Comment Letter #86

CALIFORNIA AIR RESOURCES BOARD

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

CalEPA California Environmental Protection Agency

October 1, 2020

Mr. Andrew R. Wheeler, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington D.C. 20460

Subject: Docket ID No. EPA-HQ-OAR-2015-0072

Dear Administrator Wheeler:

I. Introduction

On behalf of the California Air Resources Board (CARB), the California Environmental Protection Agency (CalEPA) and the California Office of Environmental Health Hazard Assessment (OEHHA), we are writing to oppose the United States Environmental Protection Agency's (U.S. EPA's) Proposed Rule for National Ambient Air Quality Standards (NAAQS) for Ozone (Proposal) and urge substantial strengthening of the standards.

Our agencies vigorously strive to protect the public from the harmful effects of air pollution and to follow the most up-to-date science in making policy decisions that protect all Californians, including vulnerable and disadvantaged communities. Consequently, we urgently ask you to heed the science and abide by the Clean Air Act's directive to protect public health with an adequate margin of safety by lowering the current 8-hour Ozone primary standard to 60 parts per billion (ppb). We also urge you to strengthen the secondary standard by requiring a more appropriate one-year metric to protect public welfare including agriculture and sensitive ecosystems.

II. Stronger Ozone Standards are Essential to Protect All Communities.

Despite California's comprehensive and cutting-edge air pollution control policies and regulations implemented under the Federal Clean Air Act, many areas still experience too many days with harmful ozone levels. Communities in the Los Angeles, the San

Joaquin Valley and other regions breathing elevated ozone levels are at higher risk of pollution-related health impacts such as hospitalizations, asthma and other emergency department visits, lost work and school days, and premature deaths. Communities hardest hit by air pollution in California, including low income communities and communities of color, are also experiencing the dire consequences of climate change including increased severity of wildfires, which itself adds to dangerous levels of air pollution, as well as the harmful effects of the Covid-19 pandemic. The increasing frequency of weather conditions linked to climate change, including heat waves and droughts in addition to wildfires are contributing to and worsening elevated ozone levels and health-related impacts.

California residents can suffer health risks from elevated ozone pollution for weeks or months depending on the region. For example, some communities in the Los Angeles region experienced up to four months of ozone-polluted days in 2019. Strengthening the ozone standard combined with continued strong state and local control efforts will provide tremendous health benefits for the millions of California residents suffering from these elevated pollution levels.

A. Robust Scientific Evidence Demonstrates the Need to Lower the Primary Ozone NAAQS.

A large body of scientific evidence demonstrates the dire need to lower the primary ozone standard to 60 ppb in order to protect public health with an adequate margin of safety. Despite acknowledging the findings of key studies that demonstrate the health impacts of ozone exposure below the current standard, U.S. EPA chooses to disregard this information, to the detriment of public health.

1. *Scientific Evidence Considered in the 2015 Proposal Demonstrated the Need to Set the Standard at 60 ppb.*

In response to U.S. EPA's previous ozone NAAQS proposal in 2015, our agencies urged the U.S. EPA to heed the strong scientific evidence, which demonstrated that setting the 8-hour standard level at 70 ppb would not provide an adequate margin of safety for the general public, and would fail to protect vulnerable subgroups. In that review, the scientific evidence from epidemiologic studies, controlled human exposure studies and toxicological evidence of biological mechanisms and modes of action demonstrated adverse health effects in young healthy adults at ozone levels as low as 60 ppb.

2. *Additional Evidence Made Available Since the 2015 Review Further Demonstrates the Need to Lower the Standard.*

Since the last review, the scientific literature related to ozone health effects and exposure has become even more compelling. Additional scientific evidence of adverse

health impacts below 70 ppb makes it even more apparent now that U.S. EPA should adopt a more protective standard. For example, additional scientific papers since the last review have found associations between long-term ozone exposure and increased mortality at levels below 70 ppb. Other studies have demonstrated lung function decline, increases in childhood asthma onset, preterm births, and increased emergency room visits at levels near or below the current standard. The evidence from all of these studies together demonstrate that the current standard is clearly inadequate.

B. The Current Standard Fails to Protect Sensitive and Vulnerable Subgroups and Communities of Color.

A stronger standard is critical to protect those living in the most vulnerable and highly impacted neighborhoods, including communities of color, which too often are faced with unhealthy levels of ozone exposure. In addition, those living in communities of color are known to have a greater sensitivity to the impacts of ozone even at the same levels of exposure. Strengthening the ozone NAAQS would ensure a higher level of protection for all communities, as well as the millions of particularly vulnerable individuals in these overburdened and sensitive subgroups.

Scientific studies underscore the impacts of ozone on sensitive and vulnerable groups. A study of ozone-related asthma emergency department visits in California's Central Valley showed the strongest effects for children aged 6-18 years, adults 19-40 years, and Black persons respectively, and ozone was significantly related to ED visits (Gharibi et al. 2019). In another study of children's hospital admissions for asthma in New York State, associations were stronger for younger children and lower socioeconomic groups (Lin et al. 2008). Another study, cited in the ISA, noted that seniors, women, Black persons, and those with atrial fibrillation were particularly vulnerable to dying from ambient ozone exposure, and that vulnerability differences were notable in cities with ambient ozone levels (Medina-Ramon & Schwartz 2008). As explained below, the decision to retain the current primary standard will perpetuate the public health disparities suffered by sensitive groups, including individuals living in disadvantaged communities.

1. *U.S. EPA's Decision Fails to Protect Sensitive Individuals whoare Most Vulnerable to the Impacts of Ozone Exposure.*

The Administrator's proposed decision inexcusably fails to follow the federal Clean Air Act and protect vulnerable individuals including children and teenagers, seniors, pregnant women, those with pre-existing cardiovascular or respiratory disease, outdoor workers, individuals who engage in strenuous outdoor activities and those who are exposed disproportionately to unhealthy levels of air pollution.

California's population includes large segments of sensitive subgroups who are most vulnerable to the impacts of air pollution. These individuals suffer from elevated health risks scientifically linked to ozone exposure. U.S EPA disregards the serious impacts on the health of sensitive individuals despite robust scientific evidence demonstrating adverse health consequences of exposure to pollution below the current standard. As discussed in the Legal Appendix below, the decision to retain the standard stands in direct contravention to U.S. EPA's statutory mandate to provide an "adequate margin of safety," which must account for the health of vulnerable individuals.

The Administrator and the Policy Assessment (PA) recognize that young, healthy adults experience significant impacts at levels as low as 60 ppb. Furthermore, EPA's Integrated Science Assessment (ISA) and PA recognize that children and asthmatics are at greater risk, however, U.S. EPA failed to act to protect the safety and wellbeing of these and other at-risk groups from exposures below the current standard. For example, while scientists would never perform controlled exposure studies on severely asthmatic children, evidence clearly points to increased effects. Given the airway responses to ozone in healthy adults and EPA's acknowledgment of higher breathing rates in children combined with greater airway reactivity in asthmatics, many scientific experts find that asthmatic children are not protected with an adequate margin of safety at the current standard level. Indeed, U.S. EPA's own proposal acknowledges the significant exposures of asthmatic children to unhealthy levels of ozone: "Approximately 3% to nearly 9% of each study area's simulated children with asthma, on average across the 3-year period, are estimated to experience one or more days per year with a 7-hour average exposure at or above 60 ppb."[1] Unfortunately, the EPA Administrator's decision ignores this important information in reaching its ultimate decision.

Indeed, U.S EPA acknowledges certain subsections of the population, including children and outdoor workers, spend disproportionate amounts of time outside, increasing their exposure to unhealthy levels of pollution. Studies considered in the previous review found that "estimates for percent of children experiencing exposure at or above the benchmarks were higher than percent of adults due to the greater time that children spend outdoors and engaged in activities at elevated exertion."[2] U.S. EPA's decision is particularly concerning due to California's high numbers of outdoor workers, who risk their health by continuing to provide essential services including firefighting and working in farming or construction, which all too often means exposing themselves to dangerous levels of air pollution.

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[1] U.S. EPA Proposal at pdf p. 32
[2] U.S. EPA Proposal at pdf p. 13
[3] Apte, J., Chambliss, S., Tessum, C., & Marshall, D. (2019). A Method to Prioritize Sources for Reducing High PM2.5 Exposures in Environmental Justice Communities in California. CARB Research Contract Number 17RD006. Available at https://ww3.arb.ca.gov/research/single-project.php?row_id=67021

2. *U.S. EPA's Decision Fails to Protect Low-Income Individuals and Disadvantaged Communities of Color.*

Millions of Californians living in low-income and disadvantaged communities. Communities of color already face higher risks for adverse health effects from air pollution exposure, and ozone adds to those existing health risks. California research has demonstrated that disadvantaged communities experience up to 45% higher levels of average exposure to harmful pollutants than the statewide average.[3] To make matters worse, communities of color often suffer from disproportionately high levels of asthma and other conditions that are exacerbated by air pollution. For example, Native American children suffer from asthma at twice the rate of the country's general population and, therefore, are at increased risk of health hazards from ozone.

III. U.S. EPA's Ozone NAAQS Review Process Is Flawed

U.S. EPA's decision to retain the current standard is the product of a critically flawed process and the exclusion of CASAC experts necessary for an adequate analysis of the applicable science. For example, no current member of CASAC has expertise in epidemiology, plant physiology, forestry, plant ecology, or related fields necessary to review the primary and secondary standards for ozone. U.S. EPA also prohibited scientific experts who receive U.S. EPA grant funding from serving on CASAC. This blanket prohibition denied CASAC expertise essential to a thorough evaluation. The exclusion of key scientific experts from CASAC's review was exacerbated by U.S. EPA's failure to convene an ozone NAAQS review panel, the working group that has historically provided additional input on the relevant science.
U.S. EPA's recent changes to the NAAQS review process undercut long-held agency and scientific procedures that U.S. EPA followed in past reviews, shirking the Agency's statutory obligations. U.S. EPA's new procedures have fundamentally eroded the Agency's ability to weigh scientific evidence and draw sound scientific conclusions on the health impacts of ozone.

Furthermore, U.S. EPA's review process failed to provide adequate time or opportunity for expert analyses and feedback regarding the scientific evidence that forms the basis of this proposal. Specifically, U.S. EPA abandoned its long established practice of completing its Integrated Science Assessment (ISA) prior to drafting the Policy Assessment (PA). This order of operations is critical because the ISA analyzes the relevant scientific materials, which form the basis of the PA. The PA then determines what policy actions are necessary based on the science in order to meet the statutory objectives. This premature initiation of the PA prior to the completion of the ISA fundamentally undermined the review process. U.S. EPA also abandoned its practice of developing an independent Risk and Exposure Assessment (REA), instead inexplicably choosing to bundle that critical evaluation into the PA.

U.S. EPA failed to adequately explain departures from past practices or to demonstrate that it has met its statutory obligations. U.S. EPA cannot shirk its responsibility by postponing an evaluation of whether the new "efficiencies" in the process suffice to meet the statutory requirements. U.S. EPA stated the "successfulness of these and other efficiencies implemented in this review will be considered by the EPA in planning for other future NAAQS reviews."[3] These failures run counter to U.S. EPA's past practices and short-circuits a process designed to ensure comprehensive review of relevant scientific research. In sum, these failures render U.S. EPA's proposal to retain the standards arbitrary and capricious.

IV. U.S EPA Must Strengthen the Ozone Secondary Standards to Adequately Protect Public Welfare and Sensitive Ecosystems.

The Administrator proposes to retain the secondary ozone standard despite evidence that it does not adequately protect public welfare, including agriculture and ecosystems. Clearly, the current CASAC lacks sufficient expertise to evaluate evidence related to the secondary standard, including negative effects on plant health, tree growth, and crop yields, and the resulting deterioration of sensitive ecosystems and impairment of agricultural productivity.

Additionally, scientific experts, including the previous CASAC, recommended using a single-year exposure metric to adequately address seasonal plant growth cycles. Nevertheless, U.S. EPA ignored this sound scientific advice and opted for a three-year average in the 2015 ozone standard. Indeed, in *Murray Energy*, the DC Circuit Court found that U.S. EPA failed to adequately justify its decision to use the three-year-average exposure metric. U.S. EPA must properly account for the cumulative impacts of ozone on tree growth and evidence of threshold responses to ozone in plant species by adopting a cumulative dose approach metric (single-year W126 exposure metric). This strengthening of the secondary standard will mitigate long-term detrimental consequences for plant growth and ecosystems that are essential to California's environment and the economy.

V. Conclusion

Given the available science, CARB, OEHHA, and CalEPA strenuously object to the Administrator's proposed conclusion that "the current standard is requisite to protect the public health with an adequate margin of safety, and that it is appropriate to retain the standard without revision." As stated in our letter and appendices, a strong body of scientific evidence demonstrates that adverse health impacts occur at levels below the current primary ozone standards, even among healthy individuals but particularly

[3] EPA, Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards, p. 1-9 (Aug. 2019)

for sensitive subgroups. Robust scientific evidence also shows that elevated ozone levels are threatening ecosystems, and the current 3-year metric inadequately reflects yearly and seasonal plant growth cycles. Therefore, retaining the current ozone standards is contrary to the best interests of public health and welfare. CARB, OEHHA and CalEPA urge U.S. EPA to abandon the current proposal and instead adopt stronger standards that will protect the public health and welfare of Californians and all U.S. residents as required by the law and science. We, therefore, urge U.S. EPA to do the following:

- Strengthen the primary 8-hour ozone standard to 60 ppb; and
- Strengthen the secondary ozone standard by adopting a 1-year W126 metric.

You will find our detailed comments that expand upon and explain our comments in this letter in Appendix A ("Detailed Legal Comments") and Appendix B ("Additional Comments On Scientific Basis For Lower Ozone Standards and References"). Thank you for the opportunity to comment on the proposed ozone standards. For additional information, please contact Bonnie Holmes-Gen, Chief of the CARB Health and Exposure Branch at (916) 327-8225 or Bonnie.Holmes-Gen@arb.ca.gov, or Vince Cogliano, OEHHA Deputy Director for Scientific Affairs at (510) 622-3203 or Vincent.Cogliano@oehha.ca.gov.

Sincerely,

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APPENDIX A - LEGAL ANALYSIS

I. Introduction

A. *Overview of NAAQS*

The National Ambient Air Quality Standards (NAAQS) are at the heart of the Clean Air Act's cooperative federalism structure.[1] As the Supreme Court has held, the Clean Air Act's language is "absolute" and directs that these standards be set based on "the latest scientific knowledge . . . at a level that is requisite to protect public health from the adverse effects of the pollutant in the ambient air."[2] Recognizing that science is ever evolving, Congress provided that the benefit of the doubt must go to public health, directing each NAAQS to be set with "an adequate margin of safety."[3]

Congress wisely required U.S. EPA to regularly revisit the NAAQS to ensure that they remained stringent enough in light of evolving science. Responding to this direction and steadily accumulating evidence that air pollution is harmful even at very low levels, U.S. EPA has steadily lowered the NAAQS, producing vast and lasting public benefits.[4] The Ozone NAAQS Proposal now before the public departs from this direction. If finalized, this Proposal could jeopardize the health and wellbeing of Americans, particularly those who suffer from asthma or other respiratory or cardiovascular conditions exacerbated by excessive ozone exposure.

II. The Proposal is Legally Flawed on Procedural and Substantive Grounds.

A. Overview

U.S. EPA's Proposal is unlawful on substantive and procedural grounds. First, U.S. EPA's decision to retain the current standards ignores scientific evidence demonstrating that the standards fail to protect human health and welfare with an

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[1] *See* 42 U.S.C. §§ 7401 (setting out cooperative federalism principles); § 7408-7410.
[2] *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 465, 473 (2001).
[3] 42 U.S.C. § 7409(b)(1).
[4] U.S. EPA, *The Benefits and Costs of the Clean Air Act from 1990 to 2020* (2011), Available at: https://www.epa.gov/sites/production/files/2015-07/documents/fullreport_rev_a.pdf

adequate margin of safety. As detailed in the attached Health Appendix, the scientific literature related to ozone health effects and exposure has become even stronger since the last ozone review. This literature shows clear evidence of adverse health impacts below 70 ppb. For example, additional scientific papers since the last review have found associations between long-term ozone exposure and increased mortality at levels substantially less than 70 ppb. Other studies have demonstrated lung function decline, increases in childhood asthma onset, and preterm births at levels near or below the current standard. Additional studies show that under the current standard some of the most vulnerable and disadvantaged subpopulations of society, including children, populations of color and those of low socioeconomic status are disproportionately affected by air pollution exposures. Finally, as to the secondary standard, scientific evidence demonstrates that the current standard does not adequately protect the public against ozone's impacts to sensitive ecosystems, including its negative effects on plant health, tree growth, and crop yields. In light of the evidence supporting the need to increase the stringency of the ozone NAAQS, it is hard to imagine how U.S. EPA could arrive at a decision to issue this proposal considering it's the Agency's statutory mandate to protect public health and welfare.

Second, U.S. EPA's flawed process was an unjustified diversion from well-established precedent and law. Specifically, CARB calls out U.S. EPA's (1) unreasonable abandonment of the very procedures it had previously utilized to ensure scientific rigor in its NAAQS reviews, (2) failure to convene a review panel of subject matter experts to aid CASAC, and (3) exclusion of recognized subject matter experts from CASAC on the basis of their past receipt of U.S. EPA grants for research. These unwarranted changes served to undermine the scientific integrity of the process in contravention of the Clean Air Act.

These scientific and legal flaws are grounds for reversal of the Proposal. As Chief Justice Roberts recently observed for the Court, "when so much is at stake, . . . the Government should turn square corners in dealing with the people" by scrupulously observing the bounds of the law.[5] U.S. EPA instead is making a wrong turn. The current Proposal reflects an arbitrary, capricious, rushed, and inadequately explained departure from the Agency's own procedural precedents as well as its congressional mandate.

B. The Proposal Illegally Endangers the Public.

[5] *Dep't of Homeland Security et al. v. Regents of the University of California et al.*, 140 S.Ct. 1891, 1909 (2020) (internal quotation omitted).

The Clean Air Act aims "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population."[6] Public health is a fundamental goal of the Act, which has been repeatedly amended to strengthen protections.[7] The Act requires U.S. EPA to set primary NAAQS at a level that is "requisite to protect the public health" with "an adequate margin of safety."[8]

The Proposal violates the Clean Air Act's basic commands that NAAQS be based on the science, and be set with an adequate margin of safety. U.S. EPA abused its discretion and violated the Clean Air Act in deciding to retain the current ozone NAAQS despite copious scientific evidence that demonstrates the current standards fail to protect public health (particularly health of sensitive subpopulations) and welfare with an adequate margin of safety. Although we acknowledge that U.S. EPA has discretion in setting ozone NAAQS, U.S. EPA has failed to reasonably exercise that discretion, and their decision to retain the current standards is arbitrary and capricious. Under the Clean Air Act, courts will set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[9] Further, U.S. EPA has failed to present a rational basis that justifies its decision. A "'searching and careful' inquiry into the underlying facts" here displays the lack of any rational basis to support EPA's decision.[10]

i. *U.S. EPA's Decision is Unreasonable and Arbitrary and Capricious.*

Robust epidemiological studies demonstrate the need to lower the standard in order to protect public health. U.S. EPA's failure to consider this evidence renders its decision unreasonable, and arbitrary and capricious. As discussed in the Health Appendix to this comment, since 2015 there have been multiple epidemiological studies demonstrating health and respiratory outcomes from short and long-term ozone exposures near and below the level of the current standard. These outcomes

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[6] 42 U.S.C. § 7401(b) (2018).

[7] *Nat'l Res. Def. Council v. EPA*, 896 F.3d 459, 464 n.4 (D.C. Cir. 2018), citing 42 U.S.C. § 7619(b)(3) (in promulgating regulations relating to air quality monitoring, "the Administrator shall follow the principle that protection of public health is the highest priority.").

[8] 42 U.S.C. § 7409(b)(1).

[9] 42 U.S.C. § 7607(d)(7)(9) (2018).

[10] *Am. Trucking Ass'ns, Inc. v. EPA.*, 283 F.3d 355, 362 (D.C. Cir. 2002).

included lung function decline, asthma and preterm birth outcomes, exacerbation of cardiovascular conditions, and increased emergency room visits.

The current NAAQS are no longer based on the best available science. Indeed, even in 2015, when U.S. EPA lowered its primary ozone NAAQS standard from .075 ppm to .070 ppm, CASAC opined that a standard set at .070 ppm "may not meet the statutory requirement to protect public health with an adequate margin of safety" but ultimately recommended that U.S. EPA choose a level between .060 ppm and .070 ppm.[11] In other words, the standard was set unduly high five years ago; since that time, it has only become more clear that it is not sufficiently protective. As documented in the Health Appendix and References, the science has only matured since to show that .070 ppm fails to protect public health with an adequate margin of safety, particularly for vulnerable subpopulations.

CASAC already seriously questioned the adequacy of a 70 ppb standard in 2015 due to evidence of health impacts below 70 ppb. "Evidence of respiratory effects from controlled human exposure studies" considered in U.S. EPA's 2015 review demonstrated "reduced lung function and increased pulmonary inflammation . . . following such exposures to O_3 concentrations of 60 ppb or higher."[12] These health impacts are not limited to sensitive populations "the previously available studies . . . document statistically significant O_3-induced reduction in lung function (FEV_1) and increased pulmonary inflammation in *young healthy adults* exposed to O_3 concentrations as low as 60 ppb."[13]

In the following five years, additional studies have further demonstrated serious health impacts from ozone exposure down to 60 ppb. Indeed, U.S. EPA's proposal repeatedly acknowledges evidence of serious health impacts from repeated exposure to ozone at levels above 60 ppb. These impacts are more severe for vulnerable subpopulations, such as children with asthma.

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[11]Letter from Christopher H. Frey, Ph.D, *et. al.*, re: CASAC Review of the EPA's *Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards*, p. ii (Jun. 26, 2014) (EPA-CASAC-14-004). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/%24File/EPA-CASAC-14-004+unsigned.pdf.

[12] 85 Fed.Reg. 49830, 49840 (Aug. 14, 2020) emphasis added. (See also p. 49842 "exposures to O_3 concentrations as low as 60 ppb have been shown to decrease lung function and to increase airway inflammation.")

[13] *Id.* at p. 49851

U.S. EPA's decision to disregard the robust evidence of significant health impacts below the current standard had no rational basis, and is arbitrary and capricious. By continuing to discount information available during the previous review, and devaluing new information, the Proposal contravenes U.S. EPA's congressional mandate to "protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population."

As the D.C. Circuit has emphasized, U.S. EPA cannot proceed on such a flimsy basis. "We do not assign 'presumptive validity' to the prior NAAQS; the question is whether EPA reasonably explains the current standards."[14] "Although the EPA is entitled to rely upon its experience, it must have a reasonable explanation of how its experience supports its conclusion."[15] U.S. EPA's proposal to retain the ozone standard disregards evidence of serious health impacts from exposure to levels below the current standard and its explanation of this decision is unreasonable.

ii. *U.S. EPA's Decision Fails to Provide an Adequate Margin of Safety.*

The current NAAQS must "accurately reflect the latest scientific knowledge" and indicate the "kind and extent of *all* identifiable effects on public health . . . which *may* be expected."[16] Nevertheless, U.S. EPA has abandoned the "preventative" and "precautionary" nature of the Clean Air Act.[17] It must take into account the margin of safety adequate to protect public health based not solely on known adverse effects, but also considering scientific uncertainty and erring on the side of caution in the face of such uncertainty.

To fulfill the preventative and precautionary purpose of the Clean Air Act "[t]he 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."[18] "Congress deliberately subordinated economic and technological feasibility concerns to the

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[14] *Nat'l Ass'n of Mfrs.*, 750 F.3d at 925.

[15] *Id.* at p. 523, *citing DSE Inc. v. United States*, 169 F.3d 21, 30 (D.C. Cir. 1999).

[16] *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 516, 526 (D.C. Cir. 2009), *quoting* 42 U.S.C. § 7408(a)(2) (quotations omitted, and emphasis added).

[17] *See Lead Indus. Ass'n, Inc. v. EPA*, 647 F.2d 1130, 1155 (D.C. Cir. 1980).

[18] *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998).

achievement of public health goals."[19] Because the standard requires an adequate margin of safety, U.S. EPA must "err on the side of caution."[20] U.S. EPA erred on the side of pollution rather than caution in retaining the current standard.

Despite statistically significant evidence available in 2015 of the inadequacy of the current standard, and despite five additional years of research further establishing this inadequacy, U.S. EPA has elected to risk public health and welfare by retaining the current standard. In doing so, they effectively remove the requirement to provide an "adequate margin of safety" from the Clean Air Act, risking the health and wellbeing of Americans, in particular at-risk individuals.

iii. *U.S EPA's Decision Fails to Protect At-Risk Individuals*

The Proposal is particularly concerning because it fails to protect people who are most at risk. NAAQS are meant to protect "not only average healthy individuals, but also 'sensitive citizens.'"[21] The current standard is especially problematic for the health of sensitive individuals such as children, seniors, and people with respiratory conditions, as well as minority communities who are disproportionately impacted by poor air quality.

The epidemiological evidence discussed throughout this comment show that children, as well as the elderly and other sensitive populations experience adverse, ozone-related health effects, including mortality, in areas that meet the current standard.[22] In light of extensive scientific evidence discussed in the Letter and Health Appendix, U.S. EPA cannot reasonably conclude that these sensitive populations are adequately protected by the current NAAQS. Moreover, failure to consider these sensitive populations is inconsistent with EPA's prior rulemakings, where potential impacts to sensitive individuals influenced final actions towards a protective stance.[23] This is further evidence of the arbitrary and capricious nature of the current Proposal.

iv. *Environmental Justice Demands Lowering the Standards*

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[19] *Id.*

[20] *Id.* at 393, *quoting Lead Indus. Ass'n, Inc.*, 647 F.2d at 1155-57.

[21] *Am. Farm Bureau Fed'n*, 559 F.3d at 524.

[22] *Am. Trucking Ass'ns*, 283 F.3d at 365.

[23] E.g. 78 Fed.Reg. 3086, 3127 (Jan. 15, 2013)

These requirements bind U.S. EPA not just under the Clean Air Act but under the federal government's commitment to environmental justice. Under Executive Order 12898, federal agencies must identify and address "disproportionately high and adverse human health and environmental effects" of their actions on minority and low-income communities.[24] By failing to acknowledge that low-income and minority populations will be disproportionately impacted by the Proposal and failing to analyze the extent of that impact, U.S. EPA has not met the requirements of Executive Order 12898.

A stronger standard is critical to protect those living in the most vulnerable and highly impacted neighborhoods, which all too often disproportionately falls on communities of color. As discussed in the Letter and Health Appendix, California research has demonstrated that disadvantaged communities experience up to 45% higher levels of average exposure to harmful pollutants than the statewide average.[25] Communities of color often suffer from disproportionately high levels of asthma and other conditions that are exacerbated by air pollution. For example, Native American children suffer from asthma at twice the rate of the country's general population and, therefore, are at increased risk of health hazards from ozone.

Not only has U.S. EPA failed to uphold its statutory duty to set the standard at a level requisite to protect public health, it has also failed to explain how the physical effects experienced by sensitive populations such as asthmatics "do not amount to a public health problem."[26] Indeed, U.S. EPA's proposal accepts that under the proposed standard some asthmatic children will suffer negative health consequences.[27] Accepting that harm, even in a limited percentage of the sensitive subpopulation, makes clear that this standard is inadequately health protective. U.S. EPA cannot disregard these significant impacts, which endangers the health of asthmatic children. "Approximately 3% to 9% of each study area's simulated children with asthma, on average across the 3-year period, are estimated to experience one or more days per year with a 7-hour average exposure at or above 60 ppb."[28]

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[24] 59 Fed. Reg. 7629 (Feb. 16, 1994).

[25] Apte, J., Chambliss, S., Tessum, C., & Marshall, D. (2019). A Method to Prioritize Sources for Reducing High PM2.5 Exposures in Environmental Justice Communities in California. CARB Research Contract Number 17RD006. Available at https://ww3.arb.ca.gov/research/single-project.php?row_id=67021

[26] *Am. Lung Ass'n*, 134 F.3d at 388.

[27] 85 Fed. Reg. at 49872-49873.

[28] 85 Fed.Reg. 49830, 49840 (Aug. 14, 2020) U.S. EPA Proposal at pdf p. 33

v. *Any Scientific Uncertainty Councils Lowering the Standards*

Any residual uncertainty surrounding these studies is also an insufficient reason for keeping ozone NAAQS at current levels. As the Proposal itself acknowledges, the requirement that primary standards provide an adequate margin of safety is intended to address uncertainties associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards not yet identified.[29] "Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree."[30]

Given the well-documented risk surrounding current ozone concentrations faced by the general population, and the even greater risk faced by particularly vulnerable populations, the Administrator *must* set the primary ozone NAAQS at levels substantially below the current levels in order to provide an adequate margin of safety for all affected populations. Scientific uncertainty exists regarding impacts on sensitive populations due to ethical and health concerns that prevent certain human exposure studies on such individuals, including severe asthmatics, children, and the elderly. However, this uncertainty cannot be used as an excuse to endanger their health by making assumptions to the detriment of such sensitive individuals. Such inherent scientific uncertainty must be resolved in favor of public health. Indeed, in 2015, the then Administrator "recognized there to be limitations and uncertainties in the evidence base with regard to unstudied population groups. As a result, she judged it appropriate for the standard, in providing an adequate margin of safety, to provide some control of exposures at or above the 60 ppb benchmark."[31]

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[29] 85 Fed.Reg. at 49833. (See also *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980); *American Petroleum Institute v. Costle*, 665 F2d at 1186; *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 617-18 (D.C. Cir. 2010); *Mississippi v. EPA*, 744 F.3d 1334, 1353 (D.C. Cir. 2013)).

[30] 85 Fed.Reg. at 49833.

[31] 85 Fed.Reg. at 49841.

C. The Process to Develop the NAAQS Impermissibly Abandoned U.S. EPA's Established Practices Developed to Ensure Scientific Rigor and Excluded Scientific Expertise.

This flawed Proposal emerged from an equally flawed process. U.S. EPA's highly irregular and rushed review process undercut long-held Agency and scientific procedures, and eroded the ability of U.S. EPA to adequately weigh scientific evidence and draw informed conclusions on the impacts of ozone exposure on health and welfare. Specifically, CARB condemns changes to the ozone NAAQS review process that (1) unreasonably abandoned procedures and processes that U.S. EPA developed in the past to ensure scientific rigor in its NAAQS reviews, (2) failed to convene a review panel of subject matter experts, and (3) barred participation by recognized experts who had received U.S. EPA grants.

1. U.S. EPA Unjustifiably Rushed and Consolidated Aspects of This NAAQS Review, Undermining Scientific Rigor and Public Process.

U.S. EPA's insufficient process failed to satisfy its statutory obligations in conducting its NAAQS review and sets a dangerous precedent moving forward. U.S. EPA's process was rushed from the outset. The Agency initiated its review of the ozone NAAQS in June of 2018.[32] Throughout the process, U.S. EPA curtailed critical steps in the review, undermining public participation and preventing full review of the relevant science. As U.S. EPA wrote in the draft Integrated Review Plan: "the current review of the O_3 NAAQS is progressing on an accelerated schedule and the EPA is incorporating a number of efficiencies in various aspects of the review process . . .."[33] As explained below, this amounts to a rejection of the scientific rigor that U.S. EPA is obligated to apply under the Clean Air Act.

Under the Clean Air Act, U.S. EPA must review its existing NAAQS every five years to determine if advances in scientific knowledge regarding the effects of the pollutant at issue on public health and welfare warrant their revision of the standard,[34] but the current review was systematically biased and flawed.

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[32] 83 Fed.Reg. 29785 (Jun. 26, 2018

[33] EPA, Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards, 1-8 (Aug.2019). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/0/E18E92A94AF87D6C852582BB004CDF75/$File/O3-IRP-draft-Oct2018-ForRelease-Oct31-2018.pdf.

[34] 42 U.S.C. § 7409(d)(1) (2018).

U.S. EPA's previous NAAQS review process followed a detailed, sequential progression to ensure consideration of all relevant evidence in deciding whether and to what extent it should revise the NAAQS. In the past, U.S. EPA's review process included four stages: planning, science assessment, risk and exposure assessment, and policy assessment.[35] In each of these stages, the Agency would draft a document setting out the analysis and conclusions of U.S. EPA's scientists and other experts. These documents, the Integrated Review Plan, the Integrated Science Assessment (ISA), the Risk and Exposure Assessment (REA), and the Policy Assessment (PA) were made available in sequence, for review and comment by CASAC and the public before they were finalized.[36]

A prelude to this flawed review occurred in July 2018 with U.S. EPA's formal request for nomination of "nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone" to sit on the Ozone NAAQS Review Panel and advise CASAC during this ozone review. This request was in keeping with U.S. EPA's established practice for NAAQS reviews.[37]

Then on October 10, 2018, without substantive explanation, U.S. EPA nixed its well-established practice of convening an expert review panel to support and inform the CASAC in its review of a NAAQS. Specifically, the Agency dismissed the existing Particulate Matter review panel, and decided not to reconvene the Ozone review panel for the upcoming Ozone NAAQS review.[38]

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[35] Memorandum from Lisa Jackson, Administrator, EPA, to Elizabeth Craig, Acting Assistant Administrator for Air and Radiation, EPA and Lek Kadeli, Acting Assistant Administrator for Research and Development, EPA, Re: Process for Reviewing National Ambient Air Quality Standards, Attachment: Major Elements of the Process for Reviewing National Ambient Air Quality Standards (May 21, 2009).

[36] *Ibid.*

[37] 83 Fed.Reg. 35636 (Jul. 27, 2018).

[38] New York Times, E.P.A. to Disband a Key Scientific Review Panel on Air Pollution, Lisa Friedman (Oct. 11, 2018). Available at https://www.nytimes.com/2018/10/11/climate/epa-disbands-pollution-science-panel.html

The current ozone review began in In October 2018 when U.S. EPA issued its draft Integrated Review Plan for the Ozone NAAQS.[39] The Integrated Review Plan is a document that sets out the schedule for a NAAQS review, the process for conducting the review, and the key policy-relevant science issues that will guide the review.

In December 2018 three current CASAC members urged U.S. EPA to reconvene the Ozone Review Panel in their comments on the draft Integrated Review Plan for Ozone NAAQS.[40]

In August 2019, U.S. EPA published the Integrated Review Plan for the Review of the Ozone NAAQS,[41] with a timeline projecting that it would finalize the Ozone NAAQS in "Winter 2020/2021," potentially pushing back the original December 2020 goal. U.S. EPA also wrote that it was "progressing on an accelerated schedule" and so did not plan to develop a REA and instead planned to include that analysis in the PA.[42]

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[39]EPA, Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards, (Aug.2019). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/0/E18E92A94AF87D6C852582BB004CDF75/$File/O3-IRP-draft-Oct2018-ForRelease-Oct31-2018.pdf

[40]Letter from Louis Anthony Cox, Jr., M.D., Chair, CASAC, et al. to U.S. EPA Administrator Wheeler, re: Consultation on the EPA's Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2018), (Dec. 10, 2018). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/A286A0F0151DC8238525835F007D348A/$File/EPA-CASAC-19-001.pdf

[41] EPA, Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards, (Aug.2019). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/0/E18E92A94AF87D6C852582BB004CDF75/$File/O3-IRP-draft-Oct2018-ForRelease-Oct31-2018.pdf.

[42] "Under the plan outlined here, the current review of the O3 NAAQS is progressing on an accelerated schedule and the EPA is incorporating a number of efficiencies in various aspects of the review process to ensure completion within the statutorily required period (Pruitt, 2018). For example, the kick-off workshop has been replaced with the addition of a call for policy-relevant information coincident with the call for scientific information that traditional initiates a NAAQS review (83 FR 29785, June 26, 2018). Also coincident with preparation of the IRP, the EPA has begun review of the literature for consideration in the ISA, as described in Chapter 4 below. The EPA is not planning to develop a Risk and Exposure Assessment (REA) Planning Document in this review; key considerations with regard to development of quantitative analyses are

Historically, the REA would be prepared after the ISA and would draw upon information and conclusions presented in the ISA to develop quantitative characterizations of exposures and associated risks of the current standard and any alternative under consideration.[43] EPA has historically made the REA available for public comment and sought CASAC's review of it independently from other assessments. Of this non-standard procedure, U.S. EPA wrote that "[t]he successfulness of these and other efficiencies implemented in this review will be considered by the EPA in planning for other future NAAQS reviews."[44] The Integrated Review Plan did not expressly state or explain U.S. EPA's ultimate decision to issue the draft PA before the ISA was finalized. Indeed, the Agency's early recognition that their non-standard process here would later need to be judged for its "successfulness" is telling.

On September 13, 2019, U.S. EPA announced that it had selected 12 consultants to answer individual questions passed through the CASAC chair from CASAC members regarding the review of the NAAQS for ozone and PM.[45] Later reporting revealed that Administrator Wheeler selected far more individuals affiliated with industry for these

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discussed in Chapter 5 of this document, which was the subject of a consultation with the CASAC. Further, the EPA has also considered combining the reviews by the CASAC and the public for some of the main documents in a review (Pruitt, 2018). As a result, the EPA is planning to incorporate the REA-related analyses into the PA, combining what had been two documents into a single document for review by the CASAC and the public. Further, we are striving to ensure that initial draft documents are sufficiently robust and complete to support a single, full review by the CASAC and the public. The successfulness of these and other efficiencies implemented in this review will be considered by the EPA in planning for other future NAAQS reviews (Pruitt, 2018)." (*Id.* at pp. 1-8 to 1-9).

[43] EPA, Process of Reviewing the National Ambient Air Quality Standards. Available at https://www.epa.gov/criteria-air-pollutants/process-reviewing-national-ambient-air-quality-standards

[44] EPA, Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards, 1-9 (Aug.2019).

[45] EPA, Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts (Sep. 13, 2019). Available at https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts

positions than those affiliated with academia.[46] The use of consultants, rather than an independent panel, departed from U.S. EPA's past practices and severely reduced the transparency and effectiveness of the review process by stymying open debate and thorough deliberation of the scientific evidence by experts.

On September 26, 2019, U.S. EPA published the draft ISA for Ozone,[47] which CASAC planned to discussed at the December 2019 meeting. The ISA is a document that seeks to comprehensively review, synthesize, and evaluate the most policy-relevant science. Historically, it has been completed before the REA and the PA as it would include key science judgments central to developing these assessments.[48]

In late October 2019, U.S. EPA released the draft PA for the Ozone NAAQS.[49] Breaking with U.S. EPA's established past practices, the draft PA was released before CASAC had reviewed and sought revisions to the ISA. This simultaneous process is at odds with U.S. EPA's description of the role of the PA as a document that is based on information presented in the ISA and the REA.[50] The PA concluded that the newly available evidence continued to support the existing ozone NAAQS levels. Like the ISA, the PA was also slated for discussion at the December 2019 CASAC meeting. The simultaneous discussion of these two documents undercuts the long-established practice of completing the ISA and then relying on its findings to inform the PA.

On Dec. 2, 2019, 18 former members of the CASAC Ozone Review Panel sent a letter to U.S. EPA stating that the changes the Agency made to the NAAQS review process

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[46]E&E News, Documents expose ties among EPA panel's experts (Sean Reilly, Feb. 7, 2020). Available at https://www.eenews.net/stories/1062289617

[47] EPA, Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants (External Review Draft). Available at https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=344670

[48] EPA, Process of Reviewing the National Ambient Air Quality Standards. Available at https://www.epa.gov/criteria-air-pollutants/process-reviewing-national-ambient-air-quality-standards

[49]EPA, Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/56F5BB9165D594C78525848C0046BECC/$File/O3-draft_PA-Oct31-2019-ERD.pdf

[50] EPA, Process of Reviewing the National Ambient Air Quality Standards. Available at https://www.epa.gov/criteria-air-pollutants/process-reviewing-national-ambient-air-quality-standards

"are collectively harmful to the quality, credibility, and integrity of EPA's scientific review process and to CASAC as an advisory body."[51] The letter goes on to state that "[t]he NAAQS review for ozone should be suspended until these deficiencies are corrected."

From December 3-6, 2019, CASAC met to discuss the ISA and PA.[52] Reviewing the ISA and PA simultaneously decreased the level of review possible by CASAC and departed from the long-standing past NAAQS process of concluding the scientific analysis prior to developing the resulting policy.

On December 6, 2019, CASAC failed to reach consensus regarding the adequacy of the existing ozone NAAQS. Six members endorsed retaining the current standards, and one member recommended tightening the standards.[53] CASAC later announced a teleconference on February 11 and 12 to continue discussing their recommendations for ozone.[54]

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[51]Letter from Christopher H. Frey, Ph.D, et. al., to Andrew Wheeler, Administrator U.S. EPA re: Advice from the former U.S. EPA Clean Air Scientific Advisory Committee Ozone Review Panel on EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft –September 2019), and EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft –October 2019) (Dec. 2, 2019) (EPA–HQ–ORD–2018–0274 and EPA–HQ–OAR–2018–0279). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/B2AF0B23ABE6A60E852584C4007312E3/$File/EPA+CASAC+O3+Review+ISA+PA+Letter+191202+Final.pdf

[52]EPA, Public Meeting of the Chartered Clean Air Scientific Advisory Committee (CASAC) on Particulate Matter and Ozone. Available at https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCalCASAC/A0D0F9D4C6BC36D88525848C00467771?OpenDocument

[53] Bloomberg Law, EPA Advisers Can't Agree on Revising Ozone Limits (Amena H. Saiyid, Dec. 7, 2019). Available at https://news.bloombergenvironment.com/environment-and-energy/epa-advisers-cant-agree-on-what-to-do-about-ozone-limits

[54]EPA, Public Meeting of the Chartered CASAC on Ozone. Available at https://yosemite.epa.gov/sab/sabproduct.nsf/bf498bd32a1c7fdf85257242006dd6cb/cdb2e140f088220f852584e6006cdb44!OpenDocument&Date=2020-02-11

In February 2020, CASAC agreed on a final report to Administrator Wheeler recommending no change to the existing ground-level ozone standard.[55] CASAC's report highlighted three "overarching issues" concerning the recommendation: (1) the inappropriateness of a simultaneous review of the draft PA and the draft ISA; (2) the problems flowing from U.S. EPA's removal of the opportunity for interactive discussion between CASAC and the pollutant-specific review panel; and (3) the lack of adequate technical depth and clarity in the use of causal concepts and analyses in the new NAAQS review. This comment quotes from CASAC's report at length below as it illustrates the irregularity and infirmity of U.S. EPA's process in this review, and lists the CASAC's recommendations to remedy these process failures, which U.S. EPA summarily disregarded.

Of the first issue, CASAC wrote:

> It is unusual for the CASAC to review a draft PA and draft Integrated Science Assessment (ISA) simultaneously, insofar as the ISA provides the scientific basis for the PA. The CASAC recommends that it be given an opportunity to review a second draft of the Ozone PA (with an updated Risk and Exposure Assessment) after the final ISA for ozone is released.[56]

Of the second issue, CASAC wrote:

> Members of the CASAC found that this pool of [non-CASAC member] consultants provided valuable insights and responses and useful information. However, the traditional review process, allowing interactive discussion between the CASAC and a pollutant-specific review panel, enables significantly more discussion and deliberation among experts with differing backgrounds and opinions, potentially resulting in a more comprehensive examination of some controversial topics. The CASAC strongly recommends that the EPA consider restoring this traditional interactive discussion process, while keeping the option of obtaining written responses from external experts in methodological and technical

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[55]CASAC, CASAC Review of the EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019), Feb. 19, 2020 (EPA-CASAC-20-003). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/4713D217BC07103485258515006359BA/$File/EPA-CASAC-20-003.pdf

[56] *Id.* at p. 1.

> areas to specific questions from the CASAC, to complement the expertise of the review panel and reduce risks of groupthink, confirmation and conformation biases, and other biases that can impair group judgments and decisions."[57]

On the third issue:

> Discussions with the EPA during the public meetings and written comments from some non CASAC member consultants raise questions regarding the clarity of causal determination categories . . .. The CASAC therefore strongly recommends that the EPA work with experts in causal analysis, biological causation, management science, decision analysis, and risk analysis to revise and improve the current causal determination framework. Experts from outside the air pollution health effects area should be included. The CASAC recommends that the EPA work with the National Academies to critically review and improve the logical and conceptual foundations for its causal analyses and the clarity with which its causal conclusions are expressed and communicated throughout the NAAQS review process and in the ISA and PA.[58]

Then, on April 1, 2020, Administrator Wheeler sent a letter to CASAC Chair Tony Cox stating that U.S. EPA would hold to its 2020 deadline for the Ozone NAAQS.[59] In that letter, Administrator Wheeler, in response to the substantive procedural issues raised in CASAC's recommendations, also acknowledged that this deadline meant many of CASAC's comments and recommendations about the ISA that were "more substantial or cross-cutting" would not be addressed in this review cycle. On May 31, 2020, U.S. EPA published the final PA for ozone, affirming the position that the most recent scientific evidence supported retaining the existing ozone NAAQS.[60]

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[57] *Ibid.*

[58] *Ibid.*

[59] EPA, Letter of Administrator Wheeler to CASAC (April 1, 2020). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsARsLastMonthCASAC/F228E5D4D848BBED85258515006354D0/$File/EPA-CASAC-20-002_Response.pdf

[60] EPA, Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (May 2020). Available at https://www.epa.gov/sites/production/files/2020-05/documents/o3-final_pa-05-29-20compressed.pdf

U.S. EPA's primary justification for these changes was its purported need to proceed on an "accelerated schedule" to meet the Clean Air Act's timing requirements for NAAQS reviews. U.S. EPA cannot delay initiating the review and then cite urgency as an excuse for its own failure to meet the statutory obligations. The impending deadline for completing their review does not excuse U.S. EPA's flawed process and sets an alarming precedent.

U.S. EPA's decision to conduct the PA prior to completion of the ISA undermined the scientific integrity of the process. The Agency disregarded the purpose of the ISA, to inform the PA, by releasing the first drafts of the ISA and the PA simultaneously. U.S. EPA actually concedes in its proposal that issuing these documents at the same time was unprecedented, yet U.S. EPA failed to explain this diversion from its usual practice.[61]

U.S. EPA also failed to issue a second draft of the ISA or the PA, depriving the public of the opportunity to review and comment on second drafts. This departure from the Agency's past practices fundamentally limits the opportunity for adequate public consideration of their contents. Following on this, U.S. EPA also only finalized the ISA after the publication of the draft PA and after the window for review and comment on the PA by CASAC and the public had closed. Additionally, U.S. EPA combined the REA with the PA. As noted above, historically, the REA would be prepared after the ISA and would draw upon information and conclusions presented in the ISA to develop quantitative characterizations of exposures and associated risks of the current standard and any alternative under consideration. Additionally, historically the REA as made independently available for public comment and CASAC review.

By integrating the REA into the PA, and then issuing the PA and the ISA simultaneously, U.S. EPA abandoned its past practice without reasonable explanation. This unwarranted abandonment of U.S. EPA's established procedural precedent critically weakened its ozone NAAQS review process by denying the public meaningful

[61] "While simultaneous review of first drafts of both documents has not been usual in past reviews, there have been occurrences of the CASAC review of a draft PA (or draft REA when the process involved a policy assessment being included within the REA document) simultaneous with review of a second (or later) draft ISA (e.g., 73 FR 19835, April 11, 2008; 73 FR 34739, June 18, 2008; 77 FR 64335, October 19, 2020; 78 FR 938, January 7, 2013)."
(85 Fed. Reg. at 49836, n.13).

participation in the review process and preventing a robust analysis of key scientific evidence.

These diversions from its past practices were conducted without explanation of how the changes would further the Agency's ability to meet its statutory obligations for the ozone NAAQS review process. Indeed, U.S. EPA acknowledged that these newly adopted practices might adversely impact the review and need to be modified for future NAAQS reviews. Their process here was inadequate under the law, as the Supreme Court recently stated "when an agency rescinds a prior policy its reasoned analysis must consider the 'alternative[s]' that are 'within the ambit of the existing [policy].'"[62]

Making these changes without adequate transparency limited CASAC's and the public's ability to meaningfully review and provide feedback on the Proposal. This feedback is an important component of the public process because it helps ensure that the Administrator receives and considers additional relevant information that may not yet be in the record as well as comments that help the Administrator to properly understand the relevant information. This lack of transparency undermined meaningful public participation.

U.S. EPA failed to provide sufficient explanation or justification for these departures, which act to deprive the public of meaningful participation. "[A]n agency must supply a 'good reason' for departing from prior policy."[63] Here, U.S. EPA has merely suggested these departures were warranted to promote efficiency while disregarding the harm that the departures cause to the fundamental business of setting an adequately health and welfare protective standard.

2. U.S. EPA Critically Undermined CASAC's Ability to Meaningfully Review the Ozone NAAQS Evidence and Proposal by Failing to Convene an Ozone Review Panel.

CASAC is central to the review process; by statute they advise U.S. EPA on whether a NAAQS revision is warranted and, if so, what threshold levels are appropriate.[64] Prior

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[62] *Dep't of Homeland Security et al. v. Regents of the University of California et al.*, 140 S.Ct. 1891, 1913 (2020).
[63] *Federal Commc'ns Comm'n v. Fox Television Stations*, 556 U.S. 502, 515 (2009).
[64] 42 U.S.C. § 7409(d)(2) (2018).

to the current review process, the seven member CASAC had assistance from a larger Review Panel of subject-matter experts. U.S. EPA abandoned these well-established procedures in the current Proposal, damaging the scientific credibility of its analysis, and rendering its decision-making process unreasonable.

U.S. EPA's ozone NAAQS review process is arbitrary and capricious because it relies only upon the seven-member CASAC's consideration of EPA's technical and policy assessments, rather than the larger panel of experts it has historically relied on. U.S. EPA abandoned its long history of augmenting CASAC, by forming a larger panel of subject-matter experts to assist CASAC in reviewing the NAAQS. U.S. EPA has used such panels since for at least the last thirty years.[65]

As a part of its previous review of the ozone NAAQS, U.S. EPA formed CASAC's Ozone review panel in January 2009. The panel completed its analysis in July 2014.[66] As explained above, U.S. EPA formally requested for nominations to an ozone expert panel, but less than four months later, without substantive explanation, chose not to convene the panel. This sudden diversion from U.S. EPA's past practices is unreasonable and prevented full consideration of scientific evidence critical to its review. Indeed, the failure to convene an expert panel undermines CASAC's ability to complete the robust independent scientific assessment that is required under the Clean Air Act.[67] The absence of any substantive explanation for the diversion demonstrates the arbitrary and capricious nature of U.S. EPA's process.

Indeed, in CASAC's ultimate review of the PA, CASAC members wrote at least six times "I have no relevant expertise" to address a given issue.[68] CASAC member, Mark Frampton summarized the situation, writing that CASAC members needed access to

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[65] Letter from Louis Anthony Cox, Jr., M.D., Chair, CASAC, et al. to U.S. EPA Administrator Wheeler, re: Consultation on the EPA's Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2018), Individual Comment of Mark Frampton, M.D., p. A-18 (Dec. 10, 2018).
[66] 83 Fed.Reg. 35635 (Jul. 27, 2018)
[67] 42 U.S. Code section 7409(d)(2)(C).
[68]CASAC, CASAC Review of the EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019), Feb. 19, 2020, at p. A-13 (EPA-CASAC-20-003). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/4713D217BC07103485258515006359BA/$File/EPA-CASAC-20-003.pdf

additional expertise in "epidemiology, toxicology, and human clinical studies, and that expertise should include active investigators in the field."[69]

> [W]hile the chartered CASAC does include one physician, the review would have benefitted, especially with regard to some of the key issues in the PA, from input from additional physicians with expertise in the respiratory effects of ozone exposure and impacts on asthma. CASAC strongly recommends that future CASAC reviews are assisted by expert panels with appropriately diverse expertise that are asked to provide written reviews and be present to interact during CASAC deliberations.[70]

U.S. EPA's ultimate decision to allow CASAC to seek input from twelve hand-picked consultants, the majority of which were affiliated with industry rather than academia, does not adequately substitute for the robust and lengthy interplay in past NAAQS reviews between CASAC and expert panels. Further, U.S. EPA did not adequately explain why it was now requiring CASAC to submit written questions to these consultants rather than allowing a dialog as was the practice in the past. These unwarranted restrictions, and departure from past practices, illustrate the arbitrary and capricious nature of U.S. EPA's Proposal.

3. U.S. EPA's Policy Prohibiting Scientists that Receive U.S. EPA Grants from Serving on Advisory Committees Undermines the Scientific Credibility of the Review Process.

In 2017, U.S. EPA issued a Directive announcing a new Agency-wide policy that generally bars scientists who have received U.S. EPA grants from serving on U.S. EPA advisory committees. The Directive was a "major break" from U.S. EPA's "prior policy under which grantees regularly served on advisory committees."[71] The Directive prevents the Agency from receiving important and necessary scientific feedback on its review of the ozone NAAQS.[72] This policy limits the input of the leading experts on

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[69] *Ibid.*

[70] *Ibid.*

[71] *Physicians for Social Responsibility v. Wheeler*, No. 19-5104, 2020 WL 1921539 (D.C. Cir. Apr. 21, 2020); *NRDC v. EPA*, 19-CV-05174, 2020 WL 615072 (S.D.N.Y. Feb. 10, 2020).

[72] Directive from E. Scott Pruitt, Administrator, EPA, *Strengthening and Improving Membership on EPA Federal Advisory Committees* (Oct. 31, 2017). Available at

topics relevant to U.S. EPA's rulemakings as they often work at universities, hospitals, or non-profits that rely heavily on government funding.[73]

U.S. EPA has not identified any benefit or evidence supporting the policy,[74] but its detriments are clear. For example, a previous member of CASAC, Dr. Charles Driscoll, Distinguished Professor of Environmental Engineering at Syracuse University, who extensively researched air quality issues, was forced to step down from the committee because he had received a U.S. EPA grant to facilitate his research.[75] As a result, the Agency did not receive scientific input and advice from one of the very experts U.S. EPA deemed most qualified to research the specific scientific issues relevant to the ozone NAAQS review.

Indeed, on February 10, 2020, the U.S. District Court for the Southern District of New York held that this policy is arbitrary and capricious in violation of the Administrative Procedure Act (APA) because U.S. EPA did not articulate a "'reasoned explanation' for its decision to 'disregard [ ] facts and circumstances that underlay or were engendered by the prior policy.'"[76] On April 15, 2020, Judge Cote vacated the "provision of the Directive specifying that 'no member of an EPA federal advisory committee be currently in receipt of EPA grants . . . or in a position that would otherwise reap substantial benefits from an EPA grant" and remanded the matter.[77]

Similarly, on April 21, 2020, the U.S. Court of Appeals for the District of Columbia found U.S. EPA's grant policy arbitrary and capricious in violation of the APA because the Agency failed to provide a reasoned explanation for the change from its prior policy.[78] The court noted that U.S. EPA and the Office of Government Ethics (OGE)

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https://www.epa.gov/sites/production/files/2017-10/documents/final_draft_fac_directive-10.31.2017.pdf at 1.

[73] *Id.* at 11.

[74] *Id.* at 13-14.

[75] Brief for State of Washington, et al. as Amici Curiae Supporting Appellants, at 11-12, *Physicians for Social Responsibility v. Wheeler*, No. 19-5104, 2020 WL 1921539 (D.C. Cir. Apr. 21, 2020).

[76] Nat. *Res. Def. Council, Inc. v. U.S. Envtl. Prot. Agency*, No. 19CV5174 (DLC), 2020 WL 615072, at *8 (S.D.N.Y. Feb. 10, 2020) (internal citations omitted).

[77] *Nat. Res. Def. Council, Inc. v. U.S. Envtl. Prot. Agency*, No. 19CV5174 (DLC), 2020 WL 2769491, at *1 (S.D.N.Y. Apr. 15, 2020).

[78] *Physicians for Social Responsibility* at 646.

had previously concluded that grantees could ethically serve on advisory committees,[79] finding that "they were capable of offering it independent advice; it now concludes they are not."[80]

U.S. EPA's "wholesale failure" to explain this reversal of course was "especially glaring given that the prior regime existed, in part, for the very purpose of facilitating the critical role played by EPA's scientific advisory committees."[81] "The administrative record produced by the EPA provides no basis for finding that membership in an EPA advisory committee by scientists who have received competitively awarded, peer-reviewed EPA grants has caused bias in the work of those committees."[82]

Even the Directive itself agrees that "it is in the public interest to select the most qualified, knowledgeable, and experienced candidates." Yet the Directive nowhere confronts the possibility that excluding grant recipients—that is, individuals who U.S. EPA has independently deemed qualified enough to receive competitive funding—from advisory committees might exclude those very candidates.[83]

Indeed, on June 24, 2020, U.S. EPA announced in a news release on its website its decision not to appeal the court's decision in *NRDC v. EPA* vacating and remanding the pertinent section of the Directive.[84] U.S. EPA explained that, in light of the related decision in *Physicians for Social Responsibility*, "any blanket prohibition on the participation of EPA grant recipients as special government employees in EPA advisory committees should be promulgated as a supplemental ethics regulation with the concurrence of the Office of Government Ethics."[85]

U.S. EPA's shift following its issuance of the Directive from advisory panels composed of highly respected academic experts to panels composed of industry affiliates is alarming and further demonstrates the arbitrary and capricious nature of the Proposal.

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[79] *Id.* at 646-47.

[80] *Id.* at 647-48.

[81] *Id.* at 647.

[82] *Nat. Res. Def. Council, Inc.* at *8

[83] *Physicians for Social Responsibility* at 647 (Internal citations omitted).

[84] *EPA Will Not Appeal Adverse SDNY Decision Regarding October 31, 2017 Federal Advisory Committee Directive* (June 24, 2020). Available at https://www.epa.gov/newsreleases/epa-will-not-appeal-adverse-sdny-decision-regarding-october-31-2017-federal-advisory.

[85] *Id.*

D. Secondary Standard

Additionally, impacts to public welfare demonstrate the need for a stronger secondary standard. Elevated ozone levels can hinder tree growth, reduce crop yields, and visibly injure foliage, impacting food production. Of particular concern, ozone can harm plants that are sacred to indigenous peoples, depriving them of important cultural resources.

Further, U.S. EPA has failed to address the direction set out in *Murray Energy v. U.S. EPA*, 936 F.3d 597 (D.C. Cir. 2019) for the form of the standard by proposing to retain 8-hour form instead of utilizing a seasonal, cumulative average such as W126. On remand, the court directed U.S. EPA to:

> [E]ither lower the standard to protect against unusually damaging cumulative seasonal exposures that will be obscured in its three-year average, or explain its conclusion that the unadjusted average is an appropriate benchmark notwithstanding CASAC's contrary advice. Alternatively, EPA could adopt the single-year W126 exposure index as the form and averaging time, which would presumably moot any problems with the way it translated that index to use as a benchmark.[86]

In retaining the standard as considered in *Murray Energy*, without adequate explanation for that decision as detailed in the Health Appendix, U.S. EPA has disregarded the court's clear direction, showing the arbitrary and capriciousness of U.S. EPA's handling of the secondary standard in this proposal.

III. Conclusion

CARB strongly opposes U.S. EPA's proposed retention of the current ozone standards. Retaining the current level of the ozone standards fails to protect public health and welfare with an adequate margin of safety. The Proposal's dismissal of robust scientific evidence of health impacts below the current standard render its decision arbitrary

[86] *Id.* at p. 618.

and capricious. U.S. EPA's numerous procedural flaws render its decision unacceptable under the applicable laws.

CARB recommends that U.S. EPA adopt stronger standards to protect children and vulnerable populations. The EPA should strengthen the annual primary standard to a level of 60 ppb. EPA should also strengthen the secondary standard by adopting a 1-year W126 metric.

APPENDIX B - ADDITIONAL COMMENTS ON SCIENTIFIC BASIS FOR LOWER OZONE STANDARDS AND REFERENCES

I. Significant Ozone Health Effect Associations Found At Levels At or Below the Current Ozone 8-hour NAAQS Standard:

The scientific health literature clearly supports significant health effects below the current 8-hour ozone standard.

- Since the last Ozone ISA was released in 2013, the majority of epidemiological studies show that both short- and long-term exposures to ozone with median or average levels below the current 8-hour NAAQS were associated with adverse health outcomes, including:
    - decreased lung function (Karakatsani et al. 2017; Ierodiakonou et al. 2016);
    - asthma (Wendt et al. 2014; Tétreault et al. 2016); and
    - preterm birth (Wallace et al. 2016; Lavigne et al. 2016).

  The clear pattern of associations between low ozone levels and adverse respiratory effects has been demonstrated in children.
- Since 2013, a few studies have shown relationships between long-term ozone exposure and increased premature death. Thus, the evidence for long-term ozone exposure's effect on overall mortality has increased since the last review. Two publications examining a Medicare cohort found an associate between both short- and long-term ozone exposures and premature mortality, even at ozone levels under 50 ppb (Di et al. 2017; Di, Dai, Wang et al. 2017).
- A study of Medicaid-enrolled children in Harris County, Texas, exposed to a mean 8-hour maximum of 37.9 ppb between 2005 and 2007, found that each 10 ppb increase in ozone was significantly associated with new-onset asthma during the warm season (May-October), with the strongest association seen when a 6-day cumulative average period was used as the exposure metric (Wendt et al. 2014).
- A study that examined singleton births between 2002 and 2008 with maternal exposure to median daily ozone exposures near 30 ppb found increased premature rupture of membranes, which is a major factor predisposing women to preterm delivery (Wallace et al. 2016).

II. Disadvantaged Communities and Other Susceptible/Vulnerable Groups Are At Greater Risk of Adverse Health Impacts from Ozone Exposure

Two articles that were not included in the 2020 Ozone ISA document demonstrate effects to vulnerable subpopulations:

- A study conducted in California's Central Valley from June to September of 2015 showed that odds ratios for asthma emergency department visits varied across different age groups and race/ethnicity, with the strongest effects evident for children (6-18 years), adults (19-40 years), and Blacks (Gharibi et al. 2019). However, this study did not show a positive association between asthma admissions for Whites, although it did for other underrepresented groups.
- A study in New York State demonstrated significant increases in children's asthma hospital admissions with increased chronic ozone exposure levels; these results were stronger for younger children and groups of low socioeconomic status (Lin et al. 2008).

Another study that was included in the ISA noted that seniors, women, Black persons, and those with atrial fibrillation were particularly vulnerable to dying from ambient ozone exposure, and that vulnerability differences were notable in cities with ambient ozone levels (Medina-Ramon & Schwartz 2008).

III. U.S. EPA's Own Staff Recommended Taking At-Risk Populations Into Account, But Were Ignored in Adminstrator's Decision

EPA staff, in their 2020 Integrated Science Assessment and Policy Assessment documents, noted the need to take into account effects on at-risk populations, which was not considered in arriving at the Administrator's proposed decision:

- Final Ozone ISA, pg. IS-57: "Overall, recent evidence expands upon evidence available in the 2013 Ozone ISA and is adequate to conclude that individuals with pre-existing asthma are at greater risk of ozone-related health effects based on the substantial and consistent evidence within epidemiologic studies and the coherence with toxicological studies."
- Final Ozone ISA, pg. IS-61: "For children, "Recent, large multicity epidemiologic studies conducted in the U.S. expand on evidence from the 2013 Ozone ISA and provide further support for an association between short-term ozone exposure and ED visits and hospital admissions for asthma. Hospital admission and ED visit studies that presented age-stratified results reported the strongest associations in children between the ages of 5 and 18 years."

> "Overall, recent evidence expands upon evidence available in the 2013 Ozone ISA and is adequate to conclude that children are at greater risk of ozone-related health effects based on the substantial and consistent evidence within epidemiologic studies and the coherence with animal toxicological studies."

The Policy Assessment and the Administrator recognize that statistically significant changes in study participants with exposures as low as 60 ppb and consistently at 70 ppb in young, healthy adults, and the ISA and Policy Assessment recognize that children and asthmatics are at greater risk. However, the Administrator's decision fails to take action to remedy the fact that these groups may suffer impacts at lower exposures, despite acknowledging higher breathing rates for children, and greater airway reactivity to ozone in asthmatics. To focus on preventing 70 ppb exposures seems to represent a failure in the Administrator's charge to apply "an adequate margin of safety" for these sensitive populations, as pointed out in the CASAC letter from the prior review.

IV. CARB/OEHHA's Letter to EPA On The Draft Ozone ISA (December 2, 2019) Pointed Out Shortcomings

A number of shortcomings in the draft Ozone ISA have already been pointed out by CARB and OEHHA:

- For some endpoints, there appeared to be an over-emphasis on findings from controlled human studies in healthy adults;
- There was insufficient consideration of effects on more vulnerable segments of the population;
- Evidence from experimental studies was under-weighted;
- Publications that could have added to the evidence for causality were missing.
- On these grounds, we question the change in determination from "likely to be a causal relationship" in the 2013 Ozone Integrated Science Assessment to "suggestive of, but not sufficient to infer, a causal relationship" in the current draft Integrated Science Assessment for short-term ozone and cardiovascular disease effects and total mortality.
- For some additional hazard traits, there is substantial evidence of effect that warrants reconsideration of the "suggestive" evidence categories assigned in the draft Ozone Integrated Science Assessment. These include long-term ozone exposures and total mortality, specific categories of pregnancy and birth outcomes, and central nervous system effects.
    - On these grounds, CARB and OEHHA questioned the change in determination from "likely to be a causal relationship" in the 2013 Ozone

Integrated Science Assessment to "suggestive of, but not sufficient to infer, a causal relationship" in the current draft Integrated Science Assessment for short-term ozone and cardiovascular disease effects and total mortality.

- For some additional hazard traits, there was substantial evidence of effect that warrants reconsideration of the "suggestive" evidence categories assigned in the draft Ozone Integrated Science Assessment. These included long-term ozone exposures and total mortality, specific categories of pregnancy and birth outcomes, and central nervous system effects.

V. CARB/OEHHA's Letter to EPA On The Draft Ozone Policy Assessment (December 16, 2019) Pointed Out Shortcomings

CARB and OEHHA identified numerous shortcomings with the draft Ozone Policy Assessment document:

- Lack of a thorough review of epidemiologic studies;
- Inconsistency with draft Ozone Integrated Science Assessment;
- Exclusion of important vulnerable populations and health endpoints;
- Use of an unjustified change in averaging time;
- Reliance on an inadequate number of study areas; and
- Underestimation of exposures

VI. The Administrator's Decision on the Secondary Ozone Standard is Inadequate

The CASAC reviewing the ozone PA and ISA lacked sufficient expertise to evaluate evidence related to the secondary standard.

- The secondary standard for ozone is based on negative effects on plant growth and a subsequent deterioration of ecosystem services. No member of the current CASAC has expertise in plant physiology, forestry, plant ecology, or related fields, meaning that this CASAC does not possess adequate expertise to review this portion of the ISA or PA. Dr. Kendall is a wildlife toxicologist, but there is little research on the effects of ozone on wildlife populations, making his expertise of little relevance to the secondary standard.

The previous CASAC recommended using a single-year exposure metric, but EPA opted for a three-year average, a decision the court found was not adequately justified in their Murray Energy ruling. In the 2020 PA, EPA conducts analyses to in an attempt to demonstrate the effect of a single severe W126 within a three-year average W126

value that meets the "protective" standard of 17 ppm-hrs would not have meaningful detrimental effects, but this analysis is flawed.

- In section 4A.3 "Analysis of Multiple-Year RBL" (Relative Biomass Loss), EPA attempts to justify the use of a three-year average W126 as a standard by completing an analysis intended to show that annual variation in W126 around the three-year mean has relatively little long-term cumulative effect on tree biomass loss, which here is intended to be a proxy for wider negative ecological outcomes. However, this analysis is flawed. While EPA notes the "Limitations, Assumptions, and Uncertainties" of the analysis, the justification for the methodology used in this analysis is incorrect. First, EPA assumes that the effects of ozone in one year have no effect on tree growth in the subsequent growing season. This is an obvious error because in developing forests such as the one used for EPA's analysis, smaller trees grow more slowly than larger trees because the greater size of the larger trees enables them to more easily acquire the light, nutrients, and water needed for growth (Binkley et al. 2013). EPA ignores the fact that this principle was the basis for an empirical model used to explain the long-term negative cumulative effects of ozone on tree growth in the very same experiment EPA used in their analysis, a study cited in both the ISA and PA (Talhelm et al. 2014). EPA attempts to justify their oversimplification by pointing to analysis in the 2020 ISA (Figure 8-17 in the ISA), which purports to show that applying the exposure-response functions annually for this experiment, as in section 4A.3, resulted predicted values that were "exceptionally close" to the experimental data over a six-year period. However, when CARB staff extracted the data from Figure 8-17, it was observed that the "exceptionally close" predicted ozone effects increasingly underestimate the observed ozone effects through time ($r^2 = 0.71$), such that the actual observed negative effect of ozone on tree growth is approximately 40% larger than predicted in year six. Because EPA ignores the cumulative effect of smaller trees growing more slowly, the effects of a severe W126 in one of the three years are simply negated by a weak W126 in one of the other three years, with the cumulative effect being very similar to the effects of a consistent W126 in each of the three years.
- The other oversimplification by EPA that allows a consistent three-year W126 to have the same effects as a variable three-year W126 is the choice of aspen (*Populus tremuloides*) for their analysis. While some trees among the 11 species with exposure-response functions in the PA show threshold responses, the response of aspen to the W126 values used in the analysis is relatively linear. If the EPA had instead selected sugar maple (*Acer saccharum*; Figure 4A-3), the consistent three-year W126 (17 ppm-hrs) would have had little effect in each of

the three years, whereas the variable three-year W126 (24, 17, 10 ppm-hrs) would have shown a substantive growth reduction in one year. EPA justifies the use of aspen by stating that multiple-year studies of tree growth "are not prevalent" in the scientific literature (p 4A-23), but this is boldly incorrect. Multi-year studies of tree growth are a foundation of forestry and such studies are prevalent enough that multi-study syntheses can be conducted for even very specialized research questions (e.g. Walker et al. 2019).

- In summary, if EPA had properly accounted for the cumulative effects of ozone on tree growth or had selected a species that exhibits a threshold response to ozone, their analysis would have led to the conclusion that single-year W126 exposures can have long-term detrimental consequences for plant growth and ecosystems.

The previous CASAC disagreed with EPA's assertion that an ozone standard in the same form as the primary standard (4th highest daily 8 hour max) would provide the same level of protection as a cumulative dose approach metric (the W126 metric), another decision that the court felt was not adequately justified in the their Murray Energy ruling.

- EPA conducts extensive analyses to show that achieving the proposed metric (i.e., the primary standard) would also achieve W126 values that are protective of ecosystems and Class I areas (Appendix 4-D). However, it is difficult to evaluate how this standard would protect ecosystems and Class I areas in California and other states in our region. EPA shows that most sites in the U.S. that meet the primary standard and the proposed metric have three-year average W126 values well below the threshold of 17 ppm-hrs that they have determined is protective of ecosystems. However, EPA also acknowledges that there is a different relationship between the average 4th highest daily 8 hour max and the W126 in the West (California and Nevada) and Southwest (Four Corners States) regions than elsewhere in the country. In particular, the Southwest region has some monitors and Class I sites that achieve the desired average 4th highest daily 8 hour max of 70 ppb, but have maximum annual W126 values greater than 17 ppm-hrs that would be indicative of ecosystem damage. This may also be true for California, but because so few sites here meet the desired average 4th highest daily 8 hour max value of 70 ppb, it is difficult to determine and the analysis presented by EPA provides little insight. Based on Figure 4D-4 and 4D-5, it appears that California sites brought into compliance with the proposed secondary standard would still suffer periods of severe W126, like similar sites in the Southwest region. EPA could have conducted additional analyses of ozone monitoring sites in the West

and Southwest region to better understand the relationship between the 4th highest daily 8 hour maximum and W126, similar to the national analysis presented in Figure 4D-8, but failed to do so.

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CALIFORNIA
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OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT

November 29, 2021

Mr. Michael S. Regan, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

RE: Docket ID No. EPA–HQ–ORD–2014–0859
EPA Docket Center (ORD Docket, Mail Code: 28221T)

Dear Administrator Regan,

The California Air Resources Board (CARB) and the Office of Environmental Health Hazard Assessment (OEHHA) are pleased to submit comments on the recently released *Supplement to the 2019 Integrated Science Assessment for Particulate Matter* External Review Draft, September 2021 (2021 ISA Supplement). We have previously submitted comments regarding *the 2019 Integrated Science Assessment* (2019 ISA) (December 10, 2018). We appreciate the opportunity to comment on the 2021 ISA Supplement as it is crucial to continue reviewing and evaluating the most up-to-date scientific evidence to protect public health from the effects of fine particulate matter. The 2021 ISA Supplement provides a foundation for updating federal ambient air quality standards.

We would like to commend the U.S. Environmental Protection Agency (EPA) staff on a high quality, well-presented 2021 ISA Supplement. The 2019 ISA document indicated that exposure to $PM_{2.5}$ shows an adverse relationship with many health endpoints, and that sensitive populations are at increased risk for many adverse health endpoints. The 2021 ISA Supplement supports and extends the evidence on confirmed causal relationships, providing the scientific groundwork for lowering the current ambient $PM_{2.5}$ annual and 24-hour standards.

Here, CARB and OEHHA staff are providing comments regarding areas in the 2021 ISA Supplement that should be strengthened. The goal of our comments is to ensure the most recent information regarding short-term and long-term health effects from $PM_{2.5}$ exposure are included in the 2021 ISA Supplement so that they will be considered in deriving a new National Ambient Air Quality Standard (NAAQS). The following summarizes our comments:

- *Fully evaluate all outcomes with "Causal" or "Likely" relationships:* Recent research has provided mounting evidence on health outcomes that are "Causal," "Likely to be Causal," or "Suggestive to be Causal," including important cancer, respiratory, and nervous system outcomes. The ISA Supplement needs to review and discuss concentration–response relationships for all "Causal" and "Likely" health outcomes so that the subsequent NAAQS can protect against all health outcomes of high concern.

- *Include additional epidemiological studies on $PM_{2.5}$ exposure and mortality*: We have listed additional studies in Attachment A finding associations between short-term and long-term $PM_{2.5}$ concentrations and mortality below the current standard of $PM_{2.5}$.

- *Give serious consideration to upgrading the classification for lung cancer to "Causal:"* The World Health Organization's International Agency for Research on Cancer found that particulate matter in outdoor air pollution is causal for lung cancer (IARC, 2013). The 2021 ISA Supplement has indicated that the evidence has strengthened since then.

- *Re-evaluate other causal relationship classifications:* Evaluate the hazard identification for health outcomes where the relationship with $PM_{2.5}$ is "Likely" or "Suggestive". New evidence has emerged, and some important respiratory or reproductive outcomes previously classified as "Likely" or "Suggestive" have gained more support and may warrant consolidation, which may lead to upgrades of the causal relationship classification.

- *Expand consideration of wildfire studies*: Wildfires are a continuing and growing public health concern. Mortality and morbidity from exposure to wildfire smoke are increasing in communities within California. Consequently, the 2021 ISA Supplement needs a sub-section on both short-term and long-term $PM_{2.5}$ exposure from wildfire smoke and health outcomes. This information would be valuable to understand the ever-increasing exposures to this complex $PM_{2.5}$ mixture and its connection to cardiovascular health effects. This would also have potential implications in reconsidering the short-term $PM_{2.5}$ NAAQS by providing further evidence supporting determinations for causal relationships.

- *Exposure disparities should be more fully discussed:* Exposure disparities due to decades of discriminatory housing and land-use practices should be quantified so they can be considered in the subsequent standard-setting process.

We further note that the next ISA should analyze the combined effects of $PM_{2.5}$ and a range of pandemics or large-scale infectious disease outbreaks that could modify health outcomes, including but not limited to COVID-19, particularly among vulnerable populations. There are also some notable inconsistencies in the COVID-19 sections in how the relevant studies were reported (see Attachment A).

Our more detailed comments are included below in Attachment A and follow the categories of the 2021 ISA Supplement that include: Cardiovascular Effects, Mortality Effects, Recent Experimental Studies at Near-Ambient Concentrations, PM and COVID-19, and Race and Ethnicity. We also include a list of additional references that should be cited, which provide additional evidence for the strengthening of the NAAQS.

If you need additional information, please contact Bonnie Holmes-Gen, Chief of the CARB Health and Exposure Assessment Branch at (916) 327-8225 or Bonnie.Holmes-Gen@arb.ca.gov, or Rupa Basu, Ph.D., M.P.H., Chief of the OEHHA Air and Climate Epidemiology Section at (510) 622-3156 or Rupa.Basu@oehha.ca.gov.

Sincerely,

Lauren Zeise
Lauren Zeise (Nov 29, 2021 15:31 PST)

Richard W. Corey
Executive Officer
California Air Resources Board

Lauren Zeise, Ph.D.
Director
California Office of Environmental Health Hazard Assessment

Enclosures

cc: Rajinder Sahota
Deputy Executive Officer
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David Edwards, Ph.D.
Chief Deputy Director
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Administrator Regan
November 29, 2021
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Attachment A

3.1 Cardiovascular Effects

- In the section discussing cardiovascular morbidity (p. 3-149), Juarez et al., 2020 seemed to be given more weight than Honda et al., 2017 (Fig 3-42). However, Honda et al., 2017 is a prospective cohort study that used clinical observations, a study design that is considered stronger than what was used in Juarez et al., 2020, a cross-sectional study using a self-reported health outcome. This difference in study strength should be stated and its implications discussed.

- Section 3.1.2.2.8 Collinearity (p. 3-39): Co-pollutant Confounding. Some new studies are discussed relating confounding of the other pollutants, but there is no text regarding collinearity, which was discussed in the 2019 PM ISA. Fig 3-7 shows the correlation between $PM_{2.5}$ and NO_2 as 0.65 (Shin et al. 2019), which suggests that there is collinearity at play that could influence a true association. Some discussion on collinearity in the new studies should be included in the 2021 ISA Supplement.

- Any null association for combined overall cardiovascular outcomes should be evaluated further, since some cardiovascular outcomes have positive associations with $PM_{2.5}$ while others have negative associations. Depending on the mechanism of PM-triggered cardiovascular effects, the incidence of some specific cardiovascular diseases, e.g., ischemic heart disease, ischemic stroke, and hypertension, may increase; however, the incidence of cardiovascular disease with other mechanisms may decrease, e.g., hemorrhage stroke and hypotension. Therefore, when combining risks from all cardiovascular diseases, the positive and negative associations with specific diseases may counterbalance, showing an artificially null relationship with the overall cardiovascular outcomes.

- The 2021 ISA Supplement should mention any health effects on subclinical biomarkers, either from exposure assessment studies or toxicological studies, for both short-term and long-term cardiovascular effects. Relevant studies investigating each of these endpoints and its relationship to $PM_{2.5}$ exposure should be reviewed. Effects on subclinical markers usually appear soon after exposures (within 24-hours), which can help elucidate the underlying mechanisms of the disease. Evidence regarding such subclinical effects should be considered in setting the standard.

- A sub-section on short-term exposure to wildfire smoke and health outcomes is necessary for documenting the connection to cardiovascular health effects. For example, the study by Yao et al. (2020) reported that short-term after exposure to wildfire smoke increased risk for myocardial infarction and ischemic heart disease.

These cardiovascular effects were observed after 1-hr and 24-hr exposures, respectively, for each 10 ug/m^3 increase in $PM_{2.5}$. This would have potential implications in reconsidering the short-term $PM_{2.5}$ NAAQS by providing further evidence supporting determinations for causal relationships.

3.2 Mortality

- Short-term $PM_{2.5}$ exposure and mortality (Sec. 3.2.1, p. 3-49): Recent studies continue to support evidence for associations between short-term $PM_{2.5}$ exposure and mortality for 24-hour average concentrations below the current standard. These studies also continue to support a linear, no-threshold relationship for concentrations as low as 5 $\mu g/m^3$. Taken together, this strengthens the evidence for lowering the current 24-hour standard to protect human health.

- Long-term $PM_{2.5}$ exposure and mortality (Sec. 3.2.2.2.7, p. 3-99): Recent studies provide more evidence for a supralinear Concentration-Response (C-R) relationship with $PM_{2.5}$ and long-term mortality, meaning there is more risk per unit of $PM_{2.5}$ air pollution at lower levels (that many people experience) when compared to a higher, more well-known linear, no-threshold approach. Both sets of evidence strengthen the need to lower the current annual standard.

    - A study from Bennett et al., 2019, emphasized that long-term exposure in excess of very low levels (3 $\mu g/m^3$) can lower life expectancy for both men and women.
    - In another study of heart failure patients, who were living in locations above and below the current annual $PM_{2.5}$ standard of 12 $\mu g/m^3$, researchers found an almost 1 year of life lost among those exposed to higher concentrations over the annual $PM_{2.5}$ standard. The authors reported that exposure to $PM_{2.5}$ over the current annual standard is a "significant mortality risk." (Ward-Caviness et al., 2020).

- Three new papers in the 2021 ISA Supplement on all-cause mortality (Lavigne et al. 2018; Liu et al., 2019, Shin et al., 2021a) were added. It is likely that the differences in statistical methodologies play a role in explaining/accounting for the differences of estimates reported by Liu et al. 2019 versus Lavigne et al. 2018/Shin et al. 2021a. The methodological differences would need to be discussed, and how these differences might bias the results toward or away from the null. 2021 ISA Supplement. (Sec. 3.2.1.2.1),

3.3.1 Recent Experimental Studies at Near-Ambient Concentrations

I. Some human exposure studies were mentioned in Section 3.3.1 (pp. 3-121 to 3-122), but there are no references referring to animal toxicological studies in this document. We have listed some references to review below. An example of a recent toxicity study conducted at near-ambient concentrations was reported by Edwards et al. (2020) on Traffic Related Air Pollution (TRAP). Rats were exposed for 14 months to unmodified real-world levels of TRAP in Northern California. The average concentration of $PM_{2.5}$ for the study period for the exposed group was 11±7.4 $\mu g/m^3$ compared to an average concentration of 2.4±1.7 $\mu g/m^3$ for the clean filtered air control group. Chronic exposure to TRAP resulted in pathological endpoints and suggested that female rats may be more susceptible to cardiac fibrosis than males.

3.3.2 $PM_{2.5}$ Exposure and COVID-19 Infection and Death

- There is substantial new research from several countries indicating that long-term public exposure to fine particle pollution, and possibly other air pollutants, could contribute to increases in incidence, severity, mortality and hospitalizations from COVID-19. However, there are also concerns with the studies, including their ecological design, potential for exposure misclassification, lack of information on confounding factors, and that the studies were conducted during an ongoing pandemic. Therefore, while this continues to be an area of active study, and one that we highly encourage, the research results currently available support EPA's conclusion that the overall link is inconclusive. As more replicable and more comprehensive research becomes available, EPA should revisit this topic to update its conclusion.

- There are potential errors and inconsistencies in Sec. 3.3.2.1 to 3.3.2.3, pp.3-123 to 3-126 ($PM_{2.5}$ Exposure and COVID-19 Infection and Death) in the 2021 ISA Supplement. The values reported in the 2021 ISA Supplement are considerably different than those reported in the original study. This is most relevant in the studies from Adhikari and Yin (2020), Wu et al. (2020b), Liang et al. (2020), Stieb et al. (2020), Mendy et al. (2021) and Chakrabarty et al. (2021). These inconsistencies could be due to conversion factors used by EPA during writing. If so, this difference needs to be revisited and any conversions need to be explained in the 2021 ISA Supplement. Addressing these inconsistencies will help in the clarification of the effect estimates.

- It may be helpful to look at past flu seasons, the H1N1 epidemic and other (if any) global pandemics to inform evidence regarding COVID-19 and disparities among population subgroups. It would make sense to track annually certain populations that face added hardship from the combined effects of particulate matter and infectious disease. The morbidity and mortality we are seeing due to the dual effects of $PM_{2.5}$ and

COVID-19 may be only a fraction of what we observe due to $PM_{2.5}$ when looked in conjunction with other large-scale infectious disease health outcomes. Other large-scale disaster events (wildfires, hurricanes, etc.) also disproportionately affect certain race/ethnicity groups and those in lower socioeconomic strata when outcomes are analyzed taking air pollution into consideration.

- Consider updating the statement in the Summary and Conclusion, "studies did not account for crucial factors that could influence results (for example, stay-at-home orders, social distancing, use of masks, and testing capacity)" (Sec. 5.4, p. 225). For example, Wu et al., 2020 and Chakrabarty et al., 2021 considered days since stay-at-home order, race/ethnicity, and other sociodemographic variables. Liang et al., 2020 adjusted for state-level COVID-19 test positive rate, days since first case and since the 100th case, population mobility, sociodemographic variables, socioeconomic status (SES), and race/ethnicity. Stieb et al., 2020 also looked at race/ethnicity and SES (according to percent below low income cutoff).

3.3.3 Socio-Economic Status and Race/Ethnicity

- This section mostly focused on mortality outcomes and considered only a few morbidity outcomes, which may underestimate risk for people of color because mortality outcomes are less common than morbidity outcomes. We recommend adding more morbidity outcomes to more fully describe the risk faced by people of color or adding language supporting more research looking into this area. We also recommend more investigation of exposure disparities experienced in communities of color.

- The epidemiological studies currently referenced may not fully account for covariates specific to people of color that could increase their risk. EPA should state this limitation that may underestimate effect estimates for vulnerable populations.

- The potential health benefits from lowering the annual and 24-hour standards are likely to be greater for communities of color and other populations that have been historically marginalized, which would be in line with U.S. Executive Order (EO) 14008 of 2021 and EO 12898 of 1994 to address environmental justice.

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CALIFORNIA
AIR RESOURCES BOARD

June 8, 2022

Dr. Elizabeth A. (Lianne) Sheppard
Chair and Members
Ozone Review Panel
Clean Air Scientific Advisory Committee
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington D.C. 20460

C/O Aaron Yeow, *yeow.aaron@epa.gov*

Dear Dr. Sheppard:

On behalf of the California Air Resources Board (CARB), I am writing to urge you to support substantial strengthening of the National Ambient Air Quality Standards (NAAQS) for ozone as reflected in the enclosed letter and appendices submitted on October 1, 2020 by CARB, the Office of Environmental Health Hazard Assessment (OEHHA) and the California Environmental Protection Agency (CalEPA) in response to the U.S. EPA's Proposed Rule for NAAQS. As stated in the enclosed letter, we urge EPA to heed the science and abide by the Clean Air Act's directive to protect public health with an adequate margin of safety by lowering the current 8-hour Ozone primary standard to 60 parts per billion (ppb). We also urge EPA to strengthen the secondary standard by requiring a more appropriate one-year metric to protect public welfare including agriculture and sensitive ecosystems.

Despite California's comprehensive and cutting-edge air pollution control policies and regulations implemented under the Federal Clean Air Act, many areas still experience too many days with harmful ozone levels and serious related health impacts. The attached letter and appendices provide our detailed assessment of the scientific, public health and legal basis for strengthening the national ozone air pollution standards to protect the health of communities, including sensitive and vulnerable subgroups and communities of color. We urge you to carefully review our enclosed letter and appendices and support our recommendations for strengthening the ozone standards.

Thank you for the opportunity to comment.

Sincerely,

/s/

Rajinder Sahota, Deputy Executive Officer

Enclosure

cc: See next page.

cc: Edie Chang, Deputy Executive Officer, CARB
Ellen Peter, Chief Counsel, CARB
Elizabeth Scheehle, Chief, Research Division, CARB