COMMENTS OF THE ATTORNEYS GENERAL OF NEW YORK, CALIFORNIA, CONNECTICUT, THE DISTRICT OF COLUMBIA, ILLINOIS, MARYLAND, MASSACHUSETTS, NEW JERSEY, OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, WASHINGTON, AND WISCONSIN, AND THE CORPORATION COUNSEL OF THE CITY OF NEW YORK

United States Environmental Protection Agency
Review of the Ozone National Ambient Air Quality Standards
85 Fed. Reg. 49,830 (Aug. 14, 2020)

Docket # EPA–HQ–OAR–2018–0279

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The Attorneys General of New York, California, Connecticut, the District of Columbia, Illinois, Maryland, Massachusetts, New Jersey, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin, and the Corporation Counsel of the City of New York (the States) submit these comments in opposition to the August 14, 2020 Notice of Proposed Rulemaking (Proposed Rule) by the Administrator of the United States Environmental Protection Agency (EPA) concerning review of the national ambient air quality standards (NAAQS) for ground-level O_3 (ozone).[1] The Administrator's proposal not to strengthen the primary or secondary ozone NAAQS is the result of a flawed and hasty process that gave short shrift to the evidence showing that more protective standards are necessary to protect human health and public welfare.[2]

I. INTRODUCTION

Ground-level ozone pollution, the principal component of "smog," harms human health and welfare in many ways. Scientific studies link ozone exposure to numerous medical conditions, including decreased pulmonary function; respiratory symptoms such as shortness of breath, pain on deep inhalation, coughing, and inflammation; and aggravation of existing conditions such as asthma and chronic obstructive pulmonary disease (COPD).[3] Numerous epidemiological studies and several reviews from health and environmental agencies have found that short-term exposure to ozone pollution is associated with increased mortality.[4] Some individuals

[1] 85 Fed. Reg. 49,830 (Aug. 14, 2020).
[2] 42 U.S.C. § 7409(b).
[3] 85 Fed. Reg. at 49,844-49,846.
[4] *See, e.g.*, A. Vicedo-Cabrera, et al., Short term association between ozone and mortality: global two stage time series study in 406 locations in 20 countries, *The BMJ* (Feb. 2020), *available at* https://www.bmj.com/content/368/bmj.m108; *see also*

are particularly at-risk from exposure to ozone pollution, including people with asthma, children, the elderly, and outdoor workers.[5] In addition to harming human health, ozone pollution harms public welfare by damaging vegetation and interfering with ecosystem function. Ozone's negative impacts to vegetation include crop yield loss, reduced tree growth and reproduction, and visible injury to foliage. These in turn lead to secondary impacts that further affect public welfare, such as inhibited ability for plants and trees to absorb carbon dioxide to mitigate harms from climate change.[6]

The States have significant interest in ensuring that ozone pollution is controlled. Our residents are directly impacted by these harms to health and welfare. State governments must allocate significant resources to the treatment of medical conditions associated with ozone exposure and to restoring state forests damaged by ozone pollution. Reduced agricultural productivity caused by ozone pollution places additional financial burdens on the States and our residents.

Acting pursuant to the Clean Air Act, previous Administrators have established several primary and secondary NAAQS for ozone. The primary ozone NAAQS are in place to protect human health, while the secondary ozone NAAQS, which are tailored to protect forests and crops from cumulative exposure, are in place to protect public welfare.[7]

The Administrator is statutorily required to review each NAAQS every five years to ensure the current standards adequately protect public health and welfare.[8] Prior to this review and the one conducted concurrently on the particulate matter NAAQS, EPA has regularly taken longer than five years, citing the need for additional time to review the latest scientific evidence and obtain advice from independent science advisors, including the Clean Air Scientific Advisory Committee (CASAC). Since the last review of the ozone NAAQS was completed in 2015, ample new data and scientific research has emerged on the negative impacts of ozone. Based on this information as well as evidence previously available, the Administrator must strengthen the ozone NAAQS to protect our States' and our residents' health, property, and other valuable assets from harm.

Notwithstanding the evidence in support of strengthening the ozone NAAQS, the Administrator proposes to retain the current 2015 standards without change. The Administrator's decision is based on reasoning that is both procedurally and substantively flawed.

EPA, Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants at 1-7 (Feb. 2013) (EPA-HQ-OAR-2018-0279-0057) [hereinafter 2013 ISA].

[5] 85 Fed. Reg. at 49,832.

[6] *Id*. at 49,883-49,892.

[7] *See, e.g.*, *id.* at 49,832.

[8] 42 U.S.C. § 7409(d)(1).

In particular, the Administrator undermined the NAAQS review process by circumventing key procedural steps necessary to make an informed decision. The NAAQS review process has historically included preparation of a variety of specialized reports, including an Integrated Science Assessment (ISA), a Risk and Exposure Assessment, and a Policy Assessment (PA), all of which were made available for public comment. As required by statute, the Administrator would seek scientific input from the CASAC. Further, with precedent going back decades, the Administrator would augment the expertise of the CASAC by empaneling a pollutant specific expert panel, known as the Ozone NAAQS Review Panel, to assist the CASAC in advising the Administrator.

In a significant departure from this process, then-Administrator Scott Pruitt issued a memorandum in May 2018 in which he eliminated and consolidated key aspects of the review.[9] In particular, he eliminated public review of second drafts of the ISA and PA and folded the Risk and Exposure Assessment into the PA, reducing its stand-alone significance. He also reduced opportunities for public comment by requiring comment on the draft PA before finalizing the ISA,[10] which contains the scientific conclusions on which the final PA[11] is based. Finally, he limited EPA's ability to consult with qualified experts, both by disbanding the Ozone NAAQS Review Panel and implementing a policy to exclude scientific experts from serving on CASAC if they received grant money from EPA. The agency failed to articulate any reason for changing its longstanding practice, and multiple courts have found the policy unlawful.[12] The current Administrator used this rushed and flawed process to conduct the current ozone NAAQS review and generate the Proposed Rule.

The Administrator's decision to leave the NAAQS unchanged is also substantively flawed. New literature on ozone health effects since the last review further demonstrates the need for a standard below 70 ppb. For example, newly available evidence indicates a likely causal relationship between short-term ozone exposure and metabolic effects, such as metabolic syndrome, diabetes, and metabolic disease mortality.[13] This proposed decision to retain the existing standards stands in

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[9] Memorandum from E. Scott Pruitt, Administrator to Assistant Administrators re. "Back to Basics Process for Reviewing National Ambient Air Quality Standards (May 9, 2018)," https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf.

[10] U.S. EPA. Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-20/012, (Apr. 2020) [hereinafter ISA], *available at* https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=348522.

[11] U.S. EPA. Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (May 2020) (EPA-HQ-OAR-2018-0279-0053) [hereinafter PA].

[12] *See, e.g., Nat. Res. Def. Council, Inc. v. U.S. Envtl. Prot. Agency*, 438 F. Supp. 3d 220 (S.D.N.Y. 2020).

[13] *See* PA, at 3-22.

stark contrast to decisions by previous Administrators to strengthen the standard when presented with similar evidence of harm at ambient concentrations below the then-existing standard. In addition, the Administrator's decision to leave the secondary standard unchanged fails to address the flaws that resulted in remand of the standard by the D.C. Circuit in 2018.

The Proposed Rule also fails to adequately consider the environmental justice impacts of the decision to leave the standards unchanged. The Administrator's finding that this action does not have disproportionately high and adverse human health or environmental impacts on minority, low-income, or indigenous populations[14] is unfounded. For example, research indicates that air quality is uneven across different demographic groups in the United States, with minorities bearing a higher health burden from ozone.[15] The States have an interest in protecting minority, low-income and indigenous communities from the disparate impacts of air pollution, but are unable to do so without reliable standards in place.

Based on these procedural and substantive deficiencies, the Administrator's proposal to retain the existing ozone NAAQS is arbitrary and capricious, does not protect public health with an adequate margin of safety, and does not appropriately protect public welfare.[16] Accordingly, the Administrator should reverse the procedural changes to the NAAQS review process made in the 2018 memorandum, reinstate the Ozone NAAQS Review Panel, and reopen the ozone NAAQS proceeding to perform a more thorough and transparent review process.

II. BACKGROUND

A. Ozone, Its Sources and Its Harms

Ozone, which is the most prevalent photochemical oxidant in the atmosphere, is a mixture of tropospheric O_3 and stratospheric O_3.[17] Tropospheric O_3 is formed when emissions of pollutants such as nitrogen oxides and volatile organic compounds (VOCs) interact with solar radiation.[18] These pollutants come from human-made sources, such as motor vehicles and power plants, and natural sources, such as vegetation and wildfires.[19] Stratospheric O_3, on the other hand, is created naturally

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[14] 85 Fed. Reg. at 49,914.

[15] *See, e.g.,* M. Bell and F. Dominici, Effect Modification by Community Characteristics on the Short-term Effects of Ozone Exposure and Mortality in 98 US Communities, *Am J. Epidemiol* (Apr. 2008); *see also* M. L. Miranda, et al., Making the Environmental Justice Grade: The Relative Burden of Air Pollution Exposure in the United States, *Int. J. Envt'l. Res. Public Health* (Apr. 2011).

[16] 85 Fed. Reg. at 49,832.

[17] 85 Fed. Reg. at 49,832.

[18] *Id.*

[19] *Id.*

in the stratosphere and forms a protective layer that shields us from the sun's harmful ultraviolet rays.[20] Ozone occurs both in the Earth's upper atmosphere (good ozone) and at ground-level (bad ozone).[21]

Ground-level ozone is a primary component of smog, which is harmful to humans when inhaled. At a minimum, there is evidence supporting a relationship between ozone and the following medical conditions:

- decreased pulmonary function;
- respiratory symptoms such as, shortness of breath, pain on deep inspiration, coughing, and inflammation; and
- aggravation of existing conditions such as asthma and COPD.[22]

Recent studies prove that individuals with asthma and children are at an increased risk of experiencing negative effects of ozone.[23] With respect to long-term ozone exposure, EPA has reported a strong positive association with new-onset asthma, respiratory symptoms in children with asthma, and respiratory mortality.[24]

The 2013 Integrated Science Assessment developed for EPA's prior review of the ozone NAAQS concluded that short-term ozone exposure likely causes mortality, adverse cardiovascular effects (including related mortality), and nervous system effects, and that long-term ozone exposure likely causes increased total mortality, as well as adverse cardiovascular effects, reproductive and developmental effects, and nervous system effects.[25]

Newly available evidence developed since the 2013 assessment indicates that ozone's health effects are even more detrimental than previously understood. Specifically, short-term ozone exposure likely causes adverse metabolic effects, including the following conditions:

- metabolic syndrome (a collection of risk factors including high blood pressure, elevated triglycerides and low high-density lipoprotein cholesterol);
- diabetes;
- metabolic disease mortality; and

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[20] *Id.*; *see also* EPA, Ground-Level Ozone Pollution, https://www.epa.gov/ground-level-ozone-pollution/ground-level-ozone-basics .
[21] *Id.*
[22] 85 Fed. Reg. at 49,844-49,846.
[23] *See, e.g.*, 85 Fed. Reg. at 49,832.
[24] ISA at ES-7.
[25] 85 Fed. Reg. at 49,839 n.21.

- indicators of metabolic syndrome that include alterations in glucose and insulin homeostasis, peripheral inflammation, liver function, neuroendocrine signaling, and serum lipids.[26]

Ground-level ozone is also harmful to vegetation, which has significant negative impacts on public welfare. By interfering with the ability of plants to produce and store food, ozone renders them more susceptible to disease, insect pests, and other stressors.[27]

Ozone has also been linked to reduced tree growth and reproduction, and foliar injury, which in turn leads to a decrease in productivity, altered forest and forest community composition, and altered ecosystem water cycling.[28] By stunting vegetative growth, ozone inhibits the ability of plants and trees to absorb and store carbon dioxide, exacerbating the impact of carbon dioxide from human activity on climate change.[29] Reduced tree growth can also interfere with a broader array of services benefiting the public, including harms to the aesthetic value of forests; reductions in the production of food, fiber, timber, other forest products; loss of habitat and recreational opportunities; reductions in capacity to regulate climate and water , to control erosion , and to remove air pollution; and interference with desired fire regimes. Additionally, ground-level ozone harms crops and other plants, reducing yields of timber, produce grown for consumption, and horticultural plants used for landscaping.[30]

B. Clean Air Act and NAAQS Review Process

The purpose of the Clean Air Act is to "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare."[31] A principal mechanism for achieving this purpose is the establishment of NAAQS for "criteria" pollutants. NAAQS set the maximum allowable concentration of pollutants in the atmosphere. Thus, pursuant to the Act, the Administrator must identify and list "criteria pollutants" that endanger public health or welfare.[32] Air quality criteria issued for criteria pollutants must "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or

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[26] PA, at 3-22.
[27] 85 Fed. Reg. at 49,884-86.
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] 42 U.S.C. § 7401(b)(1).
[32] *Id.* § 7408(a)(1).

welfare."[33] Then, using this criteria, the Administrator must establish a primary and secondary NAAQS for the pollutant.[34]

In setting NAAQS, the Clean Air Act requires the Administrator to consider only impacts to public health and welfare; EPA may not consider implementation costs in setting primary and secondary standards.[35] Instead, the Administrator must set the standards based solely on the scientific evidence of harm.[36]

C. Existing Ozone Standards

The NAAQS for each criteria pollutant consist of four basic components: an indicator, an averaging time, a form, and a level.[37] The indicator defines the parameters of the substance that will be measured (e.g. the size or composition of the pollutant).[38] In the case of ozone, the indicator is O_3.

The averaging time specifies the span of time for which the amount of a pollutant in the air will be averaged.[39] For both the primary and secondary ozone NAAQS, EPA has set that span of time at eight hours. The form describes how compliance with the level will be determined within the averaging time.[40] EPA has established the form for both ozone NAAQS at the fourth-highest daily maximum, averaged across three consecutive years. Finally, the level specifies the appropriate concentration of that indicator in the air.[41] For both the primary and secondary ozone NAAQS, the level is currently 70 ppb (0.070 ppm).

In 2008, EPA strengthened the eight-hour primary and secondary standards to 75 ppb (0.075 ppm).[42] A number of petitioners filed suit challenging these standards. The D.C. Circuit upheld EPA's primary standard, but remanded the secondary standard to the EPA for further consideration.[43]

In 2015, EPA set the current eight-hour primary and secondary standards at 70 ppb (0.070 ppm).[44] Despite evidence and expert recommendations that a seasonal, cumulative average is required to adequately protect public welfare from ozone's

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[33] *Id.* § 7408(a)(2).
[34] *Id.* § 7409; *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 516 (D.C. Cir. 2009).
[35] *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 486 (2001).
[36] 42 U.S.C. § 7409(b)(1).
[37] *Am. Farm Bureau Fed'n*, 559 F.3d at 516.
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] 73 Fed. Reg. 16,436 (Mar. 27, 2008).
[43] *See Mississippi v. EPA*, 744 F.3d 1334, 1361-62 (D.C. Cir. 2013).
[44] 80 Fed. Reg. 65,292 (Oct. 26, 2015).

adverse effects on trees and vegetation, EPA maintained a secondary standard with an identical averaging time (eight hours) and form (fourth-highest maximum averaged across three years) as the primary standard. The D.C. Circuit upheld the primary standard and remanded the secondary standard to EPA for further consideration.[45]

In the Proposed Rule, EPA would retain the same primary and secondary NAAQS that were established in 2015.

D. The Requirements for the Administrator's NAAQS Review, Including the Structure and Function of the CASAC

As noted above, after establishing the initial NAAQS, the Administrator is required to review the criteria and standards once every five years, and revise them as necessary to protect the public health and welfare. 42 U.S.C. § 7409(d)(1). To advise EPA on the standards, Congress required EPA to form the CASAC, an independent scientific review committee, to "recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate."[46] When EPA proposes the standards, it must "set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by [CASAC]."[47] If the proposed standards "differ in any important respect from any of [CASAC's] recommendations," EPA must explain the reasons for the difference.[48]

To satisfy its NAAQS review obligations under the Clean Air Act, EPA had developed a rigorous review process. Prior to the changes implemented by former Administrator Pruitt, the review process included the following stages: planning, science assessment, risk and exposure assessment, and policy assessment.[49] Each of these stages of review culminated in the preparation of a document that articulated the analysis and conclusions of EPA's scientists and other experts on these topics, referred to as the Integrated Review Plan, the ISA, the Risk and Exposure Assessment or "Risk Assessment" and the PA.[50] Each of these documents was

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[45] *See Murray Energy Corp. v. EPA*, 936 F.3d 597, 620, 627-28 (D.C. Cir. 2019).
[46] *Id.* § 7409(d)(2)(B).
[47] *Id.* § 7607(d)(3).
[48] *Id.*
[49] 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), *available at* https://www.epa.gov/sites/production/files/2020-09/documents/naaqsreviewprocessmemo52109.pdf [hereinafter Jackson Memo].
[50] *Id.*

prepared sequentially and as separate documents, and each was published for review and comment by the CASAC and the public before finalization.[51]

Importantly, this previously employed process was born out of a comprehensive "top to bottom review" of the NAAQS review process.[52] That evaluation and subsequent modification of the NAAQS review process included input not only from agency staff but also from current and former members of the CASAC, other stakeholder groups that had substantial experience with the NAAQS review process, and the public.[53] Significantly, the goal of these prior changes was to "improve the efficiency of the NAAQS review process while ensuring that the Agency's decisions are informed by the best available science and broad participation among experts in the scientific community."[54] As described in more detail below, the abandonment of these improvements to the NAAQS review process played a large role in EPA's flawed proposal here.

The Administrator's appointment of the CASAC is governed by the Federal Advisory Committee Act (FACA). 5 U.S.C. App. 2. In compliance with FACA's requirements, EPA has adopted formal procedures for selecting individuals to serve on its advisory committees.[55] The established process has three main steps: identifying potential candidates through a public nomination process, evaluating the nominees, and obtaining approvals and making final appointment decisions.[56] The evaluation process requires that EPA staff recommend the best-qualified candidates to EPA management for each open position on an advisory committee.[57] The criteria EPA staff are to consider include the candidate's relevant expertise, work in the subject area, and the point of view the candidate would bring to the committee.[58] The

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[51] *Id.*

[52] Memorandum from Marcus Peacock, Deputy Administrator, EPA to Dr. George Gray, Assistant Administrator, Office of Research and Development, EPA and Bill Wehrum, Acting Assistant Administrator, Office of Air and Radiation, Re: Process for Reviewing National Ambient Air Quality Standards (Dec. 7, 2006) [hereinafter Peacock Memo], *available at* https://www.epa.gov/sites/production/files/2020-09/documents/memo_process_for_reviewing_naaqs.pdf.

[53] EPA, Review of the Process for Setting National Ambient Air Quality Standards, 15-17 (Mar. 6, 2006), *available at* https://www.epa.gov/sites/production/files/2020-09/documents/naaqs_process_report_march2006.pdf.

[54] Peacock Memo, at 3.

[55] EPA, Federal Advisory Committee Handbook (Aug. 2017) [hereinafter FACA Handbook].

[56] GAO, EPA Advisory Committees: Improvements Needed for the Member Appointment Process, 10, Table 1 (July 2019) [hereinafter GAO Report on EPA Advisory Committees], *available at* https://www.gao.gov/assets/710/700171.pdf.

[57] FACA Handbook, at 5-4, 5-10, 5-15 through 16.

[58] *Id.* at 5-10.

goal of the selection process is to have the best people who represent key interests and balanced viewpoints.[59]

Ultimately, EPA's handbook guides the Administrator to appoint individuals to an advisory committee based on the short-list developed by the agency's staff.[60] This process helps ensure that the agency can show how the Administrator made appointment decisions to achieve the best qualified and most appropriate candidates for balanced membership.[61] Also, the uniform federal ethics rules govern EPA advisory committee members to protect advisory committees from conflicts of interest, and agencies may not supplement these rules except through concurrence and joint issuance with the Office of Government Ethics.[62]

III. EPA'S PROCESS TO REVIEW THE OZONE NAAQS WAS DEFICIENT

The Administrator injected several changes to the NAAQS review process, undermining the scientific credibility of his analysis and rendering his proposed decision to retain the current ozone NAAQS arbitrary and capricious. The changes include the decisions to: (1) eliminate several key elements of the review process and consolidate others; (2) require public comment on the draft PA before finalization of the ISA; (3) not convene the Ozone Review Panel; (4) prohibit scientific experts who receive EPA grant funding from serving on the CASAC; and (5) implement several measures that eliminated transparency from fundamental components of the review process.

Taken together, these changes have shut out scientific experts from providing EPA guidance on the adequacy of the ozone NAAQS, reduced the public's opportunity to meaningfully comment on the Administrator's proposal to retain the current ozone standards, and reduced the transparency of the process. Not only do these flaws in the process render the Administrator's proposal to retain the ozone NAAQS arbitrary and capricious for failure to consider all relevant factors, *Mississippi Comm'n on Envtl. Quality*, 790 F.3d 138, 150 (D.C. Cir. 2015), but also because EPA failed to provide any reasoned explanation—or any explanation at all—for the changes to the review process. *See American Wild Horse Preservation Campaign v. Perdue*, 873 F.3d 914, 924 (D.C. Cir. 2017) (agency must "offer a reasoned explanation" if it "decides to depart from decades-long past practice[]").

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[59] GAO Report on EPA Advisory Committees, at 12; *see also* 5 U.S.C. § 5(b)(2) (committee "membership" must be "fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee").

[60] GAO Report on EPA Advisory Committees, at 17.

[61] *Id.*

[62] *See* 57 Fed. Reg. 35,006, 35,006 (Aug. 7, 1992) (Office of Government Ethics regulation establishing "uniform standards of ethical conduct" for all executive-branch workers); 5 C.F.R. § 2635.105.

A. EPA Reduced Opportunities for Adequate Public Comment by Inappropriately Eliminating or Consolidating Key Documents Necessary to Sufficiently Review the Ozone NAAQS.

EPA initiated its review of the current ozone NAAQS more than two-and-a-half years after it finalized the current standards on October 26, 2015.[63] After allowing half of the five-year statutory review cycle to lapse, EPA is attempting to catch-up by short-circuiting the review process and eliminating several steps and opportunities for public comment. Most egregiously, EPA required the CASAC and the public to review the ISA and the PA simultaneously and did not provide an opportunity to review and comment on a second draft of either document.[64] EPA's other shortcuts include the fact that it initiated its review of the scientific literature before it even finalized its Integrated Review Plan, and it also eliminated the preparation of a Health Risk and Exposure Assessment (HREA) (also referred to as "Risk and Exposure Assessment" or "REA").[65] As explained below, these shortcuts render EPA's review of the current ozone NAAQS arbitrary and capricious and require EPA to reinitiate the review process to allow for meaningful CASAC and public involvement.

EPA's decision to issue the ISA and the PA documents for CASAC and public review and comment concurrently is illogical and arbitrary and capricious. Under EPA's normal process, the agency would prepare a PA following the finalization of the ISA and the REA.[66] This is a logical sequence because the PA should "integrate and interpret information from the ISA and the REA to frame policy options for consideration by the Administrator" and "this document is intended to help 'bridge the gap' between the Agency's scientific assessments, presented in the ISA and REA,

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[63] EPA, Review of the National Ambient Air Quality Standards for Ozone-Call for Scientific and Policy Relevant Information, 83 Fed. Reg. 29,785 (Jun. 26, 2018).

[64] EPA, Agenda Public Meeting on Particulate Matter and Ozone (Dec. 3-6, 2019) (Explaining that the purpose of meeting as to 1) peer review EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft – September 2019) and 2) to peer review EPA's PA 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/A0D0F9D4C6BC36D88525848C00467771/$File/CASAC+Dec+3-6+2019+Agenda-112719.pdf .

[65] EPA, Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards, at 1-8 (Aug. 2019), *available at* https://www.epa.gov/sites/production/files/2019-08/documents/o3-irp-aug27-2019_final.pdf ("[C]onincident with preparation of the IRP, the EPA has begun review of the literature for consideration in the ISA . . . The EPA is not planning to develop a Risk and Exposure Assessment (REA) Planning Document").

[66] Jackson Memo.

and the judgments required of the Administrator in determining whether is appropriate to retain or revise the standards."[67]

Nevertheless, EPA released the Draft ISA for public review and comment in September 2019, requiring public comments to be submitted by December 2, 2019 and released the Draft PA on November 1, 2019, requiring public comments to be submitted by December 16, 2019.[68] As a result, the public was required to review and comment on the Draft PA before EPA's analysis of the science regarding ozone pollution and health impacts was finalized. Compounding the problem, EPA required the CASAC to also review and comment on both documents concurrently.[69] The CASAC expressed serious concern with this approach in its comments, stating "[i]t is unusual for the CASAC to review a draft PA and draft [ISA]simultaneously, insofar as the ISA provides the scientific basis for the PA."[70] As CASAC's comments on the Draft PA recommended, EPA may have been able to address this problem by providing the CASAC and the public a chance to review a second draft of the PA after the ISA was finalized.[71] Not only did EPA deny CASAC the necessary opportunity to review the PA a second time, the agency did not even meaningfully respond to the CASAC's concern. Instead, Administrator Wheeler punted, saying "the Agency will develop a plan to incorporate . . . changes into future Ozone ISAs" to address the more significant or cross-cutting issues raised by the CASAC.[72] Promises to address fundamental shortcomings in a *future* review cycle is not a mark of reasoned decision making in the *present* rulemaking; nor do these promises rectify EPA's arbitrary and capricious review of the ozone NAAQS.

Further, EPA's decision to consolidate the Health Risk and Exposure Assessment into its PA further renders EPA's review of the Ozone NAAQS arbitrary

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[67] *Id*. at 2.

[68] *See* EPA, Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft), 84 Fed. Reg. 50,836 (Sept. 26, 2019) (EPA-HQ-ORD-2018-0274-0017); *see* EPA, Release of Draft Policy Assessment for the Ozone National Ambient Air Quality Standards, 84 Fed. Reg. 58,711 (Nov. 1, 2019) (EPA-HQ-OAR-2018-0279-0018); *see also* EPA, Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft) (EPA-HQ-OAR-2018-0279-0074) [hereinafter Draft ISA].

[69] EPA, Notification of a Public Meeting of the Chartered Clean Air Scientific Advisory Committee, 84 Fed. Reg. 58,713 (Nov. 1, 2019); EPA, Notification of a Public Meeting of the Chartered Air Scientific Advisory Committee, 85 Fed. Reg. 4656 (Jan. 27, 2020).

[70] CASAC, Consensus Responses to Charge Questions on the EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019), 1 (Feb. 19, 2020) (EPA-HQ-OAR-2018-0279-0050) [hereinafter CASAC Consensus Responses to PA].

[71] *Id.*

[72] PA, at 1-13.

and capricious. One of the key requirements of the NAAQS-setting process is that the science should guide the Administrator's policy determination in setting the NAAQS at a level that adequately protects public health with an adequate margin of safety. To maintain the distinction between scientific conclusions and policy judgments, EPA developed a NAAQS review process that separates issues of science and policy into their own documents. Specifically, in 2006, after an extensive review of the NAAQS review process, EPA reached the conclusion that it needed to establish a more rigorous process "that facilitate[s] the preparation and review of a policy assessment document that is based on, but separate from, the science and risk/exposure assessment."[73] In this present review of the ozone NAAQS, EPA reversed course and consolidated the Health Risk and Exposure Assessment with the PA.[74] EPA made this change without consulting the CASAC or the public. Members of the CASAC identified EPA's consolidation of the Health Risk and Exposure Assessment with the PA as a problem in comments on EPA's Integrated Review Plan.[75] EPA did not directly address this concern in the final Integrated Review Plan and has not otherwise explained how it has maintained the necessary distinction between scientific conclusions and policy judgments. EPA's failure to do so, especially in light of its prior practice to prepare the Health Risk and Exposure Assessment as a separate document, independent of the PA, is arbitrary and capricious.

B. By Failing to Convene the Ozone Review Panel, EPA Has Critically Undermined CASAC's Ability to Meaningfully Review the Ozone NAAQS Evidence and Proposal.

The Administrator's ozone NAAQS review process is also arbitrary and capricious because it relies only upon the seven-member CASAC to review and provide advice on EPA's technical and policy assessments, rather than the much larger panel of scientific experts the Administrator has historically relied on. EPA

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[73] Peacock Memo.

[74] EPA, Draft Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards – External Review Draft, at 1-8 (Oct. 2018) (EPA-HQ-OAR-2018-0279-0001).

[75] CASAC, Comments of Dr. James Boylan on the Integrated Review Plan, at A-2 (EPA-HQ-OAR-2018-0279-0048) ("In addition, the REA should not be included as part of the PA. Instead, the REA should be a stand-alone document that is reviewed by the CASAC and the public prior to the release of the first draft of the PA. This will allow scientific review of risk and exposure metrics prior to developing policy recommendations."); CASAC, Comments of Dr. Sabine Lange on the Integrated Review Plan, at A-20 (EPA-HQ-OAR-2018-0279-0048) ("EPA should further discuss how they intend to use previous documents in the review process to inform future documents – i.e. informing the PA/REA with the conclusions and feedback from the ISA. For example, it seems with this new schedule that the risk modeling would have to take place at the same time as the ISA, but the ISA conclusions on aspects like the shape of the C-R function can fundamentally impact risk modeling.").

has a long history of augmenting the CASAC to add critical perspectives and expertise, by forming a larger panel of subject-matter experts to assist the CASAC in reviewing the NAAQS. EPA has used such panels since at least 1982, and the last four Ozone Review Panels have had at minimum ten members in addition to the members of the CASAC.[76]

Traditionally, this larger panel has included experts from a broad range of scientific fields with expertise relevant to the specific pollutant at issue.[77] This larger panel has traditionally reviewed each of the documents EPA prepares as part of its review of the NAAQS and deliberated, interactively, with the members of the CASAC.[78] After the deliberative process, the pollutant-specific expert panel has historically provided its analysis to the CASAC, which in turn submits its views, as informed by the panel's views, to the Administrator.[79]

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[76] Letter from Christopher H. Frey, Ph.D, *et. al.*, Independent Particulate Matter Review Panel, to Louis Anthony (Tony) Cox, Jr., Ph.D, Chair, CASAC, EPA, re: CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018), Individual Comments of Christopher H. Frey, Ph.D, E-38, Table 1 (Dec. 10, 2018) (EPA-HQ-ORD-2014-0859-0048).

[77] *See e.g.*, Memorandum from Holly Stallworth, Ph.D, Designated Federal officer, Clean Air Scientific Advisory Committee, to Vanessa Vu, Ph.D, Director, Re: Formation of Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel (Jan. 29, 2009), *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/0/97662D128E20CA968525746B006CE9FD/$File/Ozone+Review+Panel+Determination+Memo+FINAL+Jan+29+2009.pdf(justifying the formation of the panel because of a need for "nationally-recognized experts" in atmospheric science, exposure modeling and assessment, dosimetry, toxicology, controlled human exposure, epidemiology, risk assessment and biostatistics, ecological effects, and ecological resource valuation); Comment Letter from the Former Members of the CASAC Ozone Review Panel on EPA's Draft Integrated Science Assessment for the Ozone NAAQS Review, at 4 (Dec. 2, 2019) (EPA-HQ-ORD-2018-0274-0040) [hereinafter Former Ozone Review Panel Comment Letter on Draft ISA].

[78] Former Ozone Review Panel Comment Letter on Draft ISA, at 4.

[79] *See e.g.*, CASAC, Consultation on EPA's Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (sic) (Dec. 3, 2009), https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/8A8B1D042C07DE5185257681007B7D85/$File/EPA-CASAC-10-004-unsigned.pdf; CASAC, Comments on EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (March 2011) (Aug. 10, 2011) https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/45A59F1BC8912FEE852578E80066021C/$File/EPA-CASAC-11-009-unsigned; CASAC, Review of the EPA's Policy Assessment for the Review of Ozone National Ambient Air Quality Standards (First External Review Draft – August 2012) (Nov.

Initially, EPA appeared to be following the established process for this cycle of the Ozone NAAQS review by seeking nominations of subject-matter experts for the Ozone Review Panel.[80] The notice explained that the selected panelists would be charged with "reviewing the science and policy assessments, and related documents, that form the basis of EPA's review of the Ozone NAAQS, and will provide advice through the chartered CASAC."[81] But without warning or explanation, EPA changed course in October of 2018.[82] In place of the subject-matter expert panel, the Agency charged the seven-member CASAC with the complex review task that it originally contemplated would be handled by a much larger group of experts on subjects relevant to the review of the ozone NAAQS.[83]

The CASAC, however, lacks the necessary expertise to meaningfully review and provide advice on the Administrator's review of the ozone NAAQS.[84] Indeed, the

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26, 2012) https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/E67094C7FBBECD8685257AC200727082/$File/EPA-CASAC-13-003+unsigned.pdf .

[80] Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel, 83 Fed. Reg. 35,635 (Jul. 27, 2018).

[81] *Id.*

[82] Frey, H.C., J.M. Samet, A.V. Diez Roux, G. Allen, E.L. Avol, J. Brain, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, S.R. Kleeberger, F.J. Miller, H.S. Neufeld, A.G. Russell, H.H. Suh, J.S. Ultman, P.B. Woodbury, and R. Wyzga, "CASAC Advice on the EPA's Integrated Review Plan for the Ozone National Ambient Air Quality Standards (External Review Draft),"submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–OAR–2018–0279, (Nov. 26, 2018) (EPA-HQ-OAR-2018-0279-0008)) [hereinafter Former Ozone Review Panel Comments on Integrated Review Plan].

[83] Memorandum from Aaron Yeow, Designated Federal Officer, Science Advisory Board, EPA to Thomas H. Brennan, Acting Director, Science Advisory Board, EPA, re: Determinations Associated with the Clean Air Scientific Advisory Committee (CASAC) Review of the Ozone National Ambient Air Quality Standards (NAAQS), 2 (Nov. 7, 2018) [hereinafter Yeow CASAC Charge Memo], *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/6B29A4DE74FF843985258485005F18CA/$File/Determination%20memo-Chartered%20CASAC%20Ozone-110718.pdf; *see also* EPA, "Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee," News Release (Oct. 10, 2018).

[84] CASAC, Comments on Integrated Review Plan (Dec. 10, 2018) (EPA-HQ-OAR-2018-0279-0048) (Multiple CASAC members' comments on the Integrated Review Plan recommended that EPA convene the Ozone Review Panel EPA originally contemplated, explaining that additional experts would enable the CASAC to perform the in-depth review necessary); CASAC, Comments on Integrated Science Assessment, at 1 (Feb. 19, 2020) (EPA-HQ-ORD-2018-0274-0045) [hereinafter

charge document for the newly formed CASAC states that the members only have expertise in toxicology, engineering, medicine, ecology, and atmospheric science.[85] Left out are the critical and highly specialized fields of atmospheric chemistry, causal inference, dosimetry, controlled clinical exposure, epidemiology, biostatistics, human exposure modeling, uncertainty analysis, and environmental economics—all critical to thorough assessment of the broad considerations required in reviewing NAAQS.[86] As the prior chair of the CASAC commented, "[t]he current seven-member CASAC does not have the breadth, depth, or diversity of expertise and experience needed for the ozone review, nor could any group of this size cover the needed scientific disciplines."[87] Mark Frampton, a current member of the CASAC, voiced similar concerns in comments on the ISA: "[t]he limited expertise available for this review has adversely impacted CASAC's ability to provide the best advice to the administrator."[88]

The Administrator's attempt to address the lack of expertise resulting from elimination of the Ozone Review Panel—a problem of the Administrator's own creation—falls well short of providing a meaningful remedy. Although the Administrator directed that a group of consultants would be available for "the seven-person chartered CASAC, through the chair, [to] draw from as needed to support its particulate matter and ozone reviews," that process was insufficient to fill the gaps in expertise that decades of experience have proven necessary.

First, even this larger pool of consultants lacked the necessary breadth of expertise. For example, the pool of subject-matter expert consultants "did not include any individuals participating in ozone health effects research, and did not include

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CASAC Comments on ISA] ("[T]he CASAC *strongly* recommends that the EPA consider restoring a traditional interactive discussion process in which the CASAC can interact directly with external expert panels.").

[85] Yeow CASAC Charge Memo.

[86] *Compare* Yeow CASAC Charge Memo, at 2 (listing the fields of expertise of the CASAC formed for this NAAQS review) *with* Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel, 83 Fed. Reg. 35,635 (Jul. 27, 2018) (listing the expertise EPA sought and believed was needed when it initially sought to form the Ozone Review Panel).

[87] Former Ozone Review Panel Comments on Draft ISA, at 3. *See also* CASAC, Comments of Mark Frampton on PA, at A-13 (EPA-HQ-OAR-2018-0279-0050) ("For this ozone review, additional expertise is needed in epidemiology, toxicology, and human clinical studies, and that expertise should include investigators in the field. While 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.").

[88] CASAC, Comments of Mark Frampton on ISA, at A-16 (EPA-HQ-OAR-2018-0279-0049).

expertise in human clinical studies, which are critically important in understanding ozone health effects."[89]

Second, EPA severely limited the ability of CASAC members to communicate freely with the expert consultant pool by requiring that communications be in writing and routed through the CASAC chair and the CASAC's designated federal official. This new hurdle for open communications stands in stark contrast to the transparent public meetings held for prior NAAQS subject-matter review panels, where the members could respond to each other's opinions and work toward consensus recommendations. The CASAC noted that the new structure was problematic and requested that EPA provide the CASAC with an additional opportunity to review the Draft PA after "restoring a traditional interactive discussion process in which the CASAC can interact directly with external expert panels."[90] As one CASAC member noted, "the traditional review process (with pollutant specific review panels) is significantly more informative to CASAC's recommendations since it allows verbal discussions and deliberations among experts . . . resulting in a more comprehensive examination of controversial topics."[91] Additionally, EPA's siloed approach cut off the ability of the consultants to independently raise issues and concerns in their areas of expertise. Lacking expertise in numerous critical areas, the CASAC members would have been unaware of problems with EPA's analysis, even if those errors would have been apparent to experts in other fields. As a result, the one-way structure of communication results in a catch-22: the CASAC would have had to affirmatively raise those issues with the members of the expert pool to obtain their views; yet the CASAC members would have lacked sufficient expertise to identify those issues before discussing with those outside consultants. Accordingly, EPA's decision to disband the Ozone Review Panel has rendered its review of the ozone NAAQS arbitrary and capricious.

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

EPA's proposal is also arbitrary and capricious because it relies on a process for gathering information and expertise that multiple courts have invalidated as arbitrary and capricious. Specifically, EPA's process was tainted by its adherence to a now-invalidated agency-wide directive that generally barred scientists receiving

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[89] *Id.*

[90] Letter from Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee, to Administrator Andrew R. Wheeler. Re: CASAC Review of the EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019). EPA-CASAC-20-003, at 2 (Feb. 19, 2020) (EPA-HQ-OAR-2018-0279-0050) [hereinafter CASAC Comments on PA].

[91] CASAC, Comments of James Boylan on PA, at A-2 (EPA-HQ-OAR-2018-0279-0050).

EPA grants from serving on EPA advisory committees, which prevented EPA here from receiving important and necessary scientific feedback on the Agency's review of the ozone NAAQS. *See Physicians for Social Responsibility v. Wheeler*, 956 F.3d 634 (D.C. Cir. 2020) (finding directive arbitrary and capricious); *NRDC v. EPA*, 438 F.Supp.3d 220 (S.D.N.Y. Feb. 10, 2020) (same).[92] That revised EPA policy runs counter to EPA's prior policy, which "allow[ed] . . . grantees to serve on advisory committees . . . in part to 'ensure that the scientific and technical bases of its decisions . . . are based upon the best current knowledge from science, engineering, and other domains of technical expertise; and . . . are credible.'" *Physicians for Social Responsibility*, 956 F.3d at 647 (quoting Science and Technology Policy Council, EPA, Peer Review Handbook, A-4 (4th ed. 2015)) (finding EPA's failure to even address its prior contrary conclusions "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").

As many of the States argued in opposing the directive, leading experts on the scientific topics relevant to EPA's rulemakings work at universities, hospitals, or non-profits, and rely heavily on government funding. Brief for State of Washington, et al. as Amici Curiae Supporting Appellants, at 11-12, *Physicians for Social Responsibility v. Wheeler*, Case No. 19-5104, Docket No. 1820684, 2019 WL 6916010 at *11 (D.C. Cir. filed Dec. 18, 2019). As a result, the directive "disproportionately" excluded "independent, public-interest researchers" from advisory-committee service, skewing the composition of advisory committees toward industry-funded scientists. *See id*. For example, Dr. Charles Driscoll is a Distinguished Professor of Environmental Engineering at Syracuse University who has conducted extensive research on air quality issues. He was previously a member of CASAC, but he was barred from serving on the CASAC during this review cycle. *Id.* at 11-12. Dr. Driscoll was forced to step down from CASAC due to his receipt of an EPA grant to study particulate matter, ozone, and water quality issues. *Id*. Thus, the agency did not receive scientific input and advice from the very experts—like Dr. Driscoll—who EPA has deemed through its grants to be the most qualified to research the specific scientific issues relevant to the ozone NAAQS review.

Worse still, EPA has not identified *any* benefit or evidence supporting the directive. *Id*. at 13-14. The problem is further exacerbated here, where there are

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[92] *See also Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020) (finding advisory committee directive judicially reviewable and remanding for determination whether directive "skewed composition of EPA committees in favor of regulated industries" in violation of Federal Advisory Committee Act and whether EPA "offered no rational reason for finding that any benefits of the policy justified the alteration of balance and influence on the committees" in violation of the Administrative Procedure Act).

serious concerns about the qualifications of the scientists EPA has appointed to the CASAC.[93]

EPA has all but conceded that its implementation of the directive was arbitrary and capricious.[94] Although the federal court's decision did not, of its own force, require EPA to reopen and reform advisory committees that had been selected under the invalidated directive, the directive's impacts on EPA's ability to rigorously review the scientific bases of the ozone NAAQS has rendered its review arbitrary and capricious. Accordingly, EPA's concession cannot turn back the clock and does not correct the infirmities of EPA's scientific review that resulted from EPA's implementation of this misguided directive.

D. EPA's Lack of Transparency in Implementing these Changes Undermines the Scientific Credibility of EPA's Ozone NAAQS Review.

Finally, most of the process changes discussed above were adopted or implemented without any public notice or comment or even any explanation why such changes would improve the ozone NAAQS review process. The process and resulting ozone NAAQS are thus arbitrary and capricious for that reason, too. Most importantly, the historical NAAQS review process was established after EPA completed a thorough review of the then-existing process. This review included input from then current and former members of the CASAC, other interested stakeholders, including States, as well as the public. After engaging in this lengthy review, EPA staff developed a recommendation on how it could improve the NAAQS review process. Only then, in 2006, did the EPA Administrator adopt the NAAQS review process that remained in place until Administrator Wheeler and former Administrator Pruitt drastically changed course. EPA's inexplicable changes to the NAAQS review process undermine the transparency and conclusions of its review of the ozone NAAQS.

The lack of transparency also infected the Administrator's process for selecting the scientific experts he appointed to the CASAC and expert pool of consultants. The Administrator reconstituted the *entire* CASAC after adopting its new advisory

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[93] Brennan Center for Justice, *Proposals for Reform, Vol. II*, 34 (2019) (explaining that the CASAC chairman has received funding from the American Petroleum Institute, and that six of the seven members of the committee are "state regulators with views outside the scientific mainstream"); Scott Waldman, *Science Adviser Allowed Oil Group to Edit Research*, Climatewire, (Dec. 10, 2018), https://www.eenews.net/climatewire/stories/1060109129.

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

committee directive governing the appointment of scientific experts. However, the Administrator has not disclosed the criteria he used to select the new appointees.[95] Furthermore, he appointed the CASAC members from the full roster of scientists nominated, not a short-list of the most qualified individuals developed by EPA staff as is required by EPA's FACA Handbook.[96] And EPA's pool of expert consultants is similarly tainted by a lack of transparency. Specifically, the entire selection process was condensed into a 37-day window, only allowing 14 days for EPA to receive nominations and no time for public comment on the nominations.[97] Further, the Administrator directly vetted the candidates, rather than relying on a list that had been vetted by the EPA Science Advisory Board Staff Office.[98] The shroud EPA has draped over its selection process for the CASAC and the pool of expert consultants formed to assist the CASAC makes it impossible to determine whether the purportedly independent scientific advisors are in fact independent and unbiased. Accordingly, the lack of transparency on the changes to the review process, the schedule of the review, and the process for selecting scientists to review and advise EPA in the ozone NAAQS review undermine the scientific integrity of the process and render that review arbitrary and capricious.

IV. THE EXISTING PRIMARY STANDARD DOES NOT PROTECT PUBLIC HEALTH WITH AN ADEQUATE MARGIN OF SAFETY

The Act directs the Administrator to set the primary standard at a level that "allowing an adequate margin of safety, [is] requisite to protect the public health." 42 U.S.C. § 7409(b)(1). The primary standard must protect not only average healthy persons, but also sensitive or at-risk populations and groups, *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998), and must be designed to provide these groups with an adequate margin of safety "from the pollutant's adverse effects – not just known adverse effects, but those of scientific uncertainty or that research has not yet uncovered," *id.* During its last review, EPA revised the primary ozone standard to 70 ppb, measured as the three-year average of the annual fourth-highest eight-hour

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[95] GAO Report on EPA Advisory Committees, at 17.

[96] *Id.*

[97] Request for Nominations of Consultants to Support the Clean Air Scientific Advisory Committee (CASAC) for the Particulate Matter and Ozone Reviews, 84 Fed. Reg. 38,625 (Aug. 7, 2019).

[98] *Compare id.* ("The Administrator shall select the expert consultants. In selecting these consultants, the Administrator will consider information provided by the candidates themselves, and additional background information") *with* Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel, 83 Fed. Reg. 35,635 (Jul. 27, 2018) (stating that EPA's selection of the subcommittee will be in accordance with procedures explained in the *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board*).

daily maximum ozone concentration at a given monitoring site.[99] In the Proposed Rule, the Administrator proposes to maintain this same level without revision.

That proposal is unlawful and arbitrary and capricious because it fails, given the existing and growing body of scientific evidence, to protect public health of all groups with an adequate margin of safety. EPA failed to apply the correct methodological approach, improperly discounted or flatly ignored a wealth of evidence demonstrating that a more stringent primary standard is necessary, and failed to provide the type of reasoned explanation for its decision-making that is required by law.

A. EPA's Proposed Approach to the Primary Standard

To assess the impacts on public health, EPA reviewed evidence available at the time of the last review of the NAAQS as well as evidence newly available or not previously considered. Consistent with its previous review, EPA's Proposed Rule recognizes that short-term exposure to ozone causes numerous types of adverse health effects, such as lung function decrements, respiratory symptoms, airway responsiveness, and respiratory inflammation. 85 Fed. Reg. at 49,862. The Proposed Rule also newly recognizes that short-term exposure to ozone causes metabolic effects. *Id.* The Administrator also proposes to conclude that long-term exposure to ozone causes respiratory effects. *Id.* The Administrator, however, proposes to alter the agency's conclusions with respect to cardiovascular effects, mortality, reproductive and developmental effects, and nervous system effects, finding in this review that there is a relationship suggestive of, but not sufficient to infer, causal relationships between ozone exposures (short- and long-term) and these health effects. *Id.*

EPA continues to recognize that the portion of the U.S. population with asthma—most recently estimated at 7.9%—is particularly vulnerable to elevated ozone levels and accordingly "one of the principal populations that the primary O_3 NAAQS is designed to protect." 85 Fed. Reg. at 49,849. The Proposed Rule acknowledges that "children and outdoor workers with asthma may be at increased risk of more severe outcomes, such as asthma exacerbation." *Id.*

Despite the evidence and causal links acknowledged in the Proposed Rule, the Administrator proposes to conclude that the 70 ppb standard provides sufficient protection because he asserts it protects populations from most days when ozone is above the current standard as well as lower concentrations, such as 60 ppb. However, the Proposed Rule acknowledges that the agency did not identify any alternative primary standards for consideration in this review. *See* 85 Fed. Reg. at 49,868 (discussing Policy Assessment); *cf.* 79 Fed. Reg. at 75,310 (EPA, in the 2015 review, requesting comment on whether to lower the standard to 60 ppb). The

[99] 80 Fed. Reg. at 65,294.

Administrator's proposed conclusion that the primary standard is requisite to protect public health with an adequate margin of safety and his failure to meaningfully evaluate any alternative standard lower than 70 ppb do not meet the requirements of the Act and if finalized, would be unlawful, arbitrary and capricious.

B. EPA Should Adopt a Primary Standard More Stringent Than 70 ppb.

The level of the primary standard must be driven by health effects to sensitive and at-risk populations. *Am. Lung Ass'n*, 134 F.3d at 389. Thus, "[i]f a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *Id.* at 389 (citation omitted).[100] In the prior review, the evidence demonstrating adverse health impacts at ozone concentrations at and below 70 ppb led the prior, properly constituted CASAC to conclude that "based on the scientific evidence, a level of [70 ppb] provides little margin of safety for the protection of public health, particularly for sensitive subpopulations."[101] Similarly, a portion of the current CASAC correctly advised EPA of this same recommendation. [102]

The States agree with the prior CASAC's recommendation as well as the current CASAC's members who have determined that the current primary standard does not provide adequate protection for sensitive subpopulations, such as adults and children with asthma, with an adequate margin of safety. Evidence in the ISA and PA demonstrates that the current standard is not protective and that a lower standard is needed to provide an adequate safety margin from the effects of short- and long-term ozone exposures.

1. Evidence Assessed in the Proposed Rule Demonstrates that Adverse Health Effects Will Occur if EPA Maintains the Current Standard.

The Proposed Rule acknowledges that the controlled human exposure studies of healthy adults demonstrate a statistically significant reduction in lung function and increase in respiratory symptoms at 72 ppb, and reduced lung function and increased pulmonary inflammation have been reported from ozone exposures as low as 60 ppb. 85 Fed. Reg. at 49,840; 49,856 (noting statistically significant respiratory

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[100] *See also* S. Rep. No. 91-1196, at 10 (1970) (stating that "the Secretary would be required to set a national minimum standard of air quality which will protect the health of persons regardless of where such persons reside" and discussing that such standard must protect "particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment.").

[101] Clean Air Scientific Advisory Committee, CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards. (June 26, 2014) (EPA-HQ-OAR-2018-0279-0069) [hereinafter CASAC 6/26/14 letter].

[102] CASAC Comments on PA, at 1.

effects at 60ppb of decrease in lung functions and increase in markers of airway inflammation); 49,870 (stating that controlled human exposure studies reported decrements in lung function (FEV_1) at 60 ppb and increases in airway inflammation at 60 ppb); *see also id.* at 49,851 tbl. 1 (EPA's summary chart of 6.6-hour human exposure study results showing a 6.1% decrement as the group mean response to 70ppb.). The Proposed Rule states that "[t]he previously available studies of this design 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." 85 Fed. Reg. at 49,851 & 49,870.

The magnitude of the observed lung function decrements at concentrations at or below the current standard for *healthy adults* are a group mean FEV_1 decrement of 6.1% at 70 ppb and 1.7 to 3.5% at 60 ppb. *See* PA, at 3-41. The PA found that there is limited evidence of the magnitude of effects experienced by populations with asthma because the controlled human exposure studies for ozone exposure are generally conducted with young, healthy adults. *Id.* at 3-32 (citing ISA App'x 3, § 3.1.5.4.1. But the PA concluded that the limited available evidence for adults with asthma indicates that members of this subpopulation experience similar magnitudes of lung function decrements, increased respiratory symptoms, airway responsiveness and increased lung inflammation in response to ozone exposure. *Id.* at 3-32 to -33. Nothing in the evidence suggests that adults or children with asthma experience *less* severe health effects than healthy adults. Rather, the Proposed Rule acknowledges that there is a potential for ozone exposure to elicit health outcomes more serious than those assessed in controlled human exposure studies of healthy adults. *See* 85 Fed. Reg. at 49,858. The Proposed Rule acknowledges that increased risk to sensitive populations, such as people with asthma, is further supported by epidemiologic evidence linking ozone exposure with increased risks of asthma and COPD, as well as respiratory infections and combinations of respiratory diseases. 85 Fed. Reg. at 49,845.

Even at the magnitudes of lung function decrements measured in healthy adults at 60 ppb and 70 ppb, sensitive populations can experience adverse health effects. The Proposed Rule and PA discuss the American Thoracic Society's guidance stating that "small lung function changes" in individuals with preexisting compromised function (*e.g.*, asthma) should be considered adverse, even without accompanying symptoms. 85 Fed. Reg. at 49,848; PA, at 3-31. Here, the studies of healthy adults at ozone concentrations at and below the current standard have detected both lung function decrements and increase in markers of airway inflammation. If the magnitude of these effects in people with asthma will be similar or more severe, as the evidence suggests, then even without additional respiratory symptoms, the anticipated lung function impairments can be considered adverse. The evidence in the ISA and PA demonstrates that the sizeable subpopulations of adults and children with asthma can be expected to experience adverse health effects from ozone concentrations at the current primary standard. 85 Fed. Reg. at 49,851 tbl. 1.

The potential for such adverse health effects increases with anticipated exposures at elevated levels, and evidence in the record shows the significant potential exposures to harmful levels of ozone with the current standard in place. The Proposed Rule acknowledges the link between children with asthma and ozone exposures, with repeated exposures worsening effects. *See* 85 Fed. Reg. at 49,845-46. Estimates for days of exposure by children with asthma from risk assessment modeling based on eight[103] urban study areas across the United States demonstrate repeated exposures for this sensitive population. *See* 85 Fed. Reg. at 49,860 tbl. 2. For air quality conditions just meeting the current 70 ppb standard, EPA estimates that, on average, 3.3 to 8.8% of children with asthma per year would be exposed to one or more days of ozone with concentrations above the 60 ppb level at which adverse health effects are expected. *Id.* For the same conditions, up to 3.2% of children with asthma, on average, would experience two or more days with ozone at or above 60 ppb, and up to 4.9% of children with asthma would experience two or more days of exposure in the highest ozone year. *Id.* These modeled percentages show that nearly 5% of children with asthma could face repeated ozone exposures expected to produce adverse health effects in a high ozone year if the current standard is maintained.

With the standard set at its current level, the Proposed Rule acknowledges that in 2016-2018 (the most recent data available at the time of proposal), 142 counties, home to approximately 112 million people, had ozone concentrations exceeding the 70 ppb standard. *See* 85 Fed. Reg. at 49,867 n. 99. This demonstrates widespread exposure across the country to ozone levels even above the levels expected to produce adverse health effects in people with asthma. Although the PA found that lowering the standard even to 65 ppb would result in "appreciably lower" estimated exposures of children with asthma to ozone levels above 70 ppb, *see* PA, at 3-78, the Administrator—despite acknowledging this finding, *see* 85 Fed. Reg. at 49,867—arbitrarily refused to consider a more stringent standard in this review. The Administrator has failed to explain why it is acceptable to subject thousands of children with asthma to decreased lung function and its attendant increased risks at least one or more times per year, rather than choosing or at least *considering* a more protective standard that would "appreciably" reduce that harm.

2. The Proposed Rule and ISA Fail to Properly Weigh Evidence Demonstrating the Need for a More Stringent Standard

The Proposed Rule and ISA should have applied a weight of evidence approach, under which and agency considers the body of scientific evidence spanning exposure assessment, dosimetry, health and welfare effects related to a criteria pollutant that,

[103] The risk assessment developed in the prior review of the ozone NAAQS used 15 study sites. HREA 2014, Section 5.2.1, p.5-9.

when taken together, provides evidence of causality.[104] Under this approach, determinations about the health effects of exposure at different concentrations are made by considering evidence from controlled human exposure, animal toxicology and epidemiological studies together. The keys to the weight of evidence approach include consistency (agreement among studies on the existence of an effect), coherence (evidence of an effect along multiple lines of evidence) and biological plausibility (evidence of a mechanism by which the exposure may cause a health outcome.)

Instead, the ISA and resulting Proposed Rule focus myopically on controlled human exposure studies, which have overwhelmingly studied one particular cohort in one particular manner: healthy young adult subjects who are exposed to various ozone concentrations over a seven- or eight-hour period while engaging in moderate physical exercise. Even as EPA recognizes that epidemiological studies further support a link between children with asthma and ozone exposures,[105] the Proposed Rule, in contrast to the prior review, largely deemphasizes epidemiological studies that show links between ozone concentrations and asthma-related health outcomes, such as emergency room visits and hospitalizations in various cities. However, epidemiological studies continue to provide significant and important evidence of the links between ozone exposure and adverse health effects, particularly to at-risk populations. As the PA stated, "numerous epidemiological studies document associations with O_3 with asthma-related health outcomes (e.g., emergency department visits and hospital admissions)." PA, at 3-32. The Proposed Rule fails to give sufficient weight to this critical evidence demonstrating a more stringent standard is required.

3. Additional Evidence Not Considered or Insufficiently Addressed in the ISA, PA and Proposed Rule Demonstrates Adverse Health Effects Will Occur if EPA Maintains the Current Standard.

In addition to literature considered in the ISA and discussed in the Proposed Rule, health effects literature that either became available after the arbitrarily truncated ISA cut-off date or that was available but not reviewed in the ISA and PA further demonstrates the need for a standard below 70 ppb. Even the current CASAC agreed that EPA's review of available science was insufficient, commenting that "[t]he Draft Ozone PA depends on a Draft [ISA] that, as noted in the CASAC Report on the Draft [ISA], does not provide a comprehensive, systematic assessment of the available science relevant to understanding the health impacts of changes in exposure to ozone, due largely to lack of a sufficiently comprehensive, systematic,

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[104] Richmond-Bryant, Jennifer. In defense of the weight-of-evidence approach to literature review in the Integrated Science Assessment (2020) (EPA-HQ-OAR-2018-0279-0356).

[105] Moreover, the Proposed Rule relies heavily on epidemiologic evidence that it asserts shows uncertainties in its prior causality finding of a link between ozone exposure and cardiovascular effects and mortality. 85 Fed. Reg. at 49,847.

accurate, and balanced review of relevant scientific literature; inadequate evidence and rationale for altered causal determinations; and a need for clearer discussion of causality and causal biological mechanisms and relevance to public health of the evidence presented."[106]

Numerous recent epidemiologic studies have examined respiratory, cardiovascular, and mortality endpoints that have considered co-pollutants and have reported significant results for ozone impacts on certain endpoints. These studies are discussed in more detail in the sections below. The ISA and PA either failed to include these studies entirely, or for those included, failed to incorporate their findings. As a result, the Administrator's proposed conclusions concerning the primary standard are not based on the best evidence available, but instead are contradicted by these more recent epidemiologic findings.

a. Respiratory disease

EPA's evaluation of evidence concerning respiratory effects was flawed and incomplete. As discussed above, the majority of evidence examining respiratory mortality that EPA relies on consists of studies evaluated in the 2013 Ozone ISA, which reported positive associations for respiratory mortality in all-year and summer/warm season analyses. The current ISA reviewed only one additional study in this area, noting "[o]f the recent multicity studies evaluated, only Vanos et al. (2014) examined respiratory mortality and reported positive associations in all-year and summer season analyses, which is consistent with the multicity studies previously evaluated." ISA, section 3.1.9, at 3-70. The ISA also gave insufficient weight to the study by Zu, et al., which found that a 10 ppb increase in average daily 8-hour maximum ozone concentrations increased the risk for asthma hospitalization by 4.7 % for school aged children and 1.8% among young adults. Furthermore, these effects were seen starting at 40 ppb.[107] Even the current CASAC criticized EPA's narrow focus on lung function decrements, commenting that "[o]zone has respiratory effects beyond its well-described effects on lung function. . . These effects beyond lung function decrements likely contribute to the risk of an asthma exacerbation. Yet they are not captured or considered in the Draft Ozone PA's risk analysis."[108]

Additional studies not considered in the ISA further support a link between adverse respiratory effects and ozone exposures with the current standard in place and should have also been included in EPA's consideration:

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[106]CASAC Comments on PA, at 1.

[107] Zu K, Liu X, Shi L, et al. Concentration-response of short-term ozone exposure and hospital admissions for asthma in Texas. Environment International. 2017;104:139-145. doi:10.1016/j.envint.2017.04.006.

[108] CASAC Consensus Responses to PA, at 8.

- Requia WJ, Adams MD, Arain A, Papatheodorou S, Koutrakis P, Mahmoud M. Global Association of Air Pollution and Cardiorespiratory Diseases: A Systematic Review, Meta-Analysis, and Investigation of Modifier Variables. Am J Public Health. October 2017:e1-e8. doi:10.2105/AJPH.2017.303839.

- Castner J, Guo L, Yin Y. Ambient air pollution and emergency department visits for asthma in Erie County, New York 2007-2012. Int Arch Occup Environ Health. 2018;91 {2):205-214. doi:10.1007 /s00420-017-1270-7

- Mohamed A, Goodin K, Pope R, Hubbard M, Levine M. Association Between Asthma Hospital Visits and Ozone Concentration in Maricopa County, Arizona (2007-2012). J Environ Health. 2016;78(9):8-13.

b. Cardiovascular Disease

The Administrator also unreasonably and arbitrarily changed the causality determinations with respect to cardiovascular effects and mortality, leading him to dismiss epidemiologic evidence in the Proposed Rule that would support a more stringent standard. The previous finding of an association with ozone and cardiovascular mortality in epidemiology studies should result in the retention of the causality determinations for cardiovascular effects and for mortality. And additional epidemiological studies have reported additional results for various cardiovascular endpoints (cardiovascular disease, myocardial infarction and stroke). EPA lowered the causality determination asserting "a paucity of epidemiologic evidence indicating more severe cardiovascular morbidity endpoints," lack of control of potential confounding by copollutants in epidemiological studies," and a lack of coherence between epidemiological studies and controlled human exposure studies. PA, at 3-29. But there are several epidemiologic studies, provided below, that include cardiovascular mortality, stroke, and cardiovascular disease as an endpoint and considered copollutants. Properly considered, the epidemiologic evidence of cardiovascular effects and mortality, even at the current primary standard, demonstrates the need for a more stringent level.

The following studies showing harmful effects were insufficiently considered in the ISA and PA:

- Ensor, KB; Raun, LH; Persse, D. (2013). A case-crossover analysis of out-of-hospital cardiac arrest and air pollution. Circulation 127: 1192-1199. http://dx.doi.org/10.1161/CIRCULATIONAHA.113.000027.

- Wang M, Sampson PD, Sheppard LE, Stein JH, Vedal S, Kaufman JD. Long-Term Exposure to Ambient Ozone and Progression of Subclinical Arterial Disease: The Multi-Ethnic Study of Atherosclerosis and Air Pollution. *Environ Health Perspect*. 2019;127(5):57001. doi:10.1289/EHP3325.

- Wing JJ, Adar SD, Sanchez BN, Morgenstern LB, Smith MA, Lisabeth LD, Short-term exposures to ambient air pollution and risk of recurrent ischemic stroke, Environmental Research, Jan. 2017, 152:304-7.

- Lim CC, Hayes RB, Ahn J, et al. Long-Term Exposure to Ozone and Cause-Specific Mortality Risk in the United States. Am J Respir Crit Care Med. 2019;200(8): 1022- 1031. doi:10.1164/rccm.201806-1161 OC.

- Raza A, Dahlquist M, Lind T, Ljungman PLS. Susceptibility to short-term ozone exposure and cardiovascular and respiratory mortality by previous hospitalizations. Environ Health. 2018;17(1):37. Published 2018 Apr 13. doi:10.1186/s12940-018-0384-z.

- Shin HH, Burr WS, Stieb D, Haque L, Kalayci H, Jovic B, Smith-Doiron M. Air Health Trend Indicator: Association between Short-Term Exposure to Ground Ozone and Circulatory Hospitalizations in Canada for 17 Years, 1996-2012. /ntJ Environ Res Public Health. 2018 Jul 24;15(8):1566. doi: 10.3390/ijerph 15081566. PMID: 30042335; PMCID: PMC6121235.

- Shao Q, Liu T, Korantzopoulos P, Zhang Z, Zhao J, Li G. Association between air pollution and development of atrial fibrillation: A meta-analysis of observational studies. *Heart Lung*. 2016;45(6):557-562. doi:10.1016/j.hrtlng.2016.08.001.

- Xu X, Sun Y, Ha S, Talbott EO, Lissaker CT, Association between ozone exposure and onset of stroke in Allegheny County, Pennsylvania, USA, 1994-2000, Neuroepidemiology, 2013, 41(1):2-6.

- Yang B-Y, Qian ZM, Li S, et al. Long-term exposure to ambient air pollution (including PM1) and metabolic syndrome: The 33 Communities Chinese Health Study (33CCHS). Environ Res. 2018;164:204-211. doi:10.1016/j.envres.2018.02.029.

c. Mortality

The Administrator also failed to account for the evidence demonstrating a link between ozone exposure and mortality, particularly evidence that long-term ozone exposure increases risk of death. EPA reports on the multiple new studies, including a massive study of Medicare participants that found premature deaths associated with levels of ozone at concentrations down to and below 60 ppb, even while controlling for $PM_{2.5}$. exposure (Di, et.al). EPA also finds strong documentation of the biological plausibility for the respiratory morbidity. EPA concludes that the "strong evidence" is "consistent within and across disciplines and provides coherence and biological plausibility for the positive respiratory mortality associations reported

across epidemiologic studies." EPA acknowledges that these findings are consistent with the findings in the 2013 ISA, but the Administrator proposes to maintain the current standard despite these findings.

EPA also failed to consider the following additional evidence that showed mortality effects occurring with exposure to ozone levels at and below the current 70 ppb standard:

- Zanobetti A, Schwartz J. Ozone and survival in four cohorts with potentially predisposing diseases. Am J Respir Crit Care Med. 2011;184(7):836-841. doi:10.1164/rccm.201102-0227OC.

- Bell, M. L., et al. (2014). "Who is more affected by ozone pollution? Am J Epidemiol 180(1): 15-28.

- Raza A, Dahlquist M, Lind T, Ljungman PLS. Susceptibility to short-term ozone exposure and cardiovascular and respiratory mortality by previous hospitalizations. Environ Health. 2018;17(1):37. Published 2018 Apr 13. doi:10.1186/s12940-018-0384-z.

- Lim CC, Hayes RB, Ahn J, et al. Long-Term Exposure to Ozone and Cause-Specific Mortality Risk in the United States. Am J Respir Crit Care Med. 2019;200(8): 1022- 1031. doi:10.1164/rccm.201806-1161 OC.

- Kazemiparkouhi F, Eum KD, Wang B, Manjourides J, Suh HH. Long-term ozone exposures and cause-specific mortality in a US Medicare cohort. J Expo Sci Environ Epidemiol. 2019 Apr 16. doi: 10.1038/s41370-019-0135-4. [Epub ahead of print] PubMed PMID: 30992518.

Overall, EPA departed from a weight-of-evidence approach addressing impacts on at-risk populations (cardiovascular mortality in humans and findings from studies in animal strains selected for cardiovascular studies, such as spontaneously hypertensive rats), to narrowly and unreasonably focus on the absence of effects in healthy adults. Across the exposure assessment, epidemiological and toxicological studies, EPA consistently over-emphasized determinations from controlled human studies in healthy adults, insufficiently considered effects on the more vulnerable segments of the population, and discounted the evidence from systemic inflammation and oxidative stress. As a result, the Administrator's evaluation of the health effects from ozone exposures under the current primary standard ignores critical evidence that undermines his proposed conclusion that the primary standard is sufficiently protective.

In sum, the evidence available in the ISA and PA and discussed in the Proposed Rule, as well as additional evidence ignored or not fully considered, clearly demonstrates that health effects linked to ozone exposure occur in the population at

ozone concentrations even below the current 70 ppb primary standard, with anticipated adverse effects on adults and children with asthma and a severity and range of effects increasing at ozone concentrations just meeting the standard. *See* PA, at 3-58. The Proposed Rule arbitrarily maintains a standard that the evidence demonstrates can be expected to produce adverse health effects in a sizeable portion of the United States population, failing to protect the public health and particularly that of sensitive or at-risk groups and populations.

C. The Current Primary Standard Does Not Provide an Adequate Margin of Safety.

EPA's proposal to maintain the current standard does not provide an adequate margin of safety, particularly for populations with asthma, a sensitive subpopulation that the NAAQS must protect. 42 U.S.C. § 7409; *see Am. Lung Ass'n*, 134 F.3d at 389; *Am. Farm Bureau Fed'n*, 559 F.3d at 526. As discussed, the standard must protect public health "from the pollutant's adverse effects – not just known adverse effects, but those of scientific uncertainty or that research has not yet uncovered." *Am. Lung Ass'n*, 134 F.3d at 389. EPA must "err on the side of caution" in setting the primary standard, *see Coalition for Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 621 (D.C. Cir. 2010) (citation omitted). Congress "specifically directed" EPA "to protect against … effects whose medical significance is a matter of disagreement." *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1154 (1980); *accord NRDC v. EPA*, 824 F.2d 1146, 1152 (D.C. Cir. 1987) (en banc) (discussing legislative history). Courts have rejected EPA determinations that there is no need to lower a NAAQS level to protect public health or to provide an adequate margin of safety when the agency has failed to properly consider relevant new evidence. *Am. Farm Bureau Fed'n,* 559 F.3d at 520-26; *see also Am. Lung Ass'n*, 134 F.3d at 392-93 (EPA must provide adequate explanation for failure to revise NAAQS in light of relevant evidence). In maintaining the primary standard without revision in the face of contrary evidence, the Administrator has provided no margin of safety, much less an adequate one.

EPA can choose reasonable means to provide an adequate margin of safety, but it must also fully and rationally explain how it did so, why it believes the proposed standard will provide an adequate margin of safety, and "why [the agency] chose one method rather than another" for ensuring the margin of safety. *Am. Farm Bureau Fed'n*, 559 F.3d at 526; *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 368 (D.C. Cir. 2002); *Lead Indus. Assn'n v. EPA*, 647 F.2d at 1161-1162. EPA has failed to provide such an explanation here. EPA asserts that "[i]n NAAQS reviews generally, evaluations of how particular primary standards address the requirement to provide an adequate margin of safety include consideration of such factors as the nature and severity of the health effects, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties present." 85 Fed. Reg. at 49,840/2. But nowhere does the Administrator explain: (1) how and where the margin of safety requirement was factored into the Administrator's decisionmaking on these matters in the Proposed Rule; (2) why the Administrator believes his proposed decisions on these

matters will ensure an adequate margin of safety for people with asthma; and (3) why the Administrator chose the described method for meeting the margin of safety requirement as opposed to another approach (*e.g.,* an approach whereby EPA adds the margin of safety after determining a level of likely adverse effects). The Proposed Rule offers only bare assertions that it provides for a margin a safety, assertions that fall far short of providing the legal requirements for reasoned decisionmaking. *See Am. Farm Bureau Fed'n*, 559 F.3d at 526 (remanding particulate matter standard to EPA because it failed to adequately explain how the selected level provided an adequate margin of safety to vulnerable populations shown to face increased risk at lower levels).

The Proposed Rule recognizes "that the available health effects evidence generally reflects a continuum that includes ambient air exposures for which scientists generally agree that health effects are likely to occur through lower levels at which the likelihood and magnitude of response become increasingly uncertain," 85 Fed. Reg. at 49,861. But the Administrator arbitrarily proposes to determine that any uncertainties in the health effects on populations with asthma at lower concentrations are a barrier to lowering the standard. This is backwards: uncertainty about effects in a sensitive subpopulation should compel the agency to make the standard more stringent, to ensure an adequate margin of safety for the vulnerable group that may well be susceptible to more severe health effects than measured in the studies of healthy adults. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 51-52 (1983) (agency must offer a rational connection between the facts found and the choice made).

Moreover, even if the Administrator has identified more limited evidence of health effects in adults or children with asthma and associated uncertainty, the Administrator has not explained how the current standard protects, with an adequate margin of safety, at-risk groups that experience harms at lower levels than healthy individuals and suffer more serious harms when exposed to the same concentrations. *See Am. Farm Bureau Fed'n*, 559 F.3d at 524.

D. EPA Failed to Reasonably Explain Its Departure from CASAC's Scientific Advice.

The Administrator also fails to adequately explain his departure from the CASAC's scientific advice concerning at-risk populations. When EPA proposes a NAAQS, it must "set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by [CASAC]." 42 U.S.C. § 7607(d)(3). If the proposal "differs in any important respect from any of [CASAC's] recommendations," EPA must explain the reasons for the difference. *Id.*

Congress intended that CASAC's recommendations "will not only aid the Administrator and the Congress, but also the courts in judicial review of any national ambient air quality standard or of the Administrator's failure or refusal to set or

revise such a standard with respect to any pollutant." H.R. Rep. No. 95-294, at 182 (1977). Thus, the basis for the Administrator's rejection of CASAC's advice should be carefully considered in deciding whether EPA has engaged in reasoned decision-making.

CASAC advised that transient decrements in lung function may not be the most important effect for populations with asthma; rather, an even more important concern is whether an elevated ozone concentration causes an asthma exacerbation.[109] The CASAC further advised that repeated episodes of airway inflammation may lead to irreversible reductions in lung function.[110] The evidence assessed in the ISA and PA demonstrated that up to 5% of children with asthma could face repeated ozone exposures in a high ozone year at levels expected to produce adverse respiratory effects. Yet the Administrator concluded without justification that these levels of exposure were acceptable. In so doing, the Administrator discounted this portion of CASAC's advice by concluding that even repeated exposures might be expected to fully resolve. 85 Fed. Reg. at 49,871 n. 104. EPA's approach arbitrarily departed from the CASAC's advice without reasoned explanation.

CASAC further concluded that the risk assessments underlying the PA are based exclusively on studies in healthy adults and make unverified assumptions about ozone health effects in children with asthma.[111] CASAC found that there is a "key knowledge gap" in whether low-concentration, 6-to-7-hour exposures affect people with asthma very differently from healthy adults, and this "raises legitimate questions about whether the current standard provides an adequate margin of safety for people with asthma."[112] Members of CASAC specifically advised that maintaining the current primary standard without revision would not provide an adequate margin of safety for children with asthma.[113]

Despite this scientific advice, the Administrator asserts he has discretion to depart from this prior and current CASAC advice because the Administrator in 2015 had policy discretion to pick any standard within the 60-to-70 ppb range identified by the 2014 CASAC letter. *See* 85 Fed. Reg. at 49,868 n.101. The Administrator also relies heavily on the current CASAC's support of his policy decision to maintain the current standard. However, the Administrator's explanation fails to reasonably address the 2014 CASAC's statement, again echoed by a portion of the current CASAC, that "based on the *scientific evidence*," selecting a 70 ppb primary standard fails to provide an adequate margin of safety. EPA provides no reasoned explanation

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[109] *See* CASAC Consensus Responses to PA, at 8.
[110] *Id.*
[111] CASAC Consensus Responses to PA, at 7.
[112] *Id.* at 8; *id.* at 9 (noting lack of data on persistence of respiratory effects in people with asthma following low-concentration, more prolonged exposures).
[113] *Id.* at 12.

as required by the Act why its policy determination has departed from this scientific advice from members of the CASAC.

E. EPA Arbitrarily Relies on Uncertainties to Maintain an Insufficient Standard.

In the face of evidence demonstrating respiratory effects from ozone exposures at and below the current standard, the Administrator attempts to rely on uncertainties regarding the magnitude of these effects in relatively understudied, but admittedly more at-risk or sensitive populations. Relying on uncertainty to maintain an insufficient standard is plainly inconsistent with the statutory intent of the adequate margin of safety and the well-developed case law discussing the need to protect the public from potential, if uncertain harm. Section 109(b)(1) of the Act requires a primary standard that protects public health from adverse effects even where there may be "scientific uncertainty." *Am. Lung Ass'n*, 134 F.3d at 389; *see Am. Trucking Ass'ns v. Whitman*, 283 F.3d at 369 (EPA must promulgate protective primary NAAQS even where the pollutant's risks "cannot be quantified or precisely identified as to nature or degree.") (citation omitted). Here, the Administrator acknowledges uncertainty in the health effects evidence, but resolves that uncertainty in the wrong direction: maintaining a *less* protective standard instead of adopting a fully protective one.

For example, the Administrator relies on uncertainty in lung function risk estimates with respect to children with asthma to establish the number of exposures per year at given concentrations considered to produce adverse health effects. 85 Fed. Reg. 49,872. The Proposed Rule notes that there are uncertainties in the effects evidence for population groups who have not been as well-studied as healthy adults, particularly individuals with asthma and children. *See* 85 Fed. Reg. at 49,863; 49,870. The Proposed Rule further notes uncertainty concerning the severity and prevalence of responses to short-term exposure at or below 60 ppb by these understudied populations and acknowledges that these exposures may pose an increased risk of more severe responses than those observed in healthy test subjects. Yet in determining the number of times per year that it is acceptable to expose children with asthma to ozone concentrations of 60 ppb and 70 ppb, the Administrator addresses these uncertainties by erring on the side of *more* exposures.

The Administrator relies on modeling estimating the percentage of children with asthma who will be exposed one or more times or multiple times (that is, two or more times annually) to certain concentrations of ozone depending on the level of the primary standard. Because the Administrator asserts there are uncertainties in the severity of lung function decrements experienced by children with asthma, he gives greater weight to estimated occurrences of two or more days per year rather than one or more days per year for people with asthma at or above 60 ppb. 85 Fed. Reg. at 49,872. As discussed, with the current primary standard in place, EPA's risk assessment estimates that an average of 3.2 to 8.2% of children with asthma will

experience one or more days per year at or above 60 ppb, with up to 10.6% experiencing such conditions in a single year. And the risk assessment further estimates that, on average, approximately 1 to 3% of children with asthma will experience two or more days at 60 ppb, with up to 4.3% in the highest year. As discussed, ozone exposure-related lung function decrements of 2% to 3% were reported in even healthy adults at 60 ppb, *see* 85 Fed. Reg. at 49,872, and the PA concluded that even small lung function changes in populations with asthma are considered adverse health effects. The CASAC also found that the risks of asthma exacerbation are potentially more adverse than transient lung function decrements. Despite this evidence, the Administrator relies on uncertainty about effects on at-risk populations to maintain the 70 ppb standard, with no reasoned explanation for why these exposures demonstrate that the current primary standard is requisite to protect human health; nor does the Administrator explain why uncertainty about potentially *more* severe respiratory effects for people with asthma supports a less stringent standard.

The Administrator points to consideration in the prior review of uncertainty concerning lung function decrements at exposures down to 60 ppb as well as evidence that "inflammation induced by a single exposure (or several exposures over the course of a summer) can resolve entirely" to dismiss the inflammatory response observed following the single exposure to 60 ppb in the study by Kim, et al. (2011). 85 Fed. Reg. at 49,871 n. 104. However, this study examined healthy adult test subjects and did not address the expected outcome of these exposures in children with asthma. Further, as the PA observed, there is a strong and consistent component of epidemiological studies linking ozone exposures and hospital and emergency room visits for asthma-related health events, particularly for children. PA, at 3-33. Determining that uncertainty in the severity of health effects to children with asthma justifies giving less weight to the ozone exposures that cause these adverse health effects would be arbitrary and capricious.

Moreover, the CASAC observed that a transient decrement in lung function is not necessarily the most important adverse health effect for a person with asthma, but rather advised that the Administrator should consider whether an air pollution event causes an asthmatic exacerbation.[114] Thus, uncertainty in the magnitude of additional severity of lung function decrements is not determinative of the risk posed by lower ozone concentrations. A single event of respiratory inflammation in a child with asthma can be an adverse health effect, particularly with increased risk of other, more severe health outcomes.

The Administrator's approach also unreasonably deems the 1 to 3% of children with asthma on average who will experience two or more days at 60 ppb, with up to 4.3% in the highest year, as acceptable risk. This subjects thousands of children, many of whom live in the States, to significant risk. The Administrator's dismissal of

[114] CASAC Consensus Responses to PA, at 8.

these repeated exposures on the basis of uncertainty is further arbitrary given his acknowledgment of the "potential for continued acute inflammatory responses to evolve into a chronic inflammatory state and to affect the structure and function of the lung." *See* 85 Fed. Reg. at 49,871 n.104.

Further, the Administrator's treatment of uncertainty conflicts with his acknowledgment elsewhere in the Proposed Rule and court decisions holding that the adequate margin of safety concept is meant to account for uncertainties. *See* 85 Fed. Reg. at 49,833; *see NRDC v. EPA*, 824 F.2d at 1152 (margin of safety is used as a safety factor meant to compensate for uncertainties). Properly understood, the need for an adequate margin of safety requires EPA to find that uncertainty in the severity of adverse health effects endured by children with asthma requires a more stringent primary standard that will result in *fewer* days of ozone exposure at concentrations demonstrated to produce adverse health effects even in healthy populations. Although the Proposed Rule recites the settled rule that uncertainty should play a role in setting the adequate margin of safety, 85 Fed. Reg. at 49,833, the Administrator's actual approach uses uncertainty to *avoid* establishing the requisite margin of safety. Instead, the Proposed Rule resolves uncertainty in favor of less safety and a less stringent standard. If finalized, this approach to uncertainty would be arbitrary and capricious.

F. The Proposed Rule Fails to Address the Environmental Justice Implications of the Current Primary Standard.

The Proposed Rule fails to address the environmental justice implications of ozone exposure, particularly the devastating link between ozone exposures and childhood asthma, ignoring a critical aspect of the problem facing communities across the country and shirking EPA's responsibilities under Executive Order 12,898.[115] The PA recites the grim, inequitable statistics on childhood asthma—making plain that children of color and children in families living with economic resources less than the federal poverty standard have greatly increased rates of asthma. PA, at 3-78; *see also* 85 Fed. Reg. at 49,867. The Proposed Rule notes that evidence available in the prior review was suggestive of increased risk from ozone exposures based on socioeconomic status, but arbitrarily failed to consider this factor in reaching conclusions about the primary standard. *See* 85 Fed. Reg. 49,849/3.

Moreover, a 2019 study of ozone-related asthma emergency department visits in California's Central Valley, which was not assessed in the ISA, found the strongest effects for children ages 6-18 years, adults ages 19-40 years, and Black persons

[115] *See* Executive Order No. 12,898, 59 Fed. Reg. 7629 (Feb. 16, 1994).

respectively, with ozone significantly related to emergency department visits.[116] Yet the Proposed Rule failed to address this evidence.

Further, as discussed, the Administrator concurred with the PA's conclusion that making the primary standard even 5 ppb lower to 65 ppb would result in "appreciably lower" estimates of children with asthma exposed to levels at or above even the current 70 ppb standard. 85 Fed. Reg. 49,867; PA, at 3-78. And additional evidence supports this conclusion. For example, using EPA's own BenMap tool, the Ozone Transport Commission evaluated the reduced mortality that would have occurred in 2017 through 2019 had the Ozone Transport Region experienced a 65 ppb ozone concentration and found that this would have resulted in fewer deaths due to short-term ozone exposure.[117] In many of the urban areas in the region, these additional deaths are more likely to have occurred in Black communities due to the higher rates of asthma and cardiovascular disease these communities experience. Data from the Centers for Disease Control and Prevention (CDC) show that, nationally, Black and Native American people have statistically significant higher asthma rates than their counterparts in other races.[118] As an example, in the District of Columbia, children who live in predominately Black communities have asthma-related Emergency Department visits 20 to 25 times higher than their counterparts in majority White communities.[119] Additionally, when examining state level CDC data, Black persons 35 and older experienced up to three times as many deaths per capita from cardiovascular disease from 2016-2018 as their White counterparts.[120]

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[116] Hamed Gharibi, Marcela R. Entwistle, Sandie Ha, Mariaelena Gonzalez, Paul Brown, Donald Schweizer & Ricardo Cisneros (2019) Ozone pollution and asthma emergency department visits in the Central Valley, California, USA, during June to September of 2015: a time-stratified case-crossover analysis, Journal of Asthma, 56:10, 1037-1048, DOI: 10.1080/02770903.2018.1523930].

[117] Ozone Transport Commission. 2020. Analysis of the Potential Health Impacts of Reducing Ozone Levels in the OTR Using BenMAP - 2020 Edition, *available at* https://otcair.org/upload/Documents/Reports/OTC%20BenMAP%20Rollback%20Analysis-Data%20to%202019_20200916%20final.pdf.

[118] Center for Disease Control. Most Recent National Asthma Data. https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm Accessed August 26, 2020.

[119] Children's National Medical Hospital. 2017. "Asthma Surveillance in DC Emergency Departments and Hospitals." https://childrensnational.org/-/media/cnhs-site/files/departments/impactdc/impact-dc-surveillance.pdf?la=en&hash=4235C55A9C1DE9DE9725D8D5D99D30831FCA18CF.

[120] Centers for Disease Control. Interactive Atlas of Heart Disease and Stroke. https://nccd.cdc.gov/DHDSPAtlas/Default.aspx?state=DC. Accessed September 28, 2020.

Given the evidence demonstrating that high rates of asthma affect certain communities more severely, 85 Fed. Reg. 49,867, the Administrator's failure to consider how these "appreciably lower" numbers of exposures would benefit environmental justice communities ignores an important aspect of the problem posed by ozone exposure. *See State Farm*, 463 U.S. at 43.

V. THE EXISTING SECONDARY STANDARD IS NOT SUFFICIENTLY PROTECTIVE OF PUBLIC WELFARE

The Clean Air Act requires EPA to set the secondary standard at "a level of air quality the attainment and maintenance of which in the judgment of the Administrator . . . is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." 42 U.S.C. § 7409(b)(2). Effects on welfare include, but are not limited to, "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being." *Id.*, § 7602(h).

While EPA has designed the primary standard to protect human health against exposure to days of high concentrations of ozone (peaks), EPA has found that assessing the impacts of ozone exposure on plants and trees requires consideration of cumulative effects, including seasonal time period, exposure duration, and diurnal dynamics (Musselman et al., 2006). The agency uses the "W126 index" to summarize hourly ozone data as a measure of ozone exposure to vegetation that reflects these effects (Lefohn et al., 1989). The W126 index, named after portions of the equation used to calculate it, is a weighted index designed to reflect the cumulative exposures that can damage plants and trees during the consecutive three months of the growing season when daytime ozone concentrations are the highest and plant growth is most affected.

Despite recognizing that ozone impacts people and plants differently, and that impacts on trees and vegetation are better assessed by considering the cumulative impact of exposure during the ozone season (rather than just peak exposure), EPA has declined to adopt a seasonal, cumulative standard to protect public welfare. Instead, it has used the W126 index to develop a benchmark level, and then sought to explain how adopting a secondary standard identical to the primary standard, i.e., in the form of a 3-year average of the annual 4th-highest 8-hour daily maximum ozone concentrations, protects public welfare equivalently to the W126 benchmark. The last two ozone secondary standards EPA set using this approach were found to be legally flawed and were remanded to the agency. *See Mississippi v. EPA*, 744 F.3d 1334 (D.C. Cir. 2013) (remanding secondary standards issued in 2008); *Murray Energy v. EPA*, 936 F.3d 597 (D.C. Cir. 2019) (remanding secondary standards issued in 2015).

A. EPA's Proposed Secondary Standard

EPA proposes to retain the same secondary standard adopted in 2015 (and remanded in *Murray Energy*), an 8-hour standard of 70 parts per billion (ppb), based on the fourth-highest daily maximum, averaged over 3 consecutive years. 85 Fed. Reg. at 49,831-32. EPA identified the following welfare harms that are caused or likely caused by exposure to elevated concentrations of ozone pollution:

- visible foliar (leaf) injury,
- reduced vegetation growth and reduced plant reproduction,
- reduced yield and quality of agricultural crops,
- reduced productivity in terrestrial ecosystems,
- alteration of terrestrial community composition,
- alteration of belowground biogeochemical cycles,
- alteration of ecosystem water cycling,
- reduced carbon sequestration in terrestrial ecosystems,
- increased tree mortality,
- alteration of plant-insect signaling, and
- altered insect herbivore growth and reproduction.

85 Fed. Reg. at 49,880. EPA recognized that the degree to which effects on vegetation in specially protected areas—like national parks and wildlife refuges—may be judged to be adverse involves considerations from the species level to the ecosystem level and that the "[u]ses or services provided by areas that have been afforded special protection can flow in part or entirely from the vegetation that grows there." *Id.* at 49,884. With respect to another aspect of welfare—climate—EPA acknowledged the important role of ozone in contributing to climate change, stating that:

> [T]ropospheric O_3 has been ranked third in importance for global radiative forcing, after carbon dioxide and methane, with the radiative forcing of O_3 since pre-industrial times estimated to be about 25 to 40% of the total warming effects of anthropogenic carbon dioxide and about 75% of the effects of anthropogenic methane.

Id. at 49,883.

Here, as in the last two reviews of the secondary standards, EPA identified impacts on tree growth (including productivity and carbon storage), visible foliar injury, and crop yield loss as the most relevant welfare impacts for purposes of setting the secondary standard. 85 Fed. Reg. at 49,880. EPA contends that the current standard is adequate to protect against these adverse effects, and that there is too much uncertainty related to the radiative forcing of ozone to set a more protective standard based on impacts to climate. *Id.* at 49,908. Unlike in previous ozone NAAQS

reviews, in which EPA proposed alternative standards that were supported by the scientific evidence, the agency only proposed here to retain the current standard.

EPA argues that it has addressed the flaws with the secondary standard identified in *Murray Energy*. In that case, the D.C. Circuit found two legal flaws: (1) EPA did not adequately explain its decision to use a three-year average of the W126 index as the benchmark, and (2) EPA arbitrarily failed to identify a level of air quality requisite to protect against adverse effects from visible leaf injury. The Court considered, but did not rule on, a related issue: whether an 8-hour standard rather than a seasonal, cumulative standard using the W126 index can adequately protect against adverse welfare effects EPA identified.

Regarding use of a three-year average of the W126 index as a benchmark—rather than a single year to guard against peak exposures—EPA cites "CASAC advice reaffirming the EPA's focus on a 3-year average W126, concluding such a focus to be reasonable and scientifically sound." *Id.* at 49,910. EPA further argues that based on additional analyses of the year-to-year variation observed in areas meeting the current standard, differences in tree growth would reasonably be expected to be small over their lifetimes. *Id.* at 49,904-05.

Regarding visible leaf injury, EPA proposes to find that an adverse effect is present using "biosite scores" used by the U.S. Forest Service to categorize injury in natural vegetated areas by severity levels. *Id.* at 49,909. EPA further asserts that, using that metric, currently available information shows that exposure conditions associated with air quality meeting the current secondary standard do not result in significant foliar injury. *Id.* at 49,906.

Finally, with respect to the issue of whether EPA may lawfully adopt the form of an 8-hour standard rather than a cumulative standard to protect against the welfare harms resulting from ozone exposure, EPA contends that because the current evidence indicates a role for peak concentrations in the occurrence of visible foliar injury, "an alternative standard in terms of a W126 index would be less likely to provide sufficient protection against such occurrences" compared to an 8-hour standard. *Id.* at 49,913.

B. The Current Secondary Standard Does Not Adequately Protect Public Welfare.

EPA's proposal to retain the current secondary standard is flawed in multiple respects. As an initial matter, and similar as with respect to the primary standard, the proposed secondary standard is the byproduct of a defective process. *See* Point III, *supra*. Regarding the secondary standard in particular, EPA noted that there were more than 500 new studies on welfare effects included in EPA's scientific assessment for this review. CASAC, however, lacked the expertise to be able to provide advice to EPA on these studies and more generally on the impacts of ozone exposure to trees and plants. CASAC had only one member, a wildlife toxicologist,

with any relevant background. Combined with Administrator Wheeler's refusal to convene a panel with direct experience in evaluating harms from ozone exposure, the secondary standard was not subject to the usual robust review from independent scientists provided in previous NAAQS reviews. As discussed above, EPA must fix these problems with the process and provide an opportunity for a reconstituted CASAC and new ozone-specific panel to evaluate its science, risk, exposure, and policy assessments.

Substantively, EPA did not adequately address the flaws with the secondary standard identified by the D.C. Circuit in *Murray Energy*.

First, with respect to its failure to explain how a benchmark based on a 3-year average of W126 index (as opposed to a single-year) will adequately protect against stunted growth in trees, EPA contends that its additional analysis shows that a single-year benchmark is unnecessary. As in the 2015 NAAQS review, EPA takes the position that a 3-year average of W126 index at a level of 17 parts per million-hours (ppm-hrs) adequately protects against relative biomass loss in tree seedings of 6%, an amount that CASAC found in 2014 to be "unacceptably high." 85 Fed. Reg. at 49,878. Based on the assumption that a 6% biomass loss equates to a 19 ppm-hours level, EPA chose a 17-ppm-hrs level as the benchmark, a level that would limit biomass loss to about 5.2%. *Id.* The *Murray Energy* court faulted EPA's use of a three-year average of 17 ppm-hrs, reasoning that it would allow "unacceptably high" ozone concentrations because a single year with high concentrations (at or above 19 ppm-hrs) could be averaged with concentrations below 17 ppm-hrs in other years to meet the average. 936 F.3d at 616-18. And because harm to trees is cumulative, exposure to lower ozone concentrations in later years does not offset harm to growth caused by exposure to higher concentrations in earlier years. *Id.* at 617.

In the proposal, EPA argues that recent data shows that there is little variation between three-year averages and single-year levels. EPA cites an analysis it did comparing single-year 126 index values in 2016-18 compared to three-year averages at all U.S. monitoring sites with sufficient data available during this period. EPA states that the analysis showed that single-year W126 index values differed less than 15 ppm-hrs from the average for the 3-year period. 85 Fed. Reg. at 49,893. According to EPA, of the 850 sites meeting the current secondary standard (70 ppb), over 99% of single-year W126 index values differ from the 3-year average by no more than 5 ppm-hrs and 87% by no more than 2 ppm-hrs. *Id.*

But even if EPA's analysis does show that there are not large disparities in ozone concentrations from year-to-year, the agency's charge under the statute is to set a secondary standard that "is requisite to protect the public welfare from *any* known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." 42 U.S.C. § 7409(b)(2). The agency's proposal effectively writes off the areas that EPA's own analysis suggests will experience annual ozone concentrations of 19 ppm-hrs or greater. Even if those areas are relatively few in

number, EPA's responsibility is to set the standard so as to avert "any" known or anticipated adverse welfare effects associated with air pollution, not just most adverse effects. During the last review, CASAC advised EPA that if it was going to adopt a three-year average benchmark rather than a single-year value, it could address these adverse effects at a level of 13 ppm-hrs or less. CASAC 6/26/14 letter at 15.

Second, with respect to the adverse effect of visible foliar injury, the proposal fails to explain how the current standard adequately protects against this harm. EPA purports to address the defect identified in *Murray Energy* by citing to a range of Forest Service biosite scores as providing the level of air quality requisite to protect against adverse effects from visible leaf injury. 85 Fed. Reg. at 49,909. EPA states that biosite scores that correspond with moderate to severe foliar injury "would be an indication of visible foliar injury occurrence that, depending on extent and severity, may raise public welfare concerns." *Id.* EPA then notes that based on the data, moderate to severe foliar injury appears to be common "only with W126 index values above 25 ppm-hrs. *Id.* EPA concludes that such concentrations are not found in monitoring areas meeting the current standard, and that values above 17 or 19 ppm-hrs are rare. On these bases, EPA proposes to conclude that the current standard adequately protects against visible foliar injury.

As an initial matter, EPA does not explain its proposed adoption of biosite scores to determine whether foliar injury is adverse when the agency has concluded that its understanding of the relationship between these scores and the severity of foliar injury is "still incomplete." PA, at 4C-18. Next, assuming that EPA is proposing to use the biosite scores to adopt a level of adverse effect for foliar injury that is the equivalent of 25 ppm-hrs, as the preamble discussion suggests, that would be a stark departure from the level CASAC found in the last review was necessary to protect against this harm. The proposal fails, however, to reconcile adopting a level of foliar injury that is more than *two and a half times* the level CASAC recommended in the last ozone NAAQS review. *See Murray Energy*, 936 F.3d at 619 (citing CASAC letter providing its scientific judgment that a one-year standard level of 10 ppm-hrs is necessary to address foliar injury). EPA fails to acknowledge—must less explain—this large discrepancy. EPA does not, for example, take the position that the scientific evidence CASAC relied upon to make that recommendation is no longer valid. Moreover, the biosite scores EPA cites (from 2006-10) were included in the evidence CASAC had before it when it made its recommendation of 10 ppm-hours in 2014. EPA cannot lawfully adopt a 25 ppm-hrs level for foliar injury without confronting this evidence and explaining its disagreement with CASAC. *See* 42 U.S.C. § 7607(d)(3).

The *Murray Energy* court also considered, but did not decide, a third issue concerning the existing secondary standard: whether EPA erred by adopting the identical standard as the health-based standard despite overwhelming evidence that a seasonal, cumulative standard based on the W126 index better measures welfare harms to trees and plants. *See* 936 F.3d at 618. The court did not rule on this question

because a "critical piece of the puzzle [was] missing" in determining whether EPA was correct that an eight-hour standard is "highly correlated" with a seasonal, cumulative standard based on a 3-year average: EPA's explanation "why it is reasonable to focus on a three-year average of the W126 index in the first place." *Id.* As noted above, EPA has still not reasonably explained its reliance on a 3-year average rather than a single-year average to adequately address adverse welfare effects.

EPA further argues that in light of evidence that peak ozone concentrations play a significant role in harms to trees and plants, adopting a seasonal, cumulative standard would actually be *less protective* than an 8-hour standard. 85 Fed. Reg. at 49,913. This contention is erroneous. As CASAC advised EPA in the last review, the agency had several options to address peak concentrations under a seasonal, cumulative standard based on the W126 index: abandon use of a three-year average, which can mask peak concentrations in any given year, or lower the level of the standard to 13 ppm-hrs or less. CASAC 6/26/14 letter at 15-16. EPA fails (again) to consider these alternatives, which if adopted, would enable the agency to adopt the form of the standard it acknowledges is the most biologically relevant for measuring welfare harms to plants and trees.

Finally, as explained immediately below, the proposed secondary standard is flawed in another aspect as well: it fails to protect against adverse effects on the climate caused by ozone pollution.

VI. OZONE AND CLIMATE CHANGE

The Administrator acknowledges the feedback loop between climate change and ozone, but only considers one half of that loop—the effect of ozone on the climate—while ignoring the other part, where climate change increases ozone levels.

On the one end, to the extent the Administrator is correct that there are uncertainties in the relationship between tropospheric ozone and the warming climate, he should err on the side of caution by adopting a stricter standard. At a minimum, EPA should propose alternative standards that would better protect against adverse effects to the climate. On the other end, climate change increases the number of hot days, and the increased heat and sunlight interacts with VOCs and methane to create additional ozone. By not accounting for warmer temperatures caused by climate change, the Administrator ignores the serious health impacts of the resulting increase in ozone.

A. Uncertainties in the Effect of Ozone on Radiative Forcing Should Lead the Administrator to Err on the Side of Caution, Not Simply Propose to Retain the Existing Standards.

The Administrator acknowledges that new evidence since the 2013 ISA reinforces that ozone is the third largest contributor to radiative forcing, behind only

carbon dioxide and methane.[121] The Administrator also correctly notes that evidence since the 2013 ISA "continues to support a causal relationship between . . . [ozone] in the troposphere and radiative forcing, and a likely causal relationship between . . . [ozone] in the troposphere and effects on temperature, precipitation, and related climate variables."[122]

However, though the Administrator "consider[ed] the strong evidence documenting tropospheric [ozone] as a greenhouse gas causally related to radiative forcing," he cites the "limitations and uncertainties in the evidence base that affect characterization of . . . relationships between [ozone] concentrations . . . and climate-related effects" as justification for maintaining the current standard.[123] As the latest ISA explains,"[c]urrent limitations in climate modeling tools, variation across models, and the need for more comprehensive observational data on these effects represent sources of uncertainty in quantifying the precise magnitude of climate responses to ozone changes."[124] In other words, the 2020 ISA evaluated the intervening data and maintained the "likely causal relationship" between ozone and climate effects, rather than upgrading the relationship to a "causal relationship."[125] Such uncertainty means the Administrator should err on the side of caution by strengthening the secondary standard. At a minimum, EPA should propose and take comment on alternative standards that would address that uncertainty by better protecting adverse effects to the climate from ozone. Difficulties in estimating the "precise magnitude of climate responses to ozone changes" due to current limitations means current measurements could very well be *underestimating* the impact of ozone on climate change.

B. EPA's 2009 Endangerment Finding That Climate Change Will Increase Ozone Pollution Undercuts the Administrator's Justification for Maintaining the Current Standards.

Over a decade ago, EPA warned that elevated ozone pollution is an expected consequence of climate change.[126] In the agency's 2009 Endangerment Finding, it stated that warmer temperatures caused by climate change are "expected to increase regional ozone pollution, with associated risks in respiratory illness and premature death."[127] Climate change worsens summertime surface ozone episodes especially in

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[121] 85 Fed. Reg. at 49,883; ISA, at 9-2, 9-6.
[122] *Id.*; *see* ISA at 9-17, "Highlights of Recent Evidence for Impacts on Temperature, Precipitation, and Related Climate Variables".
[123] 85 Fed. Reg. at 49,908.
[124] ISA at 9-17, "Highlights of Recent Evidence for Impacts on Temperature, Precipitation, and Related Climate Variables".
[125] *See id.*
[126] *See* Endangerment and Cause or Contribute Findings for Greenhouse Gasses Under Section 202(a) of the Clean Air Act, 74 Fed. Reg. 66,496, 66,525 (Dec. 15, 2009).
[127] *Id.*

polluted regions of North America—primarily in large metropolitan areas with existing ozone problems.[128] EPA concluded that climate change exacerbates the challenges of meeting the "air quality protection promised by the NAAQS for ozone" and that "overall . . . public health is endangered by increases in ozone resulting from climate change."[129] EPA also found that increased tropospheric ozone pollution will have "significant adverse effects on crop yields, pasture and forest growth, and species composition."[130]

C. The Proposed Rule Fails to Adequately Consider the Effects of Climate Change on Ozone Concentrations in Setting Standards.

A significant amount of compelling evidence developed since 2009 reinforces EPA's finding that climate change results in additional ozone pollution. For example, the most recent National Climate Assessment (NC4) found that climate change has already increased ozone concentrations, offsetting some of the ozone reductions attributable to implementation of the NAAQS program.[131] The NCA4 concluded with "high confidence that climate change will increase ozone levels over most of the United States, particularly over already polluted areas, thereby worsening the detrimental health and environmental effects due to ozone."[132] EPA failed to consider this evidence when determining the proposed ozone NAAQS.

1. EPA Should Incorporate the Latest Assessments of Impacts of the Warming Climate and Increased Elevated Ozone Days.

According to recent research, increased ozone pollution from climate change will cause premature deaths, hospital visits, acute respiratory symptoms and lost school days, "[u]nless offset by additional emission reductions of ozone precursors."[133] That is, independent of any drop in anthropogenic pollution that contributes to ozone formation, "climate change will result in meteorological conditions more favorable to forming ozone."[134] Reports show that this "climate penalty" has an unmistakable

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[128] *Id.*
[129] *Id.* at 66,530
[130] *Id.* at 66,525.
[131] *See* U.S. Global Change Research Program. "Fourth National Climate Assessment, Volume II: Impacts, Risks, and Adaptation in the United States." Washington, D.C.: US Global Change Research Program, 2018. Chapter 13 (Air Quality) at https://nca2018.globalchange.gov/chapter/13/.
[132] *Id.*
[133] Fann, N., T. Brennan, P. Dolwick, J.L. Gamble, V. Ilacqua, L. Kolb, C.G. Nolte, T.L. Spero, and L. Ziska, 2016: Ch. 3: Air Quality Impacts. The Impacts of Climate Change on Human Health in the United States: A Scientific Assessment. U.S. Global Change Research Program, Washington, DC, 69, 70, https://health2016.globalchange.gov/air-quality-impacts.
[134] *Id.* at 72.

effect on mortality: ozone-related premature deaths will rise in the most polluted areas of the country, even in a moderate greenhouse gas emissions scenario.[135]

Even more troubling is the feedback loop between climate change and tropospheric ozone discussed below. As temperatures increase, ozone concentrations increase, which in turn increases positive radiative forcing —which further raises temperatures, which in turn causes more ozone formation—and so on.[136] The NCA4 asserts a robust link between warmer temperatures from climate change and increased ozone pollution, but EPA has failed to fully consider this evidence in proposing to maintain the current ozone NAAQS.

2. Climate Change Increases Likelihood of More Hot Days That Will Facilitate Development of Smog, But EPA Failed to Include This Consideration in its Adequate Margin of Safety Analysis.

In selecting standards that provide an adequate margin of safety, EPA must not only prevent pollutant levels that have been demonstrated to be harmful, but also prevent lower pollutant levels that may pose an unacceptable risk of harm. Although quantitative attribution analyses of the links between recent ozone levels and climate change-triggered temperature increases are not currently available, EPA should have considered the established mechanism linking ambient temperature and ozone patterns in setting the NAAQS for ozone.

VII. CONCLUSION

EPA's periodic review of the ozone NAAQS is one of the agency's most consequential actions, affecting the health and welfare of millions of people in our States and throughout the country. The States respectfully request that EPA withdraw the Proposed Rule. The Administrator should reverse the procedural changes to the NAAQS review process made in the 2018 memorandum, reinstate the Ozone NAAQS Review Panel, and reopen the ozone NAAQS proceeding to perform a more thorough and transparent review process. This is the only way to correct its rushed, flawed review and avoid the clear errors in the Administrator's proposed decision to maintain both the primary and secondary standards without revision.

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[135] *Id.* at 73, 74 - Figure 2, "Projected Change in Temperature, Ozone, and Ozone-Related Premature Deaths in 2030."

[136] Draft ISA at 9-4; Fourth National Climate Assessment; *see also* Comments of Environmental Defense Fund, Natural Resources Defense Council, and Clean Air Task Force, 12-13 (Dec. 16, 2019) (EPA-HQ-OAR-2018-0279-0041).

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