard, then U.S. EPA must provide an alternative method, such as allowing states to use 36 months of air quality data to show attainment in lieu of three calendar years.

U.S. EPA notes that the CAA does not require U.S. EPA to promulgate new implementing regulations or issue additional guidance for every new NAAQS. 79 Fed. Reg. 75369. Furthermore, U.S. EPA states that when additional regulation or guidance is issued, the CAA does not require it be issued before the revised NAAQS is effective. While Ohio EPA appreciates U.S. EPA’s factual analysis of the regulatory language of the CAA, Ohio EPA asserts that clearly Congress did not intend for U.S. EPA to issue ill-timed regulations or guidance clearly needed by the states to address their requirements under the NAAQS. For example, U.S. EPA issued final regulations for implementation of the 2008 ozone NAAQS on February 17, 2015; approximately five months before marginal areas are to attain the standard. This implementation guidance provides insight on how states are to prepare SIPs that ensure attainment and when those attainment SIPs were due nearly seven months earlier. This is not a rare occurrence but rather a recent example of ill-timed guidance and regulations. Ohio EPA will continue to urge U.S. EPA to issue timely regulations and guidance to better assist states in performing their required role.

To that end, U.S. EPA acknowledges that the currently available guidance for infrastructure SIPs does not address certain requirements such as interstate

pollution transport requirements. 79 Fed. Reg. 75373. U.S. EPA states that should the guidance need to be modified, U.S. EPA intends to *propose* it no later than one year after finalizing this proposal. Ohio EPA cannot emphasize enough the implications and difficulties that have arisen because of the lack of proper, timely, final guidance regarding interstate transport and infrastructure SIPs. *Proposing* a rule or guidance does not give Ohio peace of mind. Often there are significant changes between a proposal and final rule or guidance that requires states to overhaul their plans based on a proposal. At times, the guidance or rule promulgation is not even known until just before or after a required submittal date, and the states have no option but to submit an incomplete SIP or a late SIP while work carries on to conform to the *final* rule or guidance. This is a significant waste of the states' very limited resources.

In addition, ill-timed and improper infrastructure SIP guidance under the 2006 PM_{2.5} standard opened the door for U.S. EPA to impose a federal implementation plan (FIP) on states and require CSAPR implementation. The majority of states still find themselves out of compliance with the interstate transport provisions under the 2008 ozone standard as U.S. EPA continues to hold discussions to "help the states" address this requirement. This will be yet another new standard with which states will quickly be out of compliance. It is not practical or logical for states, with extremely limited resources, to individually address interstate transport in a suitable manner. This has historically been the domain of U.S. EPA from the NO_x SIP Call, to CAIR, to CSAPR. U.S. EPA should not be promulgating a new NAAQS until they are prepared to provide a reasonable program as an option for states to use to comply with the interstate transport requirements. Otherwise, U.S. EPA is simply setting the states up to fail.

U.S. EPA is requesting comment on whether there are challenges that would warrant 18 additional months to complete infrastructure SIPs for the secondary standard (as afforded under Section 110(b) of the CAA) if it is distinct from the primary standard. 79 Fed. Reg. 75373. As noted above, Ohio EPA does not support a distinct secondary standard. However, if U.S. EPA decides to promulgate a distinct secondary standard, Ohio EPA can only foresee significant issues in addressing this distinct standard as proposed as part of SIPs. This will be a territory uncharted and significant guidance will be necessary. How will U.S. EPA view states requirements for addressing a distinct secondary standard with respect to interstate transport? Given U.S. EPA's record on timely guidance, that alone warrants an additional 18 months for states to prepare SIPs.

With regards to the possibility of a distinct secondary standard, Ohio EPA agrees there will obviously be unique implementation issues to consider. 79 Fed. Reg. 75375. Given the limited state resources, U.S. EPA must consider the implication of a distinct standard and weigh any perceived benefits of such a

standard in this context. States will have to shift significant resources and staff effort to address the unique circumstances that come with imposing a distinct secondary standard, such as additional prevention of significant deterioration (PSD) permitting. Ohio does not find that beneficial. Limited state resources should be focused elsewhere. Specifically with respect to PSD permitting, Ohio EPA firmly believes if a distinct secondary standard is established U.S. EPA must promulgate a surrogacy policy that would allow a demonstration of compliance with the primary standard to also address the unique secondary standard.

U.S. EPA notes they have granted a petition from Sierra club requesting, among other things, that U.S. EPA initiate rulemaking to designate air quality models for ozone. 79 Fed. Reg. 75377. Even U.S. EPA acknowledges in the January, 4, 2012 Gina McCarthy Memo that it is not technically able to designate a specific air quality model that must be used for permitting with respect to ozone because of ozone's complex chemistry. 79 Fed. Reg. 75377. Ohio EPA agrees. Flexibility must be afforded in addressing major new source review (NSR) modeling requirements for determining impacts from single sources of ozone. Further, U.S. EPA has historically entered into negotiations, accepted petitions or developed consent decrees with entities, such as the Sierra Club, with little to no involvement or consultation with state agencies. U.S. EPA should be including the states in these negotiations since many of the requirements that come out of these agreements are those that need implemented by the states.

Cost

States have worked diligently and in good faith to meet various ozone NAAQS over the last decade. Depending on the level that the Administrator chooses under this proposal, a large portion of the country could become nonattainment for the revised ozone standard soon after reaching, or nearly reaching, attainment for the 2008 ozone standard.

As mentioned previously, "Where US EPA operates in the realm of uncertain science, its decision about appropriate NAAQS level must necessarily rest largely on policy judgments." *Mississippi*, 744 F.3d at 1357 (quotations omitted). With elusive scientific certainty to establish a standard below 0.075 ppm and even less certainty below 0.072 ppm, Ohio EPA urges the Administrator to exercise discretion by not establishing a standard lower than necessary to be protective of human health with an adequate margin of safety. The predicted impact to the nation's economy from a lowering of the existing standard will be significant.

During Ohio EPA's review of this proposal and in speaking with numerous stakeholders affected by this proposal, we have heard the same message....an

ozone standard in the range of 0.060 to 0.070 ppm will be devastating to Ohio's economy. NERA Economic Consulting projected the economic impact both nationally and on an individual state basis for an ozone standard established at 0.060 and 0.065 ppm. At 0.060 ppm they predicted a reduced national GDP of \$3.4 trillion on a present value basis (as of 2014) and \$270 billion per year on an annualized basis (spread evenly from 2017 to 2040 but retaining the same present value). (Appendix G). At 0.065 ppm, they predict a reduced national GDP of \$1.7 trillion on a present value basis (as of 2014) and \$140 billion per year on an annualized basis as noted above. (Appendix H). In Ohio, a standard of 0.065 ppm is predicted to result in over 22 thousand lost jobs (or job equivalents) per year and culminate in a loss of \$22 billion in gross state product from 2017-2040. (Appendix I). If accurate, these predictions would have a suffocating effect on our nation and state's fragile economic recovery.

The NERA studies limited their analysis and economic impacts to direct costs to reduce emissions. Not considered were additional cost related to difficulty or delays obtaining permits in nonattainment areas, curtailment of development in urban economic zones, encroachment of economic zones into rural farmland, and the nexus between concurrent efforts to achieve Section 111(d) related carbon and ozone reductions.

Nonattainment designations have a crippling impact on industrial and manufacturing growth. Expansion plans are postponed and new businesses look elsewhere due to the extra hurdles and burdens required of companies in nonattainment areas. Obtaining offsets, analyzing and implementing Lowest Achievable Emissions Reductions (LAER), navigating the Major Source permit process, and conducting ambient modeling to demonstrate minimal impact present difficulties for the project as-well-as future expansion plans.

Entities fortunate enough to be pursuing expansion plans must meet specific criteria sufficient to secure development capital. When evaluating potential sites for an expansion, and/or new facility, factors including infrastructure, education base, availability of suitable utilities, environmental obligations, etc. are considered. Narrowing potential sites is done by assigning value to each variable. Many times this "value" takes the form of a numerical unit (scaled 1-10) or a pass/fail. The pass/fail "value" automatically excludes sites from consideration that fail. This evaluation is performed to ensure sound, justifiable, economic decisions are made in the best interest of the company and investors.

Ohio has observed, on more than one occasion, potential development sites in nonattainment areas excluded in the narrowing process. Numerous times foreign and domestic entities automatically exclude potential development sites unless they are considered "attainment" for all air contaminants. This evaluation is especially true for foreign companies looking to build domestic manufacturing

operations and expect supporting industries to be developed nearby. Quantifying the loss of these potential facilities is exceedingly difficult. Ohio has witnessed this firsthand under the current ozone standard of 0.075 ppm. We expect to face similar problems if the revised standard is tightened as proposed and our nonattainment areas consequently expand. Ohio EPA advises U. S. EPA to ensure that the new standard is established at a "level" that is 'requisite'- that is, not lower or higher than what necessary – to protect public health with an adequate margin of safety." (Opinion of the Court, *Whitman vs American Trucking*).

Ultimately, the unintended consequence of nonattainment areas is that manufacturing, industry, and available jobs are effectively pushed to attainment areas. Traditionally, nonattainment counties and regions overlay with major metropolitan areas. Since vehicles and other factors in a developed community contribute to ozone, as the ozone standard approaches the background-plus-vehicle/community levels, major source permitting and approval becomes more difficult and costly. Companies subsequently explore development sites deeper into rural areas which only amplify ozone issues.

At a level of 0.060, 0.065 or even 0.070 ppm, much of Ohio will be designated nonattainment. Based on 2012 to 2014 air quality data, all 48 monitors in the state of Ohio would violate a 0.060 ppm standard. At a level of 0.065 ppm, this level would be reduced by only four monitors; meaning 44 of 48 monitors would violate. At a level of 0.070 ppm, half of the states monitors would be in violation (24). However, based on U.S. EPA's factor analysis for designating nonattainment areas, Ohio EPA estimates as many as 34 of Ohio's 88 counties will be designated nonattainment whether the standard is set at 0.060 ppm or at 0.070 ppm². Therefore, if U.S. EPA chooses to unnecessarily lower the ozone standard to anywhere within their proposed range, a significant portion of Ohio will face nonattainment and the economic penalty associated with the designation.

² One additional county is nonattainment if the standard is set below 0.070 ppm.