

March 1, 2021

Acting Administrator Jane Nishida
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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,

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*

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 2 ()v2E47007 Tw 0Cu07 Tw 0Cun(de)4 (r)]TJ 0 Tw 53
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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.

II. Grounds for objection regarding the primary standard

a.

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 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 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 O_3 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 O_3 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 O_3 exposure over the United States and quantify the historical trends of such exposure. Authors estimated net estimated premature deaths attributable to long-term O_3 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 and asthma. *Environmental Health Perspectives* 128(11):117009 (2020). <https://doi.org/10.1289/EHP7255>

- 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

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 only healthy adults.”) (E)-2 fwh(“)4gt ly ext1 tr 35 yr

- 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-

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-

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 14 (2)-8 (oun26 0 T)]TJ 0 T(el)e m6 (

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 R

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..2 (ir)5y

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 thi

simulations.” Response to Comments at 14-15. Similar to the irrationality

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

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

