

March 1, 2021

Acting Administrator Jane Nishida
U.S. Environmental Protection Agency
Mail Code 1101A
1200 Pennsylvania Ave., NW
Washington, D.C. 20460
Nishida.Jane@epa.gov

BY FIRST CLASS MAIL AND EMAIL

**Re: PETITION FOR RECONSIDERATION OF EPA'S NATIONAL AMBIENT AIR
QUALITY STANDARDS FOR OZONE, 85 FED. REG. 87,256 (DEC. 31, 2020) –
EPA-HQ-OAR-2018-0279**

Dear Acting Administrator Nishida,

The Environmental Protection Agency published its review of the National Ambient Air Quality Standards for Ozone, otherwise known as the "Ozone NAAQS," on December 31, 2020. 85 Fed. Reg. 87,256 (Dec. 31, 2020).

American Academy of Pediatrics, American Lung Association, American Public Health Association, Appalachian Mountain Club, Clean Air Task Force, Chesapeake Bay Foundation, Earthjustice, Environment America, Environmental Defense Fund, Environmental Law & Policy Center, National Parks Conservation Association, Natural Resources Defense Council, and Sierra Club respectfully petition EPA to convene a proceeding for reconsideration of these standards under Section 307(d) of the Clean Air Act, 42 U.S.C. § 7607(d), and in light of President Biden's recent Executive Orders, because the 2020 review failed to rationally engage with the body of evidence that mandated strengthening the standard, did not set standards at the levels the statute's directive demands, and is the result of a truncated process that resulted in ultimately arbitrary conclusions.

The undersigned organizations represent millions of members and supporters across the country who are deeply concerned about the health, environmental, and economic impacts of air pollution and support setting strong, science-based National Ambient Air Quality Standards ("NAAQS") that ensure public health and the environment are protected.

I. Introduction

The rulemaking docket leaves no doubt: Ozone is one of the most dangerous and persistent forms of air pollution in the United States today. Scientists link ozone, the principal component of smog, to premature deaths, thousands of emergency room visits, and tens of thousands of asthma attacks each year. It is especially dangerous for small children who are uniquely vulnerable because they breathe more air for their body weight than adults and their lungs are still developing from infancy through adolescence, people with asthma, and senior citizens, who are often warned to stay indoors on polluted days. Ozone pollution disproportionately impacts low-income communities and communities of color. Across the nation, people of color are consistently overrepresented in areas with higher ozone levels and that are in nonattainment of ozone NAAQS. Furthermore, the asthma burden of people of color—particularly among Black people—is far higher than that of white people. Also, as well as being a greenhouse gas, ozone pollution can severely damage forests and plants, stunting their growth, increasing the risk of tree die-off from disease, and causing harms that affect whole ecosystems. Hundreds of counties throughout the nation, home to hundreds of millions of people and many treasured natural places, suffer from unsafe ozone levels.

The enactment of the Clean Air Act and its amendments “carries the promise that ambient air in all parts of the country shall have no adverse effects upon any American’s health.” 116 Cong. Rec. 42,329, 42,381 (Dec. 18, 1970) (remarks of Sen. Muskie). Its purpose is to “protect and enhance” air quality, 42 U.S.C. § 7401(b), and mitigate the “mounting dangers to the public health and welfare” caused by air pollution. *Id.* § 7401(a)(2). To that end, the Clean Air Act establishes both primary and secondary “National Ambient Air Quality Standards,” or NAAQS, for some of the most common “criteria” pollutants in the “ambient air.” *Id.* § 7409; *see also* 40 C.F.R. part 50.

Primary NAAQS must be “requisite to protect the public health” with “an adequate margin of safety,” to prevent not only any known or anticipated health-related effects from polluted air, but also those that are scientifically uncertain or that research has not yet uncovered. 42 U.S.C. § 7409(b)(1). Further, the statute makes clear that there are significant limitations on the discretion granted to EPA in setting the NAAQS. In exercising its judgment, EPA must err on the side of protecting public health, and “taking account of the ‘preventative’ and ‘precautionary’ nature of the act... the Administrator must then decide what margin of safety will protect the public health from the pollutant’s adverse effects – not just known adverse effects, but those of scientific uncertainty or that ‘research has not yet uncovered.’” *Am. Lung Ass’n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (citations omitted); *see also Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 464–71 (2001).

Importantly, the NAAQS must not only be adequate to protect the average member of the population, but must also protect against adverse effects in vulnerable subpopulations, such as children, pregnant people, the elderly, the socially disadvantaged, and people with heart and lung

disease. The D.C. Circuit has repeatedly found that if a certain level of a pollutant “adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.” *Am. Lung Ass’n*, 134 F.3d at 389 (citation omitted); *see also Coal. of Battery Recyclers Ass’n v. EPA*, 604 F.3d 613, 618 (D.C. Cir. 2010); *Am. Farm Bureau Fed’n v. EPA*, 559 F.3d 512, 524 (D.C. Cir. 2009). EPA must also build into the NAAQS an adequate margin of safety for these sensitive subpopulations. *See Am. Farm Bureau Fed’n*, 559 F.3d at 526.

The Clean Air Act requires that secondary NAAQS “specify a level of air quality the attainment and maintenance of which . . . is requisite to protect the public welfare from any known or anticipated adverse effects.” 42 U.S.C. § 7409(b)(2); *Am. Farm Bureau Fed’n*, 559 F.3d at 530. Effects on welfare include impacts 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, whether caused by transformation, conversion, or combination with other air pollutants.” 42 U.S.C. § 7602(h). Senator Muskie, one of the prime architects of the Act, in speaking about the amendments for public welfare during the Senate debates, noted that the protections for public welfare “are especially important because some pollutants may have serious effects on the environment at levels below those where health effects may occur” and will be set to be “protective against any known or anticipated adverse environmental effects.” Legislative History of Clean Air Act Amendments of 1970 at 227 (Senate Debate on S. 4358, Sept. 21, 1970). The congressionally mandated “ongoing, periodic review and revision process set up by Congress . . . ensure[s] that regulatory guidelines and standards which protect human safety and welfare are kept abreast of rapid scientific and technological developments,” *Am. Lung Ass’n v. Browner*, 884 F. Supp. 345, 347 (D. Ariz. 1994), and that “as the contours and texture of scientific knowledge change . . . EPA’s NAAQS review necessarily changes as well,” *Mississippi v. EPA*, 744 F.3d 1334, 1344 (D.C. Cir. 2013).

a. 2020 Ozone NAAQS Review

Prior to the 2020 review, EPA last updated the annual ozone standard in 2015, when the Obama administration completed its statutory 5-year review of the 2008 ozone standard, and slightly strengthened the health standard to 70 ppb (from 75 ppb) in October of 2015. 80 Fed. Reg. 65,292 (Oct. 26, 2015). This modest strengthening was less than what the record would have supported. In its 2014 review of the science leading up to the 2015 review, EPA’s Clean Air Scientific Advisory Committee (CASAC) concluded that the 2008 standard of 75 ppb was insufficient to protect public health. The scientific panel recommended a lower standard, in the range between 60 and 70 ppb, explaining that “[a]t 70 ppb, there is substantial scientific evidence of adverse effects . . . including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation,” and that a 70 ppb standard “may not meet the statutory

requirement to protect public health with an adequate margin of safety.”¹ Most importantly, the panel’s policy advice was “to set the level of the standard *lower than 70 ppb* within a range down to 60 ppb.” *Id.* (emphasis added). Despite this recommendation, EPA proposed a range only between 65 to 70 ppb for the 2015 review, and ultimately finalized a standard of 70 ppb, despite CASAC’s recommendations. 79 Fed. Reg. 75,234 (Dec. 17, 2014); 80 Fed. Reg. 65,292 (Oct. 26, 2015).

In the leadup to the 2020 ozone NAAQS review, then-EPA Administrator Pruitt announced a so-called “back to basics” policy for the NAAQS in 2018 that truncated scientific review processes and stripped review boards of independent scientists who had legitimately relevant expertise.² The Trump Administration proposed to maintain the 2015 standard of 70 ppb in July of 2020, and finalized the standard on December 23, making the rule effective immediately on publication in the Federal Register. *Review of the National Ambient Air Quality Standards for Ozone*, 85 Fed. Reg. 49,830 (Aug. 14, 2020) (“Proposed Rule”); *National Ambient Air Quality Standards for Ozone*, 85 Fed. Reg. 87,256 (Dec. 31, 2020) (“Final Rule”).

b. Authority for Reconsideration

Because the Agency’s final decision meets the test under Section 307(d) of the Clean Air Act, 42 U.S.C. § 7607(d), EPA must immediately undertake a reconsideration proceeding of the 2020 ozone standards. Under Section 307(d), the Administrator must grant a petition for reconsideration if a petitioner “can demonstrate to the Administrator that it was” either (1) “impracticable” to raise an objection or (2) “if the grounds for such objection arose after the period for public comment.” In addition, the objection must be “of central relevance to the outcome of the rule.” *Id.* § 7607(d)(7)(B). “The first element’s impracticability prong – rather than the ‘arising after’ prong – is met ‘when the final rule was not a logical outgrowth of the proposed rule.’” *Chesapeake Climate Action Network v. EPA*, 952 F.3d 310, 319 (D.C. Cir. 2020) (internal citation omitted). “A final rule is the ‘logical outgrowth’ of a proposed rule if ‘interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period.’” *Clean Air Council v. Pruitt*, 862 F.3d 1, 10 (D.C. Cir. 2017) (internal citation omitted); *see also Portland Cement Ass’n v. EPA*, 665 F.3d 177, 185–86 (D.C. Cir. 2011). An objection is of central relevance if it “provides substantial support for the argument that the regulation should be revised.” *Coal. for Responsible Regul. v. EPA*, 684 F.3d 102, 125 (D.C. Cir. 2012), *aff’d in*

¹ Letter to Hon. Gina McCarthy from Clean Air Scientific Advisory Committee, “CASAC Review of the EPA’s Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards,” at 2 (June 26, 2014) (EPA-CASAC-14-004) (“2014 CASAC Letter”).

² Memorandum from E. Scott Pruitt, Former Administrator, U.S. Environmental Protection Agency, on Back to Basics for Reviewing the National Ambient Air Quality Standards to EPA Assistant Administrators at 3 (May 9, 2018) (“2018 Pruitt NAAQS Memo”), available at <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>

part, rev'd in part on other grounds sub. nom. Util. Air Regul. Grp. v. EPA, 573 U.S. 302 (2014); *see also* 42 U.S.C. § 7607(d)(7)(B). When a petitioner meets these elements, EPA must convene a reconsideration proceeding. A reconsideration proceeding provides members of the public with an opportunity to comment on aspects of a final rule that they were not given adequate notice of previously.

As this Petition explains, the 2020 ozone standards violate EPA's core duty to protect public health and welfare in carrying out obligations in the Clean Air Act, and in setting the NAAQS with an adequate margin of safety. The Final Rule's rationale also differs significantly from the proposal in ways that do not represent a logical outgrowth of the Proposed Rule, making it impracticable to have raised objections to certain issues prior to issuance of the Final Rule. The Administrator must therefore "convene a proceeding for reconsideration of the rule" in accordance with the requirements of the Act. 42 U.S.C. § 7607(d)(7)(B). But not all aspects of the rule are necessarily subject to mandatory reconsideration, and, because of the seriousness of the harms ozone causes and the urgency of action to address those harms, Petitioners reserve their right to pursue litigation even without EPA action on this petition.

Further, the Biden Administration has pledged an ambitious, broad-based, "whole-of-government" approach to addressing environmental injustices. As EPA renews its commitment to environmental justice and civil rights, EPA must thus reconsider its decision to maintain outdated standards for ozone that disproportionately harm Black and brown communities.³ Section 2 of Executive Order 13990 mandates that

[t]he heads of all agencies shall immediately review all existing regulations, orders, guidance documents, policies, and any other similar agency actions (agency actions) promulgated, issued, or adopted between January 20, 2017, and January 20, 2021, that are or may be inconsistent with, or present obstacles to, the policy set forth in section 1 of this order. For any such actions identified by the agencies, the heads of agencies shall, as appropriate and consistent with applicable law, consider suspending, revising, or rescinding the agency actions.⁴

These executive orders affirm that a reconsideration of EPA's 2020 ozone standards decision is necessary.

³ Exec. Order No. 13990, *Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis*, 86 Fed. Reg. 7037 (Jan. 20, 2021); Exec. Order No. 12898, 59 Fed. Reg. 7629 (1994); *20th Anniversary of Executive Order 12898 on Environmental Justice*, Proclamation No. 9082 of Feb. 10, 2014, 79 Fed. Reg. 8819 (Feb. 13, 2014), available at <https://obamawhitehouse.archives.gov/the-press-office/2014/02/10/presidential-proclamation-20th-anniversary-executive-order-12898-environ>.

⁴ Exec. Order No. 13990, 86 Fed. Reg. 7037 (Jan. 20, 2021).

II. Grounds for objection regarding the primary standard

- a. Overwhelming scientific evidence shows ozone harms human health, including at levels the current standard allows.

The scientific evidence—including controlled human exposure studies, animal toxicology, and epidemiology described in the Integrated Science Assessment for Ozone and Related Petrochemical Oxidants (“ISA”) and in studies raised by commenters—demonstrates that significant harms to human health occur at ozone levels allowable under the current 70 ppb standard.

EPA’s failure to rationally consider certain studies and failure to rationally explain its reliance on studies of healthy individuals when selecting the level necessary to protect vulnerable populations warrant reconsideration. First, these issues are of central relevance to both whether the 70 ppb standard “accurately reflect[s] the latest scientific knowledge,” 42 U.S.C. § 7408(a)(2), and whether it is “requisite to protect the public health” with “an adequate margin of safety,” *id.* § 7409(b)(1), taking into account sensitive populations. Second, it would have been impracticable for the public to comment on these issues at the proposal stage.

EPA also failed to rationally consider “new” studies raised by commenters that demonstrate health harms below the level of the current standard. The Agency did not rationally consider American Thoracic Society (“ATS”) Guidelines and lung inflammation studies that relate to what constitutes an adverse effect in people with asthma. EPA additionally did not rationally explain how its reliance on studies that mostly include only healthy adults, where children and others are known to be more vulnerable, can lead to a final rule that provides the legally-required level of protection for vulnerable populations.

- i. EPA fails to rationally consider new studies and wrongly dismissed them on the ground that they purportedly did not materially change the broad scientific conclusions of the ISA.

EPA failed to rationally consider new studies identified by commenters and arbitrarily and capriciously dismissed these studies after having “provisionally considered” them, on the grounds that they “do not materially change the broad conclusions of the ISA.” 85 Fed. Reg. 87,289. EPA states that the provisional consideration of these new studies was not intended to “provide the kind of in-depth critical review” that was given to the studies included in the ISA, but “was focused on determining whether they warranted reopening the review of the air quality criteria to enable the EPA, the CASAC and the public to consider them further.” *Id.* at 87,262. This provisional consideration is really no consideration at all, as EPA makes clear by stating:

Accordingly, the EPA is basing the final decisions in this review on the studies and related information included in the O₃ air quality criteria that have undergone rigorous review by the EPA, the CASAC and the public. The EPA will consider these “new” studies for inclusion in the air quality criteria for the next O₃ NAAQS review

Id. at 87,263. EPA determined that reopening the review was not warranted because “the ‘new’ information and findings do not materially change any of the broad scientific conclusions regarding the health and welfare effects of O₃ in ambient air made in the air quality criteria.” *Id.* at 87,262-63.

The studies introduced by commenters provide important evidence about health effects that occur at ozone levels allowed in areas meeting the current primary standard, and therefore EPA’s decision on whether to consider them as part of this NAAQS review is of central relevance to its decision to retain the existing standard. Because EPA’s proposal did not include any indication that it would apply this “provisional consideration” to new studies raised by commenters, or consider them only in the context of “reopening review of the air quality criteria,” objections to EPA’s treatment of the new studies raised by commenters were impracticable to raise during the comment period. Additionally, EPA’s rationale for putting off consideration of the “new” studies until a future round of ozone NAAQS review was arbitrary and capricious. EPA arbitrarily does not explain what it means by “materially” and “broad” in stating that these provisionally-considered studies “do not materially change any of the broad scientific conclusions regarding the health and welfare effects” of ozone. Even if the new studies do not change unspecified “broad” conclusions, they can still have important implications for individual scientific conclusions, such as whether particular levels of ozone cause specific health effects, a point centrally relevant to the outcome of EPA’s review of the ozone standard.

In the Final Rule, EPA indicates that it “will consider these ‘new’ studies for inclusion in the air quality criteria for the next O₃ NAAQS review, which the EPA expects to begin soon after the conclusion of this review and which will provide the opportunity to fully assess these studies through a more rigorous review process involving the EPA, the CASAC, and the public.” *Id.* at 87,263. But in doing so, EPA did not engage with the findings of studies published after March 2018 and did not explain why certain studies, including several that identify health harms at currently permissible levels, were excluded from the final ISA in April 2020 or a provisional science assessment.

At the very least, EPA should have considered all studies published as of December 3, 2018, the final date for accepting comments on the ISA, or as of April 2020, when the ISA was finalized. As an example of past practice, on December 14, 2012, EPA published its *Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure*, a detailed, analytical document. EPA noted at the time that the report “presents the findings of EPA’s survey and provisional assessment of [studies published since the completion of the 2009 PM ISA]. EPA has screened and surveyed the recent literature and developed a provisional assessment that places those studies of potentially greatest relevance to the current PM NAAQS review in the context of the findings of the 2009 PM ISA.”⁵ Unlike before, EPA did not conduct a thorough provisional assessment of recently published peer-reviewed studies for the April 2020 O₃ Integrated Science Assessment prior to finalizing the O₃ NAAQS proposal. These recent studies include a 2019 study analyzing air pollution concentrations (including ozone) and asthma

⁵ EPA, *Provisional Assessment of Recent Studies on Health Effects of Particulate Matter Exposure* at vii (Dec. 2012)

incidence in children⁶ that identified reduced asthma incidence as ozone concentrations fell over time.

A sample of additional important recent studies the Agency failed to adequately consider in its Final Rule include:

Fuller, Christina H., Jordan W. Jones, and Douglas W. Roblin. “Evaluating Changes in Ambient Ozone and Respiratory-Related Healthcare Utilization in the Washington, DC Metropolitan Area.” *Environmental Research* 186 (July 2020): 109603. <https://doi.org/10.1016/j.envres.2020.109603>.

Authors estimated the association between changes in ambient ozone (exposure windows of current day, 1-day lag and 3-day moving average) and changes in healthcare utilization using linear regression controlling for census tract-level socioeconomic indicators and temperature. Increases in ozone were associated with increases in three of the four utilization event types. A 10 ppb increase in 1-day ozone was associated with a 2.95% (95% CI: 1.93%, 3.96%) increase in hospital calls/emails, a 1.56% (95% CI: 0.38%, 2.74%) increase in emergency department/urgent care visits and a 1.10% (95% CI: 0.48%, 1.73%) increase in provider visits. The mean ozone concentration during the study period was 46.1 ppb.

Gao, Hui, Kan Wang, William W. Au, Wensui Zhao, and Zhao-lin Xia. “A Systematic Review and Meta-Analysis of Short-Term Ambient Ozone Exposure and COPD Hospitalizations.” *International Journal of Environmental Research and Public Health* 17, no. 6 (Mar. 23, 2020): 2130. <https://doi.org/10.3390/ijerph17062130>.

Authors used random effect models to derive overall excess risk estimates between short-term ambient-level O₃ exposure and COPD hospitalizations. Based on the results from 26 eligible studies, analyses showed that a 5 ppb increase in maximum 8-h ozone concentration was associated with a 0.84% (95% CI: 0.09%, 1.59%) higher rate COPD hospitalizations.

Mendoza, Daniel L, Cheryl S Pirozzi, Erik T Crosman, Theodore G Liou, Yue Zhang, Jessica J Cleaves, Stephen C Bannister, William R L Anderegg, and Paine III Robert. “Impact of Low-Level Fine Particulate Matter and Ozone Exposure on Absences in K-12 Students and Economic Consequences.” *Environmental Research Letters* 15, no. 11 (Nov. 18, 2020): 114052. <https://doi.org/10.1088/1748-9326/abbf7a>.

Authors modeled PM_{2.5} and annual average O₃ concentrations at 36 schools from July 2015 to June 2018 using data from a dense, research grade regulatory sensor network and determined exposures and daily absences at each school to estimate lost school revenue, productivity, and family economic burden. Pollution exposure was associated with a rate ratio as high as 1.02 absences per $\mu\text{g m}^{-3}$ and 1.01 per ppb increase for PM_{2.5} and ozone, respectively. PM_{2.5} and ozone exposures below the air quality index breakpoints for good air quality ($<12.1 \mu\text{g m}^{-3}$ and

⁶ Garcia, Erika, et al., “Association of Changes in Air Quality with Incident Asthma in Children in California, 1993-2014.” *JAMA* 321, no. 19 (May 21, 2019), <https://doi.org/10.1001/jama.2019.5357>

<55 ppb, respectively) was associated with positive rate ratios of absences: 1.04 per $\mu\text{g m}^{-3}$ and 1.01 per ppb increase, respectively. Annual mean O₃ exposure level across all of the schools was about 28 ppb.

Seltzer, Karl M., Drew T. Shindell, Prasad Kasibhatla, and Christopher S. Malley. “Magnitude, Trends, and Impacts of Ambient Long-Term Ozone Exposure in the United States from 2000 to 2015.” *Atmospheric Chemistry and Physics* 20, no. 3 (Feb. 14, 2020): 1757–75. <https://doi.org/10.5194/acp-20-1757-2020>.

Authors modeled long-term O₃ exposure over the continental United States from 2000 to 2015 and generated a measurement-based assessment of impacts on human-health and crop yields. Overall, these results provide a measurement-based estimate of long-term O₃ exposure over the United States and quantify the historical trends of such exposure. Authors estimated net estimated premature deaths attributable to long-term O₃ exposure (at levels peaking at 55.9 ppb) ranged from 14,500 to 37,600 between 2000 and 2015.

Wagner, James G., Christina E. Barkauskas, Aaron Vose, Ryan P. Lewandowski, Jack R. Harkema, and Robert M. Tighe. “Repetitive Ozone Exposures and Evaluation of Pulmonary Inflammation and Remodeling in Diabetic Mouse Strains.” *Environmental Health Perspectives* 128, no. 11 (Nov. 2020): 117009. <https://doi.org/10.1289/EHP7255>.

Researchers assessed whether pulmonary responses to repetitive ozone exposures are exacerbated in murine strains that are hyperglycemic and insulin resistant. Results demonstrate that in diabetic animal strains repetitive ambient ozone exposure led to early and exaggerated pulmonary inflammation. The work provides a biological mechanistic framework to support the emerging epidemiological associations among air pollution, diabetes, and lung disease.

Dimakopoulou, Konstantina, John Douros, Evangelia Samoli, Anna Karakatsani, Sophia Rodopoulou, Despina Papakosta, Georgios Grivas, et al. “Long-Term Exposure to Ozone and Children’s Respiratory Health: Results from the RESPOZE Study.” *Environmental Research* 182 (March 2020): 109002. <https://doi.org/10.1016/j.envres.2019.109002>.

Investigators quantified the effects of long-term exposure to O₃ on respiratory health outcomes in 10-11-year old children. A 10 $\mu\text{g}/\text{m}^3$ (5 ppb) increase in long-term O₃ exposure was associated with lower forced vital capacity (FVC) and Forced Expiratory Volume at 1 second (FEV₁) by 17mL (95% Confidence Interval: 5-28) and 13mL (95% CI: 3-21) respectively, and small decreases in lung growth: 0.008% (95% CI: 0.002-0.014%) for FVC and 0.006% (95% CI: 0.000-0.012%) in FEV₁. The study provides evidence that long-term ozone exposure is associated with reduced lung volumes and growth.

- ii. EPA also fails to rationally consider new ATS Guidelines and lung inflammation studies.

Because the standard must be set at a level that protects sensitive populations, EPA's consideration of the following is of central relevance to the decision to retain the 2015 primary standard: (1) whether certain lung function decrements constitute adverse effects in people with asthma, a question where ATS Guidelines are especially important, and (2) whether inflammation from a single exposure is an adverse event. In the Final Rule, however, EPA provides new rationales, not included in the Proposed Rule; so it would have been impracticable for the public to comment on those rationales during the comment period.

Though the Final Rule states that commenters were incorrect that EPA had failed to rationally consider the ATS Guidelines, the Final Rule still fails to rationally explain how EPA took the Guidelines into account in coming to its decision to retain the 2015 primary standard. Notably, EPA seems to misconstrue the Guidelines' statement about the adversity of lung function changes, an error that renders EPA's consideration of the Guidelines irrational. EPA characterizes the new Guidelines as "giv[ing] weight to findings of such lung function changes in the absence of respiratory symptoms in individual with pre-existing compromised function." 85 Fed. Reg. 87,292/3. In reality, the new Guidelines are stronger than that, saying such effects "*should* be considered adverse." Guidelines at 7, EPA-HQ-OAR-2018-0279-0126 (emphasis added).

In response to comments about how the proposal failed to consider 10% FEV₁ decrement in assessing the results of the chamber studies, EPA says that it "present[ed]" results regarding such decrements in the risk assessment. 85 Fed. Reg. 87,293/1 n.118. EPA's response entirely misses the point of the comments: whether EPA considered how many participants in chamber studies experienced at least 10% decrement, rather than 15% (as it focused on in the proposal). Comments 35-36, EPA-HQ-OAR-2018-0279-0444.⁷ That EPA "present[ed]" the result of the risk assessment addressing 10% decrement is entirely unresponsive to that point. Notably in any event, EPA writes off the risk assessment pretty much entirely. *See, e.g.*, 85 Fed. Reg. 87,303/2-06/1 (explaining the basis for its final decision, EPA exclusively discusses the exposure assessment's results without even mentioning the risk assessment's result). EPA also says that it alluded in the Policy Assessment ("PA") to 10% decrement as "a focus" that "may be appropriate." *Id.* at 87,293/1. This response also fails entirely to address the core concern of the comment: without considering the number of study participants who experienced 10% FEV₁ decrement, EPA hasn't rationally shown how the current standard provides requisite protection for the sensitive populations for whom such decrement is likely an adverse health effect.

Further, in response to comments indicating that the proposal did not rationally consider studies showing lung inflammation at exposures as low as 60 ppb, the Final Rule asserts that commenters are wrong because EPA gave them "significant consideration." *Id.* at 87,294. At the same time, however, EPA also seems to assert that it need not have given weight to lung inflammation because "the inflammatory response observed following the single exposure to 60 ppb in the study by Kim et al. (2011) of largely healthy subjects is not necessarily an adverse

⁷ We attach and incorporate these comments into this petition, as well.

response.” *Id.* Stating that something is “not necessarily” an adverse response does not rationally consider the likelihood that it is an adverse response, at least in more vulnerable populations. EPA also gives an explanation for discounting this study that was not given in the Proposed Rule:

the potential for effects reported from 6.6-hour exposures to 60 ppb O₃, during quasi-continuous exercise, including the inflammation reported by Kim et al. (2011) to contribute to adverse health effects is uncertain. Newly available evidence in this review does not reduce this uncertainty or provide a contradiction to conclusion regarding the implications of inflammation induced by single or isolated exposures. . . .

Id. at 87,294 n.121. EPA acknowledges that people with asthma likely experience adverse effects as a result of this inflammation, and thus its generic reliance on uncertainty in particular studies that don’t include people with asthma is inconsistent with the Act, as the D.C. Circuit’s controlling interpretation makes clear. The D.C. Circuit has held that the Act’s mandate requires that in considering uncertainty EPA “must err on the side of caution” in terms of protecting human health and welfare: “The Act requires EPA to promulgate protective primary NAAQS even where . . . the pollutant’s risks cannot be quantified or ‘precisely identified as to nature or degree.’” *E.g., Am. Trucking Ass’ns v. EPA*, 283 F.3d 355, 369, 378 (D.C. Cir. 2002) (quoting Particulate Matter NAAQS, 62 Fed. Reg. 38,652, 38,653 (July 18, 1997)); *see also* Comments at 11-12.

Similarly, EPA states: “not every occurrence of an exposure considered to have the potential to increase airway inflammation will result in such an adverse effect. We find it important to note, however, that continued acute inflammation can contribute to a chronic inflammatory state, with the potential to affect the structure and function of the lung.” 85 Fed. Reg. 87,294. Saying that “not every” exposure to certain levels will result in harmful lung inflammation is not the same thing as rationally considering the exposures that *do* lead to such adverse effects. And, given the acknowledged potential for chronic lung inflammation to be harmful, EPA’s dismissal of lung inflammation is arbitrary and capricious. EPA’s further reliance on its exposure assessment is arbitrary, as explained in comments and below.

EPA also provides a rationale for discounting other lung inflammation studies that was not present in the Proposed Rule:

One commenter contends that inflammation is apparent from short-term O₃ exposures ranging from 12 to 35 ppb, based on air quality metrics reported in some epidemiologic studies, such as mean 24-hour averages or monthly averages of 8- hour concentrations (ISA, Table 4–28). The commenter implies that such values for these metrics are lower than the level of the standard (70 ppb) means that exposures allowed by the standard are causing outcomes analyzed in the study. However, none of the metrics for which values are cited by the commenter are in terms of design values for the current standard, such that a direct comparison of the values is not meaningful.

Id. at 87,294 n.120. Regardless, EPA has not addressed whether the values in those studies are ozone concentrations and exposures that would be expected to occur in areas with design values complying with the current standard.

- iii. EPA fails to rationally explain how its approach of reliance on studies that feature healthy adults provides requisite protection to more vulnerable populations.

EPA does not rationally explain how reliance on studies involving mostly healthy adult subjects enables it to set a standard that provides an “adequate margin of safety” that takes into account sensitive populations including adults and children with asthma. EPA’s judgments about whether the standard adequately protects these sensitive populations are centrally relevant to the question of whether EPA has fulfilled its statutory mission under the Clean Air Act.

EPA acknowledges multiple times in the Final Rule that the majority of the studies on which it relies include only healthy adults. *See, e.g., id.* at 87,269 (“Within the evidence base from controlled human exposure studies, the majority of studies involve healthy adult subjects (generally 18 to 35 years), although there are studies involving subjects with asthma... .”); *id.* at 87,293–94 (“We recognize that this evidence and the evidence represented by the three benchmark concentrations used in the exposure/risk analyses (60, 70 and 80 ppb) is for largely healthy adults and does not include data for people with asthma.”). The Final Rule also acknowledges that “[w]hile the evidence regarding the susceptibility of people with asthma to the effects of O₃ is robust, our understanding of the exposures at which various effects (of varying severity) would be elicited is less defined.” *Id.* at 87,293.

The Final Rule states that controlled human exposures studies have indicated “similar magnitude of O₃-related FEV₁ decrements for people with as for people without asthma” and that, for other respiratory effects, “the evidence has also found the observed responses to generally not differ due to the presence of asthma, although the evidence base is more limited with regard to study subjects with asthma.” *Id.* at 87,293. As pointed out in comments, EPA’s seeming assumption that the level of lung function impairment is similar for people with asthma is unfounded. Comments at 40. EPA then states that due to the uncertainty regarding the exposures eliciting effects in people with asthma and the severity of those effects, “other aspects of the evidence are informative to the necessary judgments,” and states that EPA therefore relies on the ATS Guidelines and advice from CASAC in determining whether the standard is protective of people with asthma. 85 Fed. Reg. 87,293. As already discussed above, EPA fails to rationally consider the ATS Guidelines, and does not rationally consider lung inflammation, a respiratory effect of particular concern for people with asthma. The Clean Air Act requires EPA to set a precautionary NAAQS that will be protective of human health, including the health of sensitive populations, such as children, particularly during vulnerable developmental windows. Children are not little adults, and these differences are in kind rather than degree. EPA’s failure to rationally explain how its reliance on studies of healthy adults leads it to a standard that protects vulnerable populations is therefore inconsistent with the Clean Air Act and arbitrary.

- b. EPA's failure to adopt a long-term exposure standard is arbitrary and capricious, and its explanation is new.

For the first time, EPA addresses the need for a long-term ozone standard to protect public health. Long-term exposure is particularly relevant for the susceptible population of children, especially as pertains to lung growth and capacity. EPA's rejection of such a standard is arbitrary.

EPA notes in the Final Rule that a long-term O₃ exposure is "likely" to cause respiratory effects and contends that recent studies "are generally consistent with the evidence assessed in the ISA, and, arbitrarily, as explained above, that they do not materially change the broad conclusions in the ISA regarding the scientific evidence." 85 Fed. Reg. 87,299-300. In doing so, EPA takes issue with commenters citing studies of adverse health effects linked to long-term exposure levels below the current NAAQS and argues that a short-term standard helps to reduce long-term exposure levels: "we note that the impact of standards with short averaging times, such as eight hours, is not limited to reducing short-term exposures." *Id.* at 87,300.

EPA thus acknowledges (in accordance with the scientific evidence) that long-term exposure levels far below 70 ppb pose a serious risk to public health but seeks to indirectly address long-term exposures through its consideration of revisions to the short-term standard. EPA argues that the short-term standard limits "the magnitude of concentrations to which a population is exposed in eight hour periods, [and] also limits the frequency to which the population is exposed to such concentrations over the long term," *id.*, but EPA does not make any effort to analyze the existing literature or conduct its own analysis within the Policy Assessment to determine the extent to which long-term concentrations are affected by the short-term standard and what the resulting public health impacts of changes to long-term exposure levels might be.

EPA also makes no effort to disentangle what it acknowledges to be the complex effects of combined short- and long-term exposure levels and instead argues that the entirety of health effects linked to chronic pollution exposures can be addressed through consideration of the short-term standard. Contrary to the scientific evidence described here, EPA contends that "the current standard provides control of exposures to such concentrations over both the short and long term" without quantifying the "control" that the current standard supposedly provides over long-term exposure levels. *Id.*

In dismissing long-term exposure studies, EPA takes issue with the fact that short-term O₃ levels in multiple studies "did not meet the current standard in all locations and time periods analyzed in these three multicity studies." *Id.* Yet the metric of interest in these studies—the long-term exposure level—in all cases fell far below the currently permissible short-term level. EPA conflates short- and long-term exposure levels in an attempt to ignore the independent evidence that clearly demonstrates the need for EPA to adopt a long-term standard.

In the Final Rule, EPA addresses only a sample of recent studies cited by commenters relevant to the importance of adopting a long-term exposure standard to protect public health. Importantly, it does not address the fact that multiple studies document adverse health impacts

linked to long-term exposure levels well below the current standard and argues without scientific evidence or its own analysis that the existing standard is sufficiently protective of long-term exposure levels.

As noted by Nassikas et al. (2020),⁸ the meteorological conditions that determine ozone levels are projected to be more favorable to ozone formation over much of the United States due to continued climate change, even as emissions of anthropogenic ozone precursors are expected to decrease by 2050. In particular, as noted by Archer et al. (2019),⁹ in the mid-Atlantic region of the United States, warmer temperatures caused by climate change threaten to heighten long-term ozone levels and chronic exposures to ozone.

The Final Rule does not rationally address the scientific finding that a number of studies published after March 2018, the cut-off period for study consideration in the current ozone ISA, confirm statistically significant health harms from long-term exposures to ozone.^{10,11,12} EPA cannot rationally reject these conclusions based on these studies simply because the studies did not evaluate health effects associated with air quality under the current standard.

For example, while there were no epidemiologic studies examining the association between long-term exposure to ozone and COPD available for inclusion in the 2013 Ozone ISA, a study by Paulin et al. (2019) of smokers with or at-risk for COPD found that long-term exposure is associated with worse respiratory outcomes. As noted in Limaye and Knowlton (2019),¹³ the adverse respiratory health outcomes identified in this study were found to be potentially independent of smoking intensity or exposures to air pollution on the job, underscoring the health risks that ozone air pollution poses to tens of millions of individuals who currently smoke or formerly smoked. The median O₃ exposure level in the study was 25.1 ppb, demonstrating the risks of chronic ozone exposure at levels far below the current short-term standard.

⁸ Nassikas, Nicholas, Keith Spangler, Neal Fann, Christopher G. Nolte, Patrick Dolwick, Tanya L. Spero, Perry Sheffield, and Gregory A. Wellenius. “Ozone-Related Asthma Emergency Department Visits in the US in a Warming Climate.” *Environmental Research* 183 (Apr. 2020): 109206. <https://doi.org/10.1016/j.envres.2020.109206>.

⁹ Archer, Cristina L., Joseph F. Brodie, and Sara A. Rauscher. “Global Warming Will Aggravate Ozone Pollution in the U.S. Mid-Atlantic.” *Journal of Applied Meteorology and Climatology* 58, no. 6 (June 2019): 1267–78. <https://doi.org/10.1175/JAMC-D-18-0263.1>.

¹⁰ Dominici, Francesca, Joel Schwartz, Qian Di, Danielle Braun, Christine Choirat, and Antonella Zanobetti. “Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1.” *Research Reports: Health Effects Institute 2019* (Nov. 1, 2019): 200. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7300216/>.

¹¹ Seltzer, Karl M., Drew T. Shindell, Prasad Kasibhatla, and Christopher S. Malley. “Magnitude, Trends, and Impacts of Ambient Long-Term Ozone Exposure in the United States from 2000 to 2015.” *Atmospheric Chemistry and Physics* 20, no. 3 (Feb. 14, 2020): 1757–75. <https://doi.org/10.5194/acp-20-1757-2020>.

¹² Dedoussi, Irene C., Sebastian D. Eastham, Erwan Monier, and Steven R. H. Barrett. “Premature Mortality Related to United States Cross-State Air Pollution.” *Nature* 578, no. 7794 (Feb. 2020): 261–65. <https://doi.org/10.1038/s41586-020-1983-8>.

¹³ Limaye, Vijay S., and Kim Knowlton. “Shining New Light on Long-Term Ozone Harms.” *JAMA Internal Medicine*, 2019, 2. <https://doi.org/10.1001/jamainternmed.2019.5967>.

Additional studies published after March 2018, including what EPA acknowledges in the Final Rule to be a high-quality study, demonstrate causal links between long-term exposures and adverse health outcomes. Lim et al. (2019)¹⁴ quantified associations of long-term (annual or warm season average of daily 8-h maximum concentrations) exposure with all-cause and cause-specific mortality in the NIH-AARP Diet and Health Study, a large prospective cohort of U.S. adults with 17 years of follow-up from 1995 to 2011. Long-term exposure levels ranged from 26.8 ppb to 56.3 ppb. That study found that long-term annual average exposure was significantly associated with deaths caused by cardiovascular disease (per 10 ppb; hazard ratio [HR], 1.03; 95% CI, 1.01–1.06), ischemic heart disease (HR, 1.06; 95% CI, 1.02–1.09), respiratory disease (HR, 1.04; 95% CI, 1.00–1.09), and chronic obstructive pulmonary disease (HR, 1.09; 95% CI, 1.03–1.15) in single-pollutant models. The results were robust to alternative models and adjustment for co-pollutants (fine particulate matter and nitrogen dioxide).

Another large study by Rhee et al. (2019)¹⁵ analyzed air pollution exposures at the ZIP code level in the U.S. and hospital admissions with acute respiratory distress syndrome (ARDS) among nearly 1.2 million Medicare beneficiaries aged >65 years from 2000 to 2012 and found that an increase of 1 ppb in annual average ozone was associated with statistically significant increases in annual hospital admission rates for ARDS of 0.72% (95% CI, 0.62–0.82) and 0.15% (95% CI, 0.08–0.22), respectively in areas with a median O₃ concentration of 39.1 (interquartile range: 36.7 to 41.6 ppb). Importantly, this effect remained in low-pollution regions (annual average PM_{2.5} level < 12 µg/m³ and annual average ozone level < 45 ppb). In those areas, the 1 ppb annual increase in ozone concentration was associated with a significant increase in annual hospital admission rates for ARDS of 0.27% (95% CI, 0.16–0.38).

Strosnider et al. (2019)¹⁶ conducted an analysis of respiratory emergency department visits in 894 counties, the largest U.S. multicounty study of impacts among all ages. The 869 county-specific interquartile range for daily 8-hour maximum ozone varied from 8.0 to 34.0 ppb with a mean interquartile range of 16.54 ppb. Linking daily respiratory emergency department visits with estimated ozone concentrations during the week before the date of the visit, per 20-ppb increase in ozone, rate ratios were statistically significant at 1.017 (95% CI, 1.011–1.023) among children, 1.051 (95% CI, 1.046–1.056) among adults younger than 65, and 1.033 (95% CI, 1.026–1.040) among adults 65 and older.

¹⁴ Lim, Chris C., Richard B. Hayes, Jiyoung Ahn, Yongzhao Shao, Debra T. Silverman, Rena R. Jones, Cynthia Garcia, Michelle L. Bell, and George D. Thurston. “Long-Term Exposure to Ozone and Cause-Specific Mortality Risk in the United States.” *American Journal of Respiratory and Critical Care Medicine* 200, no. 8 (May 3, 2019): 1022–31. <https://doi.org/10.1164/rccm.201806-1161OC>.

¹⁵ Rhee, Jongeun, Francesca Dominici, Antonella Zanobetti, Joel Schwartz, Yun Wang, Qian Di, John Balmes, and David C. Christiani. “Impact of Long-Term Exposures to Ambient PM_{2.5} and Ozone on ARDS Risk for Older Adults in the United States.” *Chest* 156, no. 1 (July 2019): 71–79. <https://doi.org/10.1016/j.chest.2019.03.017>.

¹⁶ Strosnider, Heather M., Howard H. Chang, Lyndsey A. Darrow, Yang Liu, Ambarish Vaidyanathan, and Matthew J. Strickland. “Age-Specific Associations of Ozone and Fine Particulate Matter with Respiratory Emergency Department Visits in the United States.” *American Journal of Respiratory and Critical Care Medicine* 199, no. 7 (Apr. 2019): 882–90. <https://doi.org/10.1164/rccm.201806-1147OC>.

Another recent study¹⁷ analyzing the health effects of long-term exposure to ozone restricted to areas meeting the current standard demonstrates that dangerous health effects are still observed in these areas. Yazdi et al. (2021) analyzed 63 million Medicare patients for ozone-related hospital admissions for four cardiovascular and respiratory outcomes (myocardial infarction, ischemic stroke, atrial fibrillation and flutter, and pneumonia) between 2000 and 2016. The study found that long-term ozone exposure was associated with an increased risk of hospital admission for pneumonia by 0.00413% (95% CI, 0.00376– 0.00447) for each 1 ppb increase in long-term exposure. The maximum 8-hour ozone exposure level considered in the study was 65.09 ppb, and at lower concentrations ozone exposure increased the probability of hospital admission with larger effect estimates than the primary results. This study deployed a doubly robust additive model and adjusted for co-pollutant exposures and many potentially confounding variables including age, race, sex, region, distance to hospital, income, education, BMI, and smoking status.

In the Final Rule, EPA contends that “the O₃ concentrations most likely to contribute to health effects are the higher concentrations” yet these recent studies show that long-term exposures at levels well below 70 ppb contribute to widespread population health harms. 85 Fed. Reg. 87,300. The recent studies build upon the existing body of evidence and coherently demonstrate significant causal links between long-term exposure to ozone and adverse health outcomes. In its Final Rule, EPA arbitrarily did not establish a long-term exposure standard despite robust evidence that doing so would benefit human health.

- c. EPA does not purport to comply with the Clean Air Act because it does not ensure the absence of adverse effects on sensitive individuals.

In the Final Rule, the Administrator highlights “the populations for which the evidence indicates increased risk” as including “people with asthma, children and outdoor workers, among other groups.” *Id.* at 87,290. He concludes that the current primary standard “provides the requisite protection of the public health with an adequate margin of safety, including for at-risk populations,” *id.* at 87,300, and the current exposure and risk analysis results describe “appropriately strong protection of at-risk populations from exposures associated with O₃-related health effects.” *Id.* at 87,306. This does not even claim to meet the Act’s requirements: “NAAQS must protect not only average healthy individuals, but also sensitive citizens such as children, and if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.” *Coal. of Battery Recyclers Ass’n*, 604 F.3d at 618; *accord Am. Lung Ass’n*, 134 F.3d at 389 (“NAAQS ‘must be set at a level at which there is ‘an absence of adverse effect’ on [] sensitive individuals’” (alteration in original; quoting *Lead Indus. Ass’n v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980)). Whatever constitutes “appropriately strong protection” is not the same as assuring the “absence of adverse effect,” as required. *Id.*

¹⁷ Danesh Yazdi, Mahdieh, Yan Wang, Qian Di, Yaguang Wei, Weeberb J. Requia, Lihua Shi, Matthew Benjamin Sabath, et al. “Long-Term Association of Air Pollution and Hospital Admissions Among Medicare Participants Using a Doubly Robust Additive Model.” *Circulation* CIRCULATIONAHA.120.050252 (Feb. 22, 2021). <https://doi.org/10.1161/CIRCULATIONAHA.120.050252>.

The 1970 Clean Air Act Amendments made clear that the millions of Americans with respiratory ailments are just as entitled to the protection of the NAAQS as those without respiratory conditions: “Included among those persons whose health should be protected by the ambient standard are particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment.” S. Rep. No. 91-1196, at 10 (1970). As the D.C. Circuit has explained:

In its effort to reduce air pollution, Congress defined public health broadly. NAAQS must protect not only average healthy individuals, but also “sensitive citizens” – children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution.

Am. Lung Ass’n, 134 F.3d at 389 (citations omitted); *Nat’l Env’t Dev. Ass’n’s Clean Air Project v. EPA*, 686 F.3d 803, 810 (D.C. Cir. 2012). NAAQS must “be set at a level at which there is ‘an absence of adverse effect’ on these sensitive individuals.” *Lead Indus. Ass’n*, 647 F.2d at 1153.

EPA must also build into the NAAQS an adequate margin of safety for these sensitive subpopulations. *See Am. Farm Bureau Fed’n*, 559 F.3d at 526. The Administrator must also rationally explain (as he has not in the Final Rule) how the standard provides requisite protection for sensitive populations. *Am. Lung Ass’n*, 134 F.3d at 392–93.

In its Proposed Rule, response to comments, and Final Rule, the Agency has refused to directly confront the coherent body of science, both from the 2020 and the 2015 review, that mandates a standard set below 70 ppb. The Agency fails to address its own analysis showing that a lower standard would significantly reduce exposures of concern for sensitive groups, much less the same information in the Comments. Even if this failure was itself not arbitrary, EPA fails to articulate a rational basis for rejecting lower standards, which substantially reduce and nearly eliminate exposures of concern for children and children with asthma—two important sensitive groups.¹⁸ For the reasons given above, EPA’s decision not to strengthen the standards is arbitrary and must be reconsidered. Further, given the evidence available to the Agency, its decision is unlawful under the Clean Air Act and further merits reconsideration.

d. EPA’s exposure and risk analysis is arbitrary.

EPA provides new arguments in an attempt to bolster its fatally flawed reliance on the exposure and risk assessment. These arguments are meritless.

Comments explained various ways in which the exposure and risk assessment arbitrarily failed to rationally consider the harms EPA predicted various standard levels would allow on

¹⁸ And by association, outdoor workers, for whom the Agency acknowledges that it uses the exposure of children as an imperfect substitute. *See, e.g.*, 85 Fed. Reg. 87,298 n.134 (“while as recognized in multiple reviews, outdoor workers are also at risk, the EPA has focused, in past reviews as in the current one, on children, the population group for which the analysis estimates in terms of percentage of population are greatest (PA, section 3.4.2). Accordingly, providing protection for this population group will provide protection for other at-risk populations as well.”)

sensitive populations, like outdoor workers and children at summer camps. Comments at 46-51. Importantly, these populations spend time outside day after day. In the Final Rule, EPA now offers irrational excuses for how it examined these populations. For outdoor workers, EPA claims “uncertainties” and “data limitations”—which didn’t prevent it from providing some analysis for this sensitive population in 2014—now purportedly led it to do no new analysis, but instead to “expect[]” its 2014 results “might” still hold. 85 Fed. Reg. 87,276/2 n.81, 87,298/1-2. EPA cannot rationally rely on generic uncertainties. Further, elsewhere, EPA touts the improvements in this health risk and exposure assessment compared with the 2014 version. *E.g., id.* at 87,278/1-2. EPA’s wan “expect[ation]” of perhaps similar results thus lacks rational basis. Thus, EPA’s failure to analyze ozone’s impacts on the important, acknowledged sensitive population of outdoor workers is arbitrary.

As for children at summer camps, EPA does not claim it actually gave that population any consideration at all. Instead, it says “to the extent that the behaviors of such children...are represented in the [consolidated human activity database (“CHAD”)], they are represented among the at-risk populations of children and children with asthma that were simulated in the exposure/risk analyses.” *Id.* at 87,298/1 n.133. EPA thus leaves unanswered the key questions of whether such behaviors are actually represented in the CHAD and, to the extent they are not, what EPA did to rationally fill the gap. Further, even if these behaviors are represented in the CHAD, EPA fails to explain how protecting such children by protecting a less sensitive population provides requisite protection to the more sensitive population. *See id.; see also id.* at 87,298/1 n.132 (EPA makes similar argument about “athletes, hikers and others who exercise outdoors, using their full lung capacity,” as it does about children at summer camps).

Finally, EPA’s new approach to the impact of averting behavior, where people respond to harmful ambient levels of ozone by avoiding outdoor activities, is unlawful and irrational. First, EPA appears to contend that standards need not protect people who are “refraining from normal activity or resorting to medical interventions to ward off adverse effects of poor air quality.” Response to Comments at 14 (quoting S. Rep. No. 91-1196, at 10 (1970)), EPA-HQ-OAR-2018-0279-0572. EPA’s claim has no valid basis in law. As explained in more detail above and in comments, the Act’s entire premise is that the air must be clean enough to breathe safely, so that people—even people who are more vulnerable to air pollution’s harmful effects than a healthy young adult—can engage in their ordinary activities. *See, e.g., Am. Lung Ass’n*, 134 F.3d at 388-89. Going against its own mandate, EPA misconstrues a snippet of legislative history. But far from supporting EPA, that legislative history confirms EPA’s error. The legislative history makes clear that standards must protect “particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment,” but not necessarily “patients in intensive care units or newborn infants in nurseries,” who, for other reasons, are not going outside. S. Rep. No. 91-1196, at 10. EPA’s redefining “the normal course of daily activity” to exclude periods when the ambient air is dangerously dirty fundamentally undermines the standards and thus the Act. EPA must abandon this illegal position.

Second, EPA points briefly to its “very limited” 2014 analysis of averting behavior and presumes, based on that analysis and unspecified other “available information,” that averting behavior “will likely have little effect on the range of exposures generated from the APEX

simulations.” Response to Comments at 14-15. Similar to the irrationality of its response to its failure to consider outdoor workers, EPA’s explanation here lacks any rational basis: it is unclear what EPA’s conclusion rests on, apart from a six-year-old sensitivity analysis carried out with different data and assumptions that EPA acknowledges is itself “very limited.”

III. Grounds for objection regarding the secondary standard

- a. EPA unlawfully changed its justification for a 3-year average standard after the close of the public comment period.

Between the Proposed Rule and the Final Rule, EPA unlawfully changed its justification for using a 3-year average for the secondary standard instead of the 2014 expert CASAC’s recommendation of a W126 single-year average. In the Proposed Rule, EPA asserted that a “3-year average was identified for considering the seasonal W126 index based on the recognition that there was year-to-year variability” in environmental factors that contribute “uncertainties” in the “projections of the potential for harm to public welfare.” 85 Fed. Reg. 49,900. This 3-year average was based on EPA’s claim in the PA that “the evidence that allows for specific evaluation of the predictability of growth impacts from single-year versus multiple-year average exposure estimates is quite limited.” *Id.* at 49,901. Based on this purported uncertainty, the Administrator stated that the available evidence supported “a conclusion that it is reasonable to use a seasonal RBL averaged over multiple years, such as a 3-year average.” *Id.* at 49,910.

But in the Final Rule, EPA added an additional justification for the use of a 3-year average metric: protection against what EPA newly deems “unusually damaging years.” *Id.* at 87,325. Underlying this criterion is an EPA staff memo by Benjamin Wells, “Additional Analyses of Ozone Metrics Related to Consideration of the Ozone Secondary Standard,” dated December 16, 2020, and uploaded to the docket on December 31, 2020, the same day EPA released its Final Rule. EPA used the memo—which analyzes various ambient air monitoring data “relat[ed] to the form and averaging time of the current secondary standard”¹⁹—to conclude that “the form and averaging time of the current standard is effective in controlling peak hourly concentrations and that a W126 index based standard would be much less effective in providing the needed protection against years with such elevated and potentially damaging hourly concentrations.” 85 Fed. Reg. 87,340. The public has had no opportunity to challenge or analyze this conclusion, which forms a core basis for EPA’s use of a 3-year average form. Petitioners object to EPA’s conclusion and the use of the Wells memo without exposing them to public comment.

EPA’s “last-minute addition to the record of a study which constituted [a] basis for the final secondary standard is disturbing,” and requires reconsideration under 42 U.S.C. § 7607(d)(7)(B). *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1190 (D.C. Cir. 1981). As stated above, under § 7607(d)(7)(B), the Administrator must grant a petition for reconsideration if a petitioner “can demonstrate to the Administrator that it was” either (1) “impracticable” to raise

¹⁹ Memorandum from Benjamin Wells, EPA, on Additional Analyses of Ozone Metrics Related to Consideration of the Ozone Secondary Standard to Ozone NAAQS Review Docket (EPA-HQ-OAR-2018-0279) at 2 (Dec. 16, 2020) (“Wells memo”).

an objection or (2) “if the grounds for such objection arose after the period for public comment.” In addition, the objection must be “of central relevance to the outcome of the rule.” 42 U.S.C. § 7607(d)(7)(B).

Here, Petitioners meet both procedural prongs of § 7607(d)(7)(B), and their objection is centrally relevant to the outcome of the rule. First, it was impracticable for Petitioners to raise an objection to EPA’s new analysis or the conclusion of the Wells memo, because, as discussed below, its conclusion was not a logical outgrowth of the data analyzed in the Proposed Rule. *See Portland Cement Ass’n*, 665 F.3d at 188 (“when an agency is simultaneously in control of both defining the universe of relevant data and of applying that data to a given rulemaking, it cannot allow itself to do the latter without having already done the former.”). And Petitioners could not have anticipated that EPA’s rejection of the W126 standard would be based on an analysis of “peak concentrations that may contribute to ‘unusually damaging years’ for vegetation,” 85 Fed. Reg. 87,340, when the Proposed Rule was explicit that the decision was based on perceived uncertainty with other data. 85 Fed. Reg. 49,910–11 (justifying the 3-year average based on uncertainty, imprecision, or inexactitude without reference to “unusually damaging years”); *see, e.g., Chesapeake Climate Action Network*, 952 F.3d at 320–21 (“EPA gave no notice that it would analyze any best performing stringency requirements, so EPA cannot now claim that Petitioners were on notice of how EPA would ultimately analyze such issues.”) Second, Petitioners’ objection to EPA’s new analysis and the Wells memo arose after the public comment period had already been closed for two months. 42 U.S.C. § 7607(d)(7)(B). Indeed, EPA placed the memo on the docket on the same day that it announced the Final Rule. And, as stated above, EPA used its new analysis and the Wells memo to avoid basing its decision to use the 3-year average on uncertainty alone, making them centrally relevant to its decision to maintain the current standard. Considering this procedural failing, EPA must reconsider the Final Rule.

Furthermore, EPA’s changed rationale and use of the Wells memo was prejudicial and unlawfully violates fundamental notice and comment requirements. As explained below, EPA critically changed the justification for the metric used to measure the protection of vegetation from ozone’s effects in violation of basic notice-and-comment requirements. *See Owner-Operator Indep. Drivers Ass’n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 201 (D.C. Cir. 2007) (“[T]he failure to provide an opportunity for comment on [a] model’s methodology... constitutes a violation of the APA’s notice-and-comment requirements.”).

Nor are EPA’s new rationale and the Wells memo themselves rational, as explained below. EPA’s new claim that “unusually damaging years” are somehow distinct from the biologically relevant W126 metric has no rational basis in the expert CASAC’s recommendations that the D.C. Circuit held in *Murray Energy* that EPA flouted. Even if that EPA claim were not meritless, the N100 metric analysis EPA uses to justify retaining the current standard was itself not exposed to public comment and is also arbitrary. Further, there are significant issues with EPA’s assertions about the E-R functions as justification for 3-year averaging. For these reasons, among others, EPA must grant this petition for reconsideration.

- i. EPA newly misconstrues the W126 standard and how it captures cumulative seasonal exposure impacts.

EPA has bifurcated the advice from CASAC on protecting vegetation from “unusually damaging years” from the context it was given, which is explicitly linked to the W126 metric, which directly addresses the cumulative effects of ozone exposure on vegetation. EPA’s failure does not satisfy EPA’s requirements under the *Murray Energy* remand. *See Murray Energy Corp. v. EPA*, 936 F.3d 597, 617 (D.C. Cir. 2019) (“EPA has not demonstrated how its chosen benchmark protects against ‘unusually damaging years that will be obscured in the average.’”). The 2014 CASAC Letter, cited in n.1 above, that articulated the need for a stronger W126 standard if EPA chose to use a 3-year average rather than the scientifically justified 1-year value was based on a form of standard that is cumulative. As the Letter shows, CASAC clearly prefaced this advice with their opposition to the 3-year averaging and their scientific justification for the biologically relevant 1-year standard based on extensive data analysis and evaluation of W126 forms and levels and the impact on vegetation.

- ii. The Wells memo is based on a flawed analysis that cannot withstand scientific rigor.

The Wells memo and data analysis are flawed and cannot be rationally used to justify a 3-year averaging form for the secondary standard. First, Wells’s analysis focuses on the use of N100, which neither EPA nor even the current CASAC discuss as a metric in the Policy Assessment or proposal. The ISA reports only one study’s use of the N100 metric in terms of foliar injury and only in combination with the SUM60 cumulative standard. *See* ISA tbl.8-4. Instead, past reviews have focused on a cumulative standard form as necessary to reflect the impacts to vegetation, citing the W126 metric by itself as an appropriate form of standard to protect against ozone impacts. *See* PA (2014) at ES-9, 5-73, EPA-HQ-OAR-2018-0279-0058. Second, the Wells memo introduces a new metric, D100, as the number of days with one or more hours at or above 100 ppb. Wells memo at 4. This D100 metric has never been evaluated in the scientific literature or past reviews. EPA’s attempt to introduce this metric through the Wells memo is arbitrary; and therefore, the D100 metric should not be considered until a rigorous scientific review has been conducted on its utility.

Furthermore, based on the description of the N100 metric on page 4 of the memo, it is unclear what hours of the day are included in its calculation. Wells states that “the N100 metric was calculated as the maximum number of hours with an hourly O₃ concentration of 100 ppb or greater in the three consecutive calendar months yielding the highest number in a given year.” The reason why it is important to note which hours of a day are included in a metric is because at some mountain and downwind sites, the transport of ozone and precursors can result in late evening or overnight maximums. But the Wells memo leaves this critical data point of the N100 metric undefined, and so commentators cannot know if the metric was calculated using all hours of the day, was restricted to the 17 hours used for the 8-hr primary standard, or was restricted to the 12 hours used for the W126 calculations that approximate daylight hours. This specificity would also illuminate the comparisons with other metrics if indeed they were appropriate. The N100 metric in the memo is also limited to three consecutive months, diminishing its utility to appropriately reflect peak ozone conditions throughout the growing season. The National Park

Service reports N100 hours across the full 7-month growing season in combination with W126.²⁰ At the very least, the N100 summing window should match the metric that it is being compared against; yet as discussed below some of the comparisons made in the memo are also nonsensical.

The Wells memo lays out a goal to describe the relationships between metrics including N100 compared to the W126 and the annual 4th highest daily maximum 8-hour O₃ concentration, averaged over 3 consecutive years, known as the “4th max metric.” Comparing N100 to W126 has no scientific basis, as the two metrics were never meant to be singular but only to complement each other.²¹ And of course, a metric that looks at maximum 8-hour average daily values would be more similar to a metric based on maximum hourly values than to one that is cumulative. Even if we were to assume that it is appropriate to examine how the N100 compares to the 4th max metric, then we must also consider that the N100 is limited to a 3-month period while the 4th max is not. Finally, the analysis provides little justification for the 4th max metric alone—even if a good proxy for N100—being sufficient to protect vegetation, as it disregards the need for a metric that protects against cumulative impacts of ozone. Indeed, another fundamental flaw in EPA’s analysis—which applies not just to this issue of averaging period but also to all other vegetation-related aspects of the secondary standard—is that it pretends the choice here is between the 4th max metric alone and a W126 cumulative standard (over whatever averaging period); in reality, it is between the 4th max metric alone and the 4th max metric in addition to a W126 cumulative standard. It is thus irrational for EPA to use the 4th max metric to justify rejecting the W126 standard when both could be in place.

- iii. EPA’s analysis that a 3-year average for the standard is compatible with the E-R functions is irrational.

In addition to the irrationality of relying on the Wells memo, EPA’s analysis of the E-R curves does not justify using a 3-year average for the secondary standard. For example, EPA argues that the E-R function methodologies supports its 3-year averaging approach because E-R functions themselves were based on exposures that spanned multiple years. 85 Fed. Reg. 87,326. These composites were originated by Lee and Hogsett (1996) from Weibull curves from 51 seedling cases, which included 11 tree species, and had a mix of exposure durations. PA app.4A. Of the 51 cases, none spanned 3 years, 22 spanned over 2 years, while 29 were conducted within 1 year. Actual exposure days for 2-year experiments ranged from 75–555 days, with 11 out of the 22 cases having exposures less than 120 days, which implies that the exposure within a year could be 60 days or less. In order to calculate composites across experiments for the same species (or across all cases) the curves were standardized to a 92-day W126. This standardization

²⁰ Kohut, Robert J., National Park Service, “Field Surveys to Assess Foliar Ozone Injury on Plants in National Parks and Monuments on the Colorado Plateau,” *Natural Resource Report* (May 2020). It is worth noting that the National Park Service (NPS) also reports EPA derived 3-month W126 metric alone in addition to the 7-month W126 plus N100 combination. The thresholds for these two sets of metrics differ greatly based on previous literature. NPS cites EPA 2010 proposed W126 3-month standard thresholds in the range of 7–15 ppm-hours to protect vegetation and 5–9 ppm-hours for foliar injury.

²¹ Lefohn, Allen S. et al, “Effect of Surface Ozone Exposures on Vegetation Grown in the Southern Appalachian Mountains: Identification of Possible Areas of Concern.” *Atmospheric Environment*, no. 31, (Mar. 1997): 1695-1708.

is not an averaging process but instead is a simple linear prorating approach to adjust to a standard exposure window. Predicted relative biomass loss as a function of W126 was calculated and then the species median response at different W126 levels used to fit the final curve for each species. EPA fails to rationally explain how the normalization step and data reduction procedure justifies averaging a W126 metric across 3 years, nor has EPA rationally explained how it justifies selecting the current standard level and form. E-R functions that are composite median values already reduce the variance within the datasets and are only one piece of evidence to be considered in setting a standard form and level.

b. EPA's reliance on its own Aspen analysis is flawed.

Commenters provided a detailed critique of EPA's analysis in the PA that applied the Aspen E-R curves to varying W126 levels based on the impacts found in King et al (2005). EPA claims that the analysis that compared E-R derived relative biomass loss (RBL) for Aspen to actual observation from King et al. (2005) in the 2013 and 2020 ISAs supports their 3-year averaging form of the standard. EPA's assertion that a 3-year average is compatible with the E-R methodology because it is normalized across multiple seasons is irrational because it does not even apply to the Aspen data. All of the 14 E-R curves for Aspen that were used in the composite spanned only one season ranging from 82-114 day exposure durations. *See* ISA tbl.8-23. Therefore, the Aspen E-R curves do not support EPA's claim that E-R functions themselves based on multiple years justify a 3-year averaging form.

EPA itself notes that the yearly approach taken in 2020 analysis, shown in Figure 8-17 on page 8-193 of ISA 2020 "indicat[es] a somewhat less tight fit to the experimental observations," compared to the cumulative approach presented in ISA 2013 shown in Figure 9-20 of that document. This implies that the cumulative approach that accounts for yearly variation or higher years and carry over, is a better approach than assuming there is no such impact.

Each species' E-R curves, even as species composites, have different shapes and may differ from the Aspen example. PA app.4A at 4A-3 to -9. Therefore, the exposure level represented and derived RBL in the Aspen example may play out differently for different species within a season or cumulatively across seasons. This one species provides one piece of evidence but should not dictate the form of the standard.

c. EPA failed to remedy the issues from the *Murray Energy* remand with regard to visible leaf damage and other areas where EPA finds there to be uncertainty.

While EPA found that its data indicated that the "risk of [visible foliar] injury. . . to be higher at the highest W126 index values," it nevertheless concluded that there was "uncertainty" with this data that precluded it from issuing an "appropriate metric (or metrics) for quantifying O₃ exposures." 85 Fed. Reg. 87,315. This conclusion fails to remedy EPA's error from the *Murray Energy* court's remand.

In *Murray Energy*, the D.C. Circuit held that EPA's decision not to set a target level to protect against visible leaf damage during the 2015 review was arbitrary and capricious. 936

F.3d at 620. CASAC had advised EPA of its “scientific judgment” that “a level of 10 ppm-hrs is required to reduce foliar injury.” *Id.* at 618 (quoting CASAC). But EPA rejected this advice in the final rule, and instead EPA concluded that there were too many “uncertainties and complexities” in the evidence to specify a level of air quality to protect against foliar injury. 80 Fed. Reg. 65,407-08. The court rejected EPA’s reasoning, holding: (1) that EPA must explain what evidence is available and rationally explain how it reached the conclusion that this evidence leaves EPA “unable to choose a level at all”; and (2) that “[w]here CASAC has ‘reached a scientific conclusion that adverse [welfare] effects [are] likely to occur,’ EPA must, ‘explain why the evidence on which CASAC relied cannot support the degree of confidence CASAC placed in it.’” *Murray Energy*, 936 F.3d at 619 (quoting *Mississippi*, 744 F.3d at 1357).

Petitioners’ comments explained how EPA continues to violate the Clean Air Act when it fails to exercise its judgment about what level of air quality is requisite to protect the public welfare. *See* Comments at 74–80. But in the Final Rule, EPA unlawfully and arbitrarily persists in failing to identify a level at which ozone’s effects on visible leaf damage would be adverse—as required by the court in *Murray Energy*. 85 Fed. Reg. 87,344.

Furthermore, EPA states that its decision to not set a standard is also based on perceived uncertainties on soil moisture. *See* 85 Fed. Reg. 87,314/1. But soil moisture is just a risk factor that may or may not make a site and its plants at risk, not a determinant in the threshold. Soil moisture status does not cause the injury: ozone does. Even if soil moisture could be considered causal also, the mere fact that air pollution is one of many causes of an adverse impact does not relieve EPA of its obligation to protect the public welfare against adverse effects from air pollution. *See, e.g.*, 42 U.S.C. § 7408(a)(2)(A). Given the robust data EPA has on foliar injury, the contribution of soil moisture does not prevent EPA from specifying a level of protection. Thus, EPA’s decision to decline to specify a secondary standard protective against foliar injury based on soil moisture is unlawful and arbitrary.

d. EPA failed to rationally consider the climate impacts of the secondary NAAQS.

In the Final Rule, EPA arbitrarily relies on supposed uncertainty to avoid setting the secondary NAAQS at a protective level consistent with the need to address global climate change. *See* 85 Fed. Reg. 87,337. (“[T]he significant limitations and uncertainties summarized here together preclude identification of an O₃ standard that could be judged to provide requisite protection of the public welfare from adverse effects linked to O₃ influence on radiative forcing, and related climate effects.”)

But the important facts about ozone’s climate impacts are known. First, it is clear that ozone has a strong warming impact, especially in Northern mid-latitudes (where the United States is) and in the Arctic. Second, whatever its exact radiative forcing, ozone is the third strongest greenhouse gas. Third, it is well-established that ozone formation is reduced through decreases in emissions of methane, nitrogen oxides, carbon monoxide and VOCs. As EPA

acknowledges, reducing these precursors would significantly benefit public health as well as climate. Finally, ozone's harmful effects on vegetation growth negatively affects carbon sequestration, thus further exacerbating climate change. Consequently, EPA must consider the direct as well as indirect climate impacts of ozone when it makes judgment about reconsidering the secondary standard.

IV. Conclusion

For the foregoing reasons, Petitioners respectfully request that the Administrator expeditiously reconsider the Final Rule.

Sincerely,

**American Academy of Pediatrics
American Lung Association
American Public Health Association
Appalachian Mountain Club
Clean Air Task Force
Chesapeake Bay Foundation
Earthjustice
Environment America
Environmental Defense Fund
Environmental Law & Policy Center
National Parks Conservation Association
Natural Resources Defense Council
Sierra Club**