UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Review of the National Ambient Air Quality Standards for Ozone, 85 Fed. Reg. 49,830	Docket ID No. EPA–HQ–OAR–2018–0279 Submitted via Regulations.gov, Oct. 1, 2020

Appalachian Mountain Club, Clean Air Task Force, Earthjustice, Environmental Defense Fund, Environmental Law and Policy Center, Natural Resources Defense Council, National Parks Conservation Association, and Sierra Club ("NGO Commenters") respectfully submit the following comments on the Environmental Protection Agency's ("EPA") "Review of the Ozone National Ambient Air Quality Standards," 85 Fed. Reg. 49,830 (Aug. 14, 2020). Our organizations represent millions of members and supporters across the country who are deeply concerned about the health, environmental, and economic impacts of air pollution and support implementation of strong, science-based National Ambient Air Quality Standards ("NAAQS") that ensure public health and the environment are protected. As the undersigned organizations explain, EPA must revise its Proposal for both the primary and secondary ozone standard to no higher than 60 ppb and 7 ppm-hrs (single-year W126 metric), respectively, propose a primary standard that directly addresses long-term ozone exposure, and then reopen the comment period.

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I. INTRODUCTION

Ozone, the principal component of smog, is one of the most dangerous and persistent forms of air pollution in the United States today. Scientists link ozone to premature deaths, thousands of emergency room visits, and tens of thousands of asthma attacks each year. Ozone is especially dangerous to small children, people with asthma and senior citizens, who are often warned to stay indoors on polluted days. Also, as well as being a greenhouse gas, smog pollution can severely damage forests and plants, stunting their growth, increasing the risk of tree die-off from disease, and causing harms that affect whole ecosystems. Hundreds of counties throughout the nation suffer from unsafe ozone levels.

The Clean Air Act requires the U.S. Environmental Protection Agency to set primary National Ambient Air Quality Standard (NAAQS) for ozone pollution at a level that protects public health with an adequate margin of safety, and it requires the nation to then achieve compliance with that level of air pollution. EPA's review of the NAAQS must "accurately reflect the latest scientific knowledge." 42 U.S.C. § 7408(a)(2). The review must be "thorough." *Id.* § 7409(d)(1). EPA's Proposal to retain the current standard of 70 ppb, set in 2015, does not reflect this knowledge and is not requisite to protect public health with an adequate margin of safety.

Just as it was true in 2015 that an extensive body of scientific literature unequivocally documented the need for a standard set below 70 ppb, so too does the literature continue to reflect that need today. Despite the fact this body of evidence has only grown since the last review, EPA's Proposal declines to set the standard at the level the statute's directive demands. It fails to meaningfully engage with the body of evidence that mandates strengthening the standard, provides no margin of safety, and is the result of a review process rife with flaws.

Though we identify numerous technical flaws in EPA's Proposal, just as importantly, EPA's proposed standard cannot be squared with the mandates of the Clean Air Act simply because it in essence requires people—especially sensitive populations such as children—to stay indoors to avoid exposures to levels of air quality that the scientific literature has repeatedly shown to be unhealthful. This is all the more problematic because some people do not have an option to limit outdoor activity, such as the nearly 9 million workers whose jobs require them to be out of doors all day.

In addition, a weak ozone standard poses a unique injustice to low-income communities and communities of color. Across the nation, people of color are consistently overrepresented in areas with higher ozone levels and that are in nonattainment of ozone NAAQS. Furthermore, across the nation the asthma burden of people of color—particularly among Blacks—is far higher than that of whites. The Proposal acknowledges as much. EPA must adopt a 60 ppb standard if it is to protect these communities. This mandate has never been more urgent, as we also know that communities of color currently face a disproportionately high risk from COVID-19. Doubly burdening these communities in the midst of a respiratory pandemic is unconscionable, and further counsels for strengthening the standard.

Ultimately, the Clean Air Act promises Americans that anyone can go outside whenever they want, for as long as they want, and where air quality is attaining the NAAQS it will be safe for them to breathe. EPA must adopt a level no higher than 60 ppb if EPA is to fulfill this promise. EPA must also adopt a standard that directly targets long-term ozone exposure, which the science shows adversely affects public health and which the 8-hour standard does not control.

As for the secondary, welfare-protective, standard, EPA's attempt to once again reverse engineer the secondary standard to precisely match the primary is unlawful and arbitrary. Rather than once again try to twist the science about how ozone harms plants—over the course of a multi-month season—so that it fits with the science about how EPA acknowledges ozone harms people—through short-term exposures, measuring in hours—EPA must set a standard that is scientifically justified. The only Clean Air Scientific Advisory Committee (CASAC) panels with relevant expertise to review the secondary standard concluded that such a standard must be of the W126 form. Nothing has changed to undermine that conclusion. Accordingly, to protect plants against a range of harms that include growth loss, loss of carbon sequestration capacity, crop yield loss, and visible leaf damage, that W126 standard must be no higher than 7 ppm-hours, measured as a 3-month average.

II. EPA'S LEGAL OBLIGATIONS IN SETTING AND REVIEWING THE NAAQS

A. Overview of the Clean Air Act's requirements for primary NAAQS

The Clean Air Act Amendments of 1970 first introduced the requirement to establish enforceable NAAQS. The amendments were intended to be "a drastic remedy to what was perceived as a serious and otherwise uncheckable problem of air pollution." *Union Electric Co. v. EPA*, 427 U.S. 246, 256 (1976). The 1970 amendments "carrie[d] the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health." 116 Cong. Rec. 42,329, 42,381 (Dec. 18, 1970) (remarks of Sen. Muskie).

The NAAQS drive the Clean Air Act's requirements for controlling emissions of conventional air pollutants. Once EPA establishes NAAQS, states and EPA identify those geographic areas that fail to meet the standards. 42 U.S.C. § 7407(d). Each state must prepare an "implementation plan" designed to control pollutant emissions in order to reduce the ambient concentrations of the pollutant to below the level of the NAAQS and maintain that improved air quality. *Id.* § 7410.

The Clean Air Act provides a clear process for establishing the NAAQS. The first step involves identifying those pollutants, the "emissions of which, in [EPA's] judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare," and "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources." *Id.* § 7408(a)(1)(A), (B). Once EPA identifies a pollutant, it must select a

NAAQS that is based on air quality criteria that "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." *Id.* § 7408(a)(2).

Primary NAAQS must be set at a level "requisite to protect the public health" with "an adequate margin of safety." *Id.* § 7409(b)(1). To ensure that the NAAQS keep pace with scientific understanding and continue to provide the necessary protection, EPA must review and revise as appropriate the underlying air quality criteria and the NAAQS themselves at least every five years. *Id.* § 7409(d)(1). Any primary NAAQS that EPA promulgates under these provisions must be adequate to protect public health and provide an adequate margin of safety, in order to prevent not only any known or anticipated health-related effects from polluted air, but also those that are scientifically uncertain or that research has not yet uncovered. Further, the statute makes clear that there are significant limitations on the discretion granted to EPA in selecting a level for the NAAQS. In exercising its judgment, EPA must err on the side of protecting public health, and may not consider cost or feasibility in connection with establishing the level of the NAAQS and its other elements (e.g., indicator, the form of the standard, and averaging time). The D.C. Circuit summed up EPA's mandate succinctly:

> Based on these comprehensive [air quality] criteria and taking account of the "preventative" and "precautionary" nature of the act, … the Administrator must then decide what margin of safety will protect the public health from the pollutant's adverse effects – not just known adverse effects, but those of scientific uncertainty or that "research has not yet uncovered." … Then, and without reference to cost or technological feasibility, the Administrator must promulgate national standards that limit emissions sufficiently to establish that margin of safety.

Am. Lung Ass'n v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998) (citations omitted); *see also Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 464–71 (2001). Each of these requirements is discussed in more detail below. Unless otherwise indicated, we discuss legal requirements for secondary standards in the section addressing those standards.

B. EPA's prior implementation of the primary ozone NAAQS

One of the first pollutants for which EPA adopted NAAQS was ozone, a principal component of urban smog, and a severe lung irritant even to healthy adults. *See* 66 Fed. Reg. 5,002, 5,012–13 (Jan. 18, 2001). The first predecessor to the current primary ozone NAAQS was promulgated in 1971 at 0.08 ppm, averaged over one hour. 36 Fed. Reg. 8,187 (April 30, 1971). *See Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1182 (D.C. Cir. 1981) (though the 1971 standard was nominally addressed to photochemical oxidants, compliance was gauged by

measuring only ozone). In 1979, EPA relaxed this standard to 0.12 ppm, also averaged over one hour. 44 Fed. Reg. 8,220 (Feb. 8, 1979).

Subsequently, a growing body of peer-reviewed scientific evidence emerged, documenting the inadequacy of the 1979 standard to protect public health with an adequate margin of safety. However, despite the Act's express mandate to review and (as appropriate) revise NAAQS at intervals of no greater than five years, 42 U.S.C. § 7409(d)(1), EPA failed to consider the new evidence, or to revise the NAAQS to reflect it. 58 Fed. Reg. 13,008, 13,013 (Mar. 9, 1993) (EPA "missed both the 1985 and 1990 deadlines for completion of [ozone NAAQS] review cycles under section 109(d)"). Even after being sued by the American Lung Association and ordered to complete a review of the NAAQS, EPA issued a final decision that still refused to consider the new evidence—and declined to revise the NAAQS. 58 Fed. Reg. at 13,008, 13,013–14, 13,016. When that decision was challenged in the D.C. Circuit, EPA sought and received a voluntary remand to consider the new science. Order of June 27, 1994 in *American Lung Association v. Browner*, D.C. Cir. No. 93-1305.

EPA completed a NAAQS review considering that evidence in 1997, many years after the scientific understanding developing in the early 1980s had coalesced. That review produced the 1997 eight-hour NAAQS, at 80 ppb (equivalent to 84 ppb under standard rounding conventions[1]). 62 Fed. Reg. 38,856 (July 18, 1997). After several years of litigation, the D.C. Circuit upheld the standard against industry challenge. *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355 (D.C. Cir. 2002); *see also Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027 (D.C. Cir. 1999), *reh'g granted in part and denied in part*, 195 F.3d 4 (D.C. Cir. 1999), *aff'd in part and rev'd in part sub nom. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001).

In 2002, EPA failed again to timely review and revise the 1997 NAAQS, leading to another suit forcing it to carry out its mandatory duty under 42 U.S.C. § 7409(d). *Am. Lung Ass'n v. Whitman*, No. 03-CV-778 (D.D.C.). In the review process, CASAC, the expert body charged with reviewing the air quality criteria and NAAQS and making scientific recommendations on them, unanimously found that the primary NAAQS should be revised to a level between 60 and 70 ppb. In 2008, EPA disagreed with CASAC's recommendations and set the primary standard at 75 ppb. 73 Fed. Reg. 16,436 (Mar. 27, 2008).

Soon thereafter, EPA itself raised concerns about whether its 2008 standards complied with the Act and began a reconsideration of the NAAQS. In early 2010, based solely on the information already before it, EPA proposed to strengthen the primary NAAQS to somewhere within the CASAC-recommended range of 60–70 ppb. 75 Fed. Reg. 2938 (Jan. 19, 2010). The Proposal stated that the Administrator "judge[d] that a standard level of 0.075 ppm is not sufficient to provide [health] protection with an adequate margin of safety." *Id*. at 2996. Then-Administrator Lisa Jackson proposed a standard set at 65 ppb, based on the advice of CASAC.

[1] *Mississippi v. EPA*, 744 F.3d 1334, 1344 (D.C. Cir. 2013).

The White House declined to finalize that proposed reconsideration, instead assuring the D.C. Circuit that it would address the reconsideration when it completed its next review and revision of the ozone NAAQS. *See Mississippi v. EPA*, 744 F.3d 1334, 1341–42 (D.C. Cir. 2013). Ultimately, the D.C. Circuit upheld the 2008 standard. *Id*. at 1342.

The 2008 standard was due for review and revision in 2013. Because EPA again missed its deadline, American Lung Association, Sierra Club, and others sued EPA and obtained an order requiring EPA to complete its review by October 1, 2015. Order, *Sierra Club v. EPA*, No. 13-CV-2809 (N.D. Cal. Apr. 30, 2014).

In its 2014 review of the science, the CASAC again concluded that the 2008 standard of 75 ppb was insufficient to protect public health. The panel again recommended a lower standard, in the range between 60 and 70 ppb. Further, it concluded 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… At 70 ppb, there is substantial scientific evidence of adverse effects as detailed in the charge question responses, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation. Although a level of 70 ppb is more protective of public health than the current standard, it may not meet the statutory requirement to protect public health with an adequate margin of safety.2

Most importantly, the panel's policy advice was "to set the level of the standard *lower than 70 ppb* within a range down to 60 ppb." *Id.* (emphasis added). Despite this recommendation, EPA proposed a range only between 65 to 70 ppb. 79 Fed. Reg. 75,234 (Dec. 17, 2014). By its own estimates, a standard set at 65 ppb instead of 70 ppb would have avoided almost 3000 deaths, and 640,000 asthma attacks in children, per year.[3] Despite these overwhelming benefits, the Obama administration completed the 5-year review of the 2008 standard, and strengthened the ozone health standard, to 70 ppb, in October of 2015. 80 Fed. Reg. 65,292 (Oct. 26, 2015).

Various industry groups, states, and environmental groups sued over the 2015 standards. *Murray Energy Corp. v. EPA*, 936 F.3d 597 (D.C. Cir. 2019). Industry petitioners argued that EPA failed to take into account the impact of "background" ozone levels—namely, ozone concentrations that come from sources other than anthropogenic U.S. sources, i.e., from natural sources and from sources in other countries. They also argued that EPA failed to consider economic, social, and energy impacts from lowering the NAAQS. After briefing was complete, the case was held in abeyance for more than a year as the new administration considered whether

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[2] Letter to Hon. Gina McCarthy from Clean Air Scientific Advisory Committee, "CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards" June 26, 2014, pg. 2.

[3] U.S. EPA, Regulatory Impact Analysis of the Proposed Revisions to the National Ambient Air Quality Standards for Ground-Level Ozone, EPA-452/P-14-006, Nov. 2014, Table ES-7.

to revisit the standard. In 2019, a three-judge panel unanimously upheld the primary standard and rejected the industry arguments. In rejecting those argument, the Court held that the Clean Air Act prohibits EPA from considering the impact of background ozone on attainability of the updated primary and secondary standards, and it also forbids the Agency from considering costs—which industry sought to rename "adverse impacts"—from the revised NAAQS under *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001). The panel also rejected the renewed argument that the Clean Air Act was somehow an unconstitutional delegation of lawmaking authority to EPA. But, as we discuss in depth in a subsequent section, the Court rejected as arbitrary EPA's secondary standard and remanded it, granting environmental groups' petition.

As well as drastically (and arbitrarily) altering the CASAC, as discussed below, then-Administrator Pruitt issued a memo in 2018 that initiated this review and committed the Agency to completing its review of the ozone standard by October of this year.

C. EPA must issue air quality criteria that accurately reflect the latest scientific knowledge, and the primary NAAQS must protect public health with an adequate margin of safety based on the criteria.

In setting or revising a primary NAAQS, section 109 of the Clean Air Act requires that EPA assure the protection of public health with an adequate margin of safety. This mandate "carries the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health," 116 Cong. Rec. 42,329, 42,381 (Dec. 18, 1970) (remarks of Senator Muskie).

Standards must be based on an air quality level requisite to protect public health and not on an estimate of how many persons will intersect given concentration levels.[4] EPA interprets the Clean Air Act as providing all people in the United States—including sensitive groups—the opportunity to pursue their normal activities in a healthy environment. 44 Fed. Reg. 8,202, 8,210 (Feb. 8, 1979). Thus, as EPA has acknowledged, it cannot deny protection from the effects of air pollution by claiming that the people experiencing those effects are insufficiently numerous, or that levels that are likely to cause adverse health effects occur only in areas that are infrequently visited.[5] Nor can EPA deny protection against adverse health and welfare effects merely because

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[4] *See* 116 Cong. Rec. 32,821, 32,901 (Sept. 21, 1970) (remarks of Sen. Muskie) ("This bill states that all Americans in all parts of the Nation should have clean air to breathe, air that will have no adverse effects on their health.").
[5] *See* 116 Cong. Rec. 32,981, 33,114 (Sept. 22, 1970) (remarks of Sen. Nelson) ("This bill before us is a firm congressional statement that all Americans in all parts of the Nation should have clean air to breathe, air which does not attack their health."); *see also id.* at 33,116 (remarks of Sen. Cooper) ("The committee modified the President's proposal somewhat so that the national ambient air quality standard for any pollution agent represents the level of air quality necessary to protect the health of persons."); 116 Cong. Rec. 42,329, 42,392 (Dec. 18, 1970) (remarks of Sen. Randolph) ("[W]e have to insure the protection of the health of the citizens of this Nation, and we have to protect against environmental insults—for when the health of the Nation is endangered, so is our welfare, and so is our economic prosperity"); *id.* at 42,523 (remarks of Rep. Vanik) ("Human health and comfort has been placed in the priority in which it belongs—first place.").

those effects are confined to subgroups of the population or to persons especially sensitive to air pollution. *See, e.g.*, *Nat'l Envtl. Ass'n's Clean Air Project v. EPA*, 686 F.3d 803, 810 (D.C. Cir. 2012).

Further, where scientific evidence confirms that, at levels allowed by current NAAQS, adverse effects occur year after year in numerous individuals, risks are by definition "significant" enough to require protection under the Act's protective and precautionary approach. *See* H.R. Rep. No. 95-294, 1st Sess., at 43–51 (1977); *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir. 1976) (en banc). That is all the more true where the effects involved include highly serious ones like hospitalization and death. *See Ethyl Corp*., 541 F.2d at 18 ("the public health may properly be found endangered … by a lesser risk of a greater harm").

1. EPA is required to establish NAAQS that protect vulnerable subpopulations.

Importantly, the NAAQS must be set at levels that are not simply adequate to protect the average member of the population, but must also protect against adverse effects in vulnerable subpopulations, such as children, the elderly, socially disadvantaged, those working and exercising outdoors, and people with heart and lung disease. The D.C. Circuit has repeatedly found that if a pollutant's concentration in the ambient air "adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *Am. Lung Ass'n*, 134 F.3d at 390 (citation omitted); *see also Coal. of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 618 (D.C. Cir. 2010); *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 524 (D.C. Cir. 2009). EPA must also build into the NAAQS an adequate margin of safety for these sensitive subpopulations. *See Am. Farm Bureau Fed'n*, 559 F.3d at 526.

The drafters of the 1970 Clean Air Act Amendments made clear that the millions of people in the United States subject to respiratory ailments are entitled to the protection of the NAAQS: "Included among those persons whose health should be protected by the ambient standard are particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the normal course of daily activity are exposed to the ambient environment." S. Rep. No. 91-1196, at 10 (1970). As the D.C. Circuit has explained:

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

Am. Lung Ass'n, 134 F.3d at 390 (citations omitted); *Nat'l Envtl. Dev. Ass'n's Clean Air Project*, 686 F.3d at 810. NAAQS must "be set at a level at which there is 'an absence of adverse effect' on these sensitive individuals." *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980).

2. The adequate margin of safety requirements addresses uncertainties in the scientific information, and EPA must err on the side of protecting public health when there is scientific uncertainty.

The D.C. Circuit has characterized the NAAQS as "preventive in nature." *E.g.*, *Ethyl Corp.*, 541 F.2d at 15; *see also* H.R. Rep. No. 95-294, at 49-51 (explaining amendments designed *inter alia* "[t]o emphasize the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs"). The Act's mandate requires that in considering uncertainty EPA "must err on the side of caution" in terms of protecting human health and welfare: "The Act requires EPA to promulgate protective primary NAAQS even where … the pollutant's risks cannot be quantified or 'precisely identified as to nature or degree.'" *E.g.*, *Am. Trucking Ass'ns v. EPA* (*ATA III*), 283 F.3d 355, 369, 378 (D.C. Cir. 2002) (quoting Particulate Matter NAAQS, 62 Fed. Reg. 38,652, 38,653 (July 18, 1997)).

Thus, in keeping with the precautionary and preventive nature of the NAAQS, EPA must set standards that protect against potential adverse health effects—not just those impacts that have been well-established by science. *See id.* at 369 (citing 1997 Ozone NAAQS, 62 Fed. Reg. 38, 856, 38,857 (July 18, 1997)) (section 109(b)(1)'s "margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information ... as well as to provide a reasonable degree of protection against hazards that research has not yet identified"); *see also Am. Petroleum Inst. v. EPA*, 684 F.3d 1342, 1352 (D.C. Cir. 2012).

In an early seminal case on setting the NAAQS, the D.C. Circuit found that Congress "specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." *Lead Indus. Ass'n*, 647 F.2d at 1154. Limited data is not an excuse for establishing a standard that permits adverse effects. To the contrary, "Congress' directive to the Administrator to allow an 'adequate margin of safety' alone plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful." *Id.* at 1154–55 (quoting H.R. Rep. No. 95-294, at 520 (1977), as reprinted in 1977 U.S.C.C.A.N. 1077, 1480)).

In another case dealing with this same "margin of safety" requirement, the D.C. Circuit rejected industry's argument that EPA was required to document "proof of actual harm" as a prerequisite to regulation, instead upholding EPA's conclusion that the Act contemplates regulation where there is "a significant risk of harm." *Ethyl Corp.*, 541 F.2d at 12–13. The court found that:

> Sometimes, of course, relatively certain proof of danger or harm from such modifications can be readily found. But, more commonly, "reasonable medical concerns" and theory long precede certainty. Yet the statutes and commonsense demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.

Id. at 25; *accord Indus. Union Dep't v. Am. Petroleum Inst*., 448 U.S. 607, 655–56 (1980) (agency need not support finding of significant risk "with anything approaching scientific certainty," but rather must have "some leeway where its findings must be made on the frontiers of scientific knowledge," and may "risk[] error on the side of overprotection rather than underprotection"). As discussed above, EPA must act in the face of "inevitable" scientific uncertainty, *Lead Indus. Ass'n*, 647 F. 2d at 1154, and set standards with a protective and precautionary approach that errs on the side of caution—*i.e.*, in favor of protecting human health—in interpreting uncertainty.

3. The only lawful consideration in setting NAAQS is the effect of the pollutant in the ambient air on health and welfare.

It is well-established that the Act requires EPA to set health- and welfare-protective NAAQS for a pollutant based solely on the health and welfare effects caused by that pollutant in the ambient air, without regard to the sources of the pollutant or any costs of implementing the standards. *E.g.*, *Whitman*, 531 U.S. at 465, 469; *Am. Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1040-41 (D.C. Cir. 1999), *reh'g granted in other part and denied in part*, 195 F.3d 4 (D.C. Cir. 1999) *aff'd in relevant part sub nom. Whitman,* 531 U.S. 457 (2001); *Nat. Res. Def. Council* v. *EPA*, 902 F.2d 962, 972-73 (D.C. Cir. 1990), *vacated in unrelated part by* 921 F.2d 326 (D.C. Cir. 1991); *Nat. Res. Def. Council v. EPA*, 824 F.2d 1146, 1157, 1159 (D.C. Cir. 1987) (en banc); *Am. Petroleum Inst. v. Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981); *Lead Indus. Ass'n*, 647 F.2d at 1148-50 & n.39.[6] This principle was reaffirmed last year in *Murray Energy Corp.*, 936 F.3d at 622-24, where the Court held that EPA must set the primary NAAQS based exclusively on public-health considerations, without regard to "background" levels of the pollutant. Costs, however named, and "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of [NAAQS]." *Id.* at 621-24 (citation omitted).

[6] The briefing in *Whitman* further shows that, in rejecting consideration of "costs," the Whitman Court rejected consideration of "overall adverse … impacts" in NAAQS reviews. Industry parties themselves said in Whitman that they were there arguing that EPA must consider precisely those types of impacts: "Congress intended that EPA exercise its public health risk management judgment based on consideration of the overall impact of its decision on society." Appalachian Power Co. Resp. Br. ("Power Co. Whitman Resp.") 34, *Whitman v. Am. Trucking Ass'ns*, No. 99-1257 (U.S.). Indeed, various parties argued to the Supreme Court that EPA must consider broad impacts beyond just the "costs of implementation." The Court found that the "text of § [74]09(b), interpreted in its statutory and historical context and with appreciation for its importance to the [Act] as a whole," foreclosed all these arguments about costs. *Whitman*, 531 U.S. at 471.The D.C. Circuit later explained, "[i]t is only health effects relating to pollutants in the air that EPA may consider." *Nat. Res. Def. Council*, 902 F.2d at 973 (emphasis in original); *see also Murray Energy v. EPA*, 936 F.3d 597, 621-22 (D.C. Cir. 2019) (making it again clear that costs—"however denominated"—cannot play any lawful role in standard-setting).

III. THE PROCESS FOR REVIEWING THESE NAAQS IS UNLAWFUL AND ARBITRARY, RENDERING THE PROPOSAL UNLAWFUL AND ARBITRARY.

The process for scientific review that provides the foundation for this Proposal has been marred by critical process flaws. Due to these process flaws, the Proposal is not based on the latest scientific knowledge, as the Act requires, and is arbitrary, capricious, and an abuse of discretion. EPA should reopen the review process to ensure that the Agency satisfies its statutory obligations to base its decision on the latest scientific knowledge in order to protect public health with an adequate margin of safety.

The numerous problems with the process for developing this Proposal include that EPA unreasonably relied on recommendations from a CASAC that was constituted illegally, undercut the necessary expertise and support for scientific review, conflated steps for scientific assessment and policy determinations, failed to conduct a thorough assessment of the most recent studies on the health and welfare harms of ozone pollution, and dramatically accelerated the entire review process, leaving insufficient time for public comment and scientific review.

These process flaws occurred due to an array of unprecedented, *ad hoc* changes that radically departed from the longstanding practice of prior reviews. For decades of prior reviews, EPA has utilized an organized, sequential review process, first drafting an integrated review plan ("IRP"), followed by a review of the science in the form of an Integrated Science Assessment ("ISA"), a Risk and Exposure Assessment ("REA"), and then a review of policy issues in its Policy Assessment ("PA"). Prior reviews conducted this process with the advice of a CASAC supported by pollutant-specific review panels.

We concur with the former members of CASAC who participated in the 2009–2015 review of the ozone NAAQS—including two former chairs and ten former members of the chartered CASAC—who unanimously wrote to the current CASAC that these "myriad unwarranted changes … are collectively harmful to the quality, credibility, and integrity of EPA's scientific review process and to CASAC as an advisory body."[7]

These deficiencies have led to an arbitrary and capricious Proposal to retain the current inadequate standards that fails to comply with the Clean Air Act's requirements for a sound scientific foundation and an adequate margin of safety.

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[7] H. Christopher Frey et al., Advice from the former U.S. EPA Clean Air Scientific Advisory Committee Ozone Review Panel on EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft – September 2019), and EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019) (Dec. 2, 2019), pg. 2, *available at* https://yosemite.epa.gov/sab/sabproduct.nsf//B2AF0B23ABE6A60E852584C4007312E3/$File/EPA+CASAC+O3+Review+ISA+PA+Letter+191202+Final.pdf. [hereinafter "Former CASAC Advice Letter"].

A. EPA cannot proceed with this rulemaking without recommendations from a lawfully-constituted CASAC.

In October of 2017, former EPA Administrator Scott Pruitt announced a new CASAC appointments policy that broke with decades of Agency practice.[8] Administrator Pruitt simply announced by memorandum that EPA would no longer allow scientists who had received grants from the Agency to serve on its scientific committees. EPA grants are awarded through a competitive process and, therefore, researchers who receive those grants are often leading experts in their fields.

Following the issuance of this directive, EPA began to replace the members of CASAC, replacing all seven members of CASAC by October 2018. Two suits were filed by environmental and health organizations, along with scientists removed from the committee. EPA lost both. The Southern District of New York declared that EPA's exclusion of these experts was arbitrary and capricious, finding that EPA failed to explain "why an outright ban on EPA grant recipients would improve the existing policies that required demanding and continuous conflict of interest reviews[.]" *Nat. Res. Def. Council v. EPA*, 438 F. Supp. 3d 220, 232 (S.D.N.Y. 2020). In the D.C. Circuit, the court faulted EPA because the agency "nowhere confront[ed] the possibility that excluding grant recipients—that is, individuals who EPA has independently deemed qualified enough to receive competitive funding—from advisory committees might exclude" those candidates who are "'the most qualified, knowledgeable, and experienced[.]'" *Physicians for Soc. Responsibility v. Wheeler*, 956 F.3d 634, 647 (D.C. Cir. 2020). The Southern District issued an order vacating the Pruitt directive on April 15, 2020, pronouncing these flaws "serious." *Nat. Res. Def. Council v. EPA*, No. 19-cv-05174, 2020 WL 2769491 (S.D.N.Y. Apr. 15, 2020). EPA has chosen not to appeal.[9] Thus, the Pruitt directive is void.

As the D.C. Circuit recognized, this directive represented "a major break from the agency's prior policy, under which grantees regularly served on advisory committees." *Physicians for Soc. Responsibility*, 956 F.3d at 645. Had the Agency adhered to its longstanding practice, the pool of potential CASAC members would have included researchers with decades of expertise and experience with CASAC reviews. As the D.C. Circuit noted, the Pruitt directive failed to address past practices for addressing conflicts, the failure of which "is 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." *Physicians for Soc. Responsibility*, 956 F.3d at 647. Instead, the decision criteria relied upon in the Pruitt directive were arbitrary, unlawful, and

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[8] EPA, "Strengthening and Improving Membership on EPA Federal Advisory Committees," (Oct. 31, 2017) [hereinafter "Pruitt directive"].

[9] Press Release, U.S. 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.

unrelated to expertise. In contrast, the directive expressed no concerns about committee members who work for or are funded by industries or government entities subject to EPA regulation. Indeed, members from industry or government comprised the majority of the CASAC's membership during this review.

The CASAC has not been reconstituted in response to these decisions. Instead, EPA has continued to rely on CASAC's advice, despite the arbitrary exclusion of the most qualified, knowledgeable, and experienced members. The exclusion of qualified experts has had grave implications for the review. The Clean Air Act requires EPA to engage with an advisory board capable of providing "independent scientific review," and to explain any departure from its recommendations.[10] EPA must conduct this engagement with a CASAC that is constituted lawfully, and that is capable of providing the necessary independence and scientific expertise.

Because the advisory panel was inadequately and unlawfully constituted, any reliance on its advice, absent independent support for that reliance, is arbitrary, capricious, and an abuse of the Agency's discretion. Before finalizing this Proposal, EPA must re-assess CASAC membership and allow a lawfully-constituted committee to conduct the required scientific review.[11]

B. CASAC lacked critical expertise and support in the development of this Proposal.

Congress established the CASAC to be an independent body providing expert scientific advice to EPA on NAAQS decisions, and EPA's decisions regarding the NAAQS must be based on the best available science. 42 U.S.C. § 7409(d). However, changes to the membership of and support provided by CASAC during this review left EPA without the necessary expertise for a proper evaluation of the science. Because CASAC lacked the expertise and support to consider the full breadth and diversity of the evidence regarding the health and welfare impacts of ambient ozone, EPA's reliance on its advice for this Proposal is arbitrary, capricious, and an abuse of discretion. CASAC was simply not equipped to provide expert advice to the Administrator on the key scientific and technical issues, and therefore its advice warranted no deference from the Administrator.

1. The members of CASAC lacked critical expertise due to turnover under EPA's arbitrary policy.

Between 2017 and 2018, due to the now-voided Pruitt directive described above, there was a complete turnover of CASAC membership such that by October 2018, no member of

[10] 42 U.S.C. §§ 7409, 7607(d)(3). .

[11] *See Bullock v. United States BLM*, 2020 U.S. Dist. LEXIS 177029, *35-36 (D. Mont. September 25, 2020) (stating improperly appointed officials' actions are unlawful under the Administrative Procedure Act as not issued "in accordance with law.").

CASAC had served on the committee for more than one year. This turnover resulted in a loss of institutional memory, a lack of experience with NAAQS reviews, and a lack of necessary technical expertise on the committee.

While Administrator Wheeler emphasized the representation of five panelists who work in state, local, or federal environmental agencies when he announced the CASAC membership,[12] the members lack diversity and breadth in expertise. The unbalanced composition of CASAC for this review included only two academic research scientists, and most members lacked prior experience with NAAQS reviews. CASAC itself highlighted this lack of adequate epidemiological expertise in an April 2019 letter to Administrator Wheeler during the review for the particulate matter NAAQS, noting that "the breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals."[13] Former ozone panel members concurred, noting that "the current CASAC has transitioned from a committee of nationally and internationally recognized researchers at the leading edge of their fields to a committee composed predominantly of stakeholders chosen based on geographic location and affiliation with state and local government, rather than scientific expertise first and foremost."[14]

As the D.C. Circuit notes, EPA's new approach goes against Congress's intent for the function and purpose of CASAC:

> Congress expected that CASAC's central role would be one of scientific analysis, explaining that CASAC's "main function" was "to assess the health and environmental effects of ambient air pollution." … CASAC would "provide an outside mechanism for evaluating whether any pollutant may reasonably be anticipated to endanger public health or environment, for evaluating the scientific and medical data which might bear on this question, and for reviewing gaps in the available data and recommending additional needs for research." … Given these functions, Congress expected that CASAC members would "be selected on the basis of their special expertise" in fields such as "environmental toxicology, epidemiology and/or clinical medicine."[15]

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[12] Press Release, EPA, "*Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee Tasks Chartered Panel to Lead Review of Ozone & Particulate Matter Standards Under Reformed Process* (Oct. 10, 2018) *available at* https://archive.epa.gov/epa/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee.html.

[13] Anthony Cox et al., "CASAC Review of the EPA's *Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)*," at 1 (Apr. 11, 2019), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/%24File/EPA-CASAC-19-002+.pdf. Though this letter came as part of the review of the PM NAAQS, this particular CASAC comment holds for the ozone review as well, for the scientific issues and evidence for the ozone NAAQS are at least similar in depth and breadth as those for the PM NAAQS.

[14] *See* Former CASAC Advice Letter, *supra* n. 7, at 3.

[15] *Mississippi v. EPA*, 744 F.3d 1334, 1354 (D.C. Cir. 2013) (citations omitted).

Thus, scientific expertise must be the primary consideration in the selection of CASAC members. The unbalanced composition of the CASAC and the dearth of academic research scientists hindered the committee's ability to conduct the "thorough" review mandated by the Act. 42 U.S.C. § 7409(d)(1). For these reasons, the Administrator's reliance on CASAC members' recommendations in the Proposal is unlawful, arbitrary and capricious, and an abuse of discretion.

2. EPA lacked critical expertise because it failed to form a truly expert review panel.

For four decades, the chartered seven-member CASAC has augmented its ranks with additional experts to allow the breadth, depth, and diversity of expertise needed to review multidisciplinary scientific issues relevant to each of the criteria pollutants regulated under the NAAQS.[16] That expanded expert panel has been in place to fulfill the statute's requirement that the NAAQS reflect the latest scientific knowledge. EPA's abandonment of that process was arbitrary and capricious, and lead to inadequate scientific review.

In July 2018, EPA issued a request for experts for the ozone review panel. In October, EPA announced that it would not form an expert ozone review panel, providing no rationale for this change. Likewise, this Proposal provides no rationale for that "modification" to the CASAC review process.[17] EPA's decision not to form an expert ozone panel left CASAC without needed supplemental expertise. As former CASAC members have put it, a specialized expert panel is needed to "augment[] CASAC with the expertise it needs via qualified review panels that deliberate, interactively, with members of the chartered CASAC."[18]

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[16] CASAC's charter provides it with the authority to convene such expert panels. That charter states: "EPA, or CASAC with the Agency's approval, may form subcommittees or workgroups for any purpose consistent with this charter." Of course, the panel is not CASAC, and does not itself make recommendations to the agency. As the CASAC charter states, "[s]uch subcommittees or workgroups may not work independently of the chartered committee and must report their recommendations and advice to the chartered CASAC for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered committee, nor can they report directly to the EPA." United States Environmental Protection Agency Charter, Clean Air Scientific Advisory Committee, June 5, 2019 (date of filing with Congress), https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf. Additional experts have been appointed to review panels that interact with members of the chartered CASAC for all reviews since the late 1970s. Over time, the chartered CASAC has typically been augmented with 12 or more additional experts in a given review cycle for a given criteria pollutant. The average number of experts among 20 such panels for which membership data is available is 14, and the average size of the review panels is 20 members, inclusive of participating CASAC members.

[17] *See* 85 Fed. Reg. at 49,836.

[18] *See supra,* n. 7, Former CASAC Advice Letter.

Administrator Wheeler has implied that this departure from past practice is justified because deliberations with an expert panel could slow the process down.[19] But former members of the ozone review panel explain that this rationale does not hold water:

> Contrary to implications of statements made by the Administrator to justify why the PM Review Panel was disbanded and why an ozone review panel was not formed, panels do not slow down or in any way hamper CASAC's role in the NAAQS review process because they work collaboratively and in parallel with the chartered CASAC. Moreover, engagement of panels is essential to CASAC having the breadth, depth, and diversity of expertise and experience needed for these complex scientific reviews. Therefore, failure to form an ozone review panel fatally undermines the ability of CASAC to complete a thorough, detailed review of the PA rooted in the best available science without providing any advantages to process efficiency.[20]

The failure to form an ozone review panel also contributes to EPA's violation of Section 108's requirement for the NAAQS to "accurately reflect the latest scientific knowledge" because its absence limits EPA's ability to learn of and evaluate new scientific information. 42 U.S.C. § 7408(a)(2).

The Administrator's late appointment of a "pool" of experts, nominally available to answer specific questions from CASAC members submitted in writing, five months after CASAC requested additional help,[21] does not rectify these failings. Appointment by the Administrator, rather than via the customary review process with SAB vetting and public participation, is an inadequate process and leads to at least the appearance of bias. Further, due to the now-voided Pruitt directive, eminent scientists were illegally barred from consideration for inclusion in the pool.[22]

There are several crucial differences between the pool of consultants available to CASAC and a traditional supplemental expert panel. First, this pool was not selected specifically for the review of the ozone NAAQS—the same consultants were involved in the particulate matter NAAQS review—and therefore lacks the expertise to provide CASAC the comprehensive support necessary for the ozone review. Additionally, no member of the consultant pool had

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[19] EPA asserts that the new approach is "focused, efficient, and transparent" without addressing whether this change actually improves the efficacy of the NAAQS review process. 85 Fed. Reg. at 49,836.

[20] *See* Former CASAC Advice Letter *supra* n. 7, at 4.

[21] Anthony Cox et al., "CASAC Review of the EPA's *Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)*," (Apr. 11, 2019), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/%24File/EPA-CASAC-19-002+.pdf.

[22] *See* Compilation of EPA Grant Information regarding Nominees to CASAC and Administrator Wheeler's Expert Pool (attached) (documenting the ineligibility of five expert-pool nominees—Peter DeCarlo, David Eaton, Joel Kaufman, Armistead Russell, and Ivan Rusyn—as a result of their EPA grants and the directive).

served on the ozone expert panel in the 2009–2015 review of the ozone NAAQS, suggesting that crucial relevant expertise is missing from the pool.

Despite the Administrator's claims to the contrary,[23] the pool of experts that Administrator Wheeler selected to answer directed questions from CASAC did not adequately address CASAC's request for additional expertise. According to a report quoting one of CASAC's members in the wake of the Administrator's announcement, no person named to the pool had "'sufficient expertise and experience' in epidemiology"—an area in which CASAC needed significant help.[24] For example, though an EPA roster identified Dr. Frederick Lipfert as an expert on "air quality" and "epidemiology," a press report later quoted him as saying: "'I'm an amateur epidemiologist at best[.]'"[25] Another member of the pool, Dr. David Parrish, repeatedly stated in his responses to CASAC's questions that he had "no relevant expertise in evaluating exposure and risk," "no relevant expertise in evaluating public health implications," "no relevant epidemiological expertise," and "no relevant health effects expertise[.]"[26] The Administrator's decision to appoint pool members lacking relevant expertise was arbitrary and unlawful, particularly given the fact that candidates with relevant expertise had been included on the list of nominees.[27]

Six of the pool's twelve original members, moreover, were reportedly nominated by or affiliated with groups that have opposed strengthening the NAAQS in the past.[28] As a report on the pool's members explained:

> Two of Wheeler's … picks work for well-known industry consulting firms that are representing clients with a stake in the reviews. … [B]oth were nominated by the National Rural Electric Cooperative Association, which opposed EPA's 2015 cut to the national ground-level ozone standard[.] … Another two—one of whom has since quit—were endorsed by the National Cattlemen's Beef Association,

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[23] *Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts*, EPA (Sept. 13, 2019), https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts#:~:text=Administrator%20Wheeler%20Announces%20New%20CASAC%20Member%2C%20Pool%20of%20NAAQS%20Subject%20Matter%20Experts,-09%2F13%2F2019&text=WASHINGTON%20(September%2013%2C%202019),Committee%20(CASAC)%2C%20Dr. (attached).

[24] Sean Reilly, *Documents Expose Ties Among EPA Panel's Experts*, E&E News (Feb. 7, 2020), https://www.eenews.net/stories/1062289617 (attached) [hereinafter, "Expert Panel Article"].

[25] *Id.* (noting that Dr. Lipfert had nominated himself for the expert pool, and that his "educational background, which includes a doctorate, is in engineering and environmental studies"); List of Nominees for CASAC PM and Ozone Consultants (Aug. 2019) (attached).

[26] Responses to CASAC Questions on the Ozone PA from Consultant Dr. David Parrish at 5-6, 9-10 (attached); *see* Expert Panel Article *supra* n. 24.

[27] S*ee* Expert Panel Article *supra* n. 24 (noting that the EPA's own "roster shows that Wheeler passed over … academic specialists in epidemiology in appointing the experts"); List of Nominees for CASAC PM and Ozone Consultants (Aug. 2019).

[28] *See* Expert Panel Article, *supra* n. 24.

> which unsuccessfully fought EPA's 2012 tightening of the annual limit on soot concentrations. … Yet another, the self-described amateur epidemiologist, is also on the advisory board of a conservative group known as the American Council on Science and Health. In comments to CASAC last fall, a trustee for the council disputed the long-established connection between soot exposure and early death. … [And] [a]nother expert working with the committee is … an independent consultant nominated by the Chicago-based Truck and Engine Manufacturers Association, which also opposed EPA's 2015 decision to trim the ozone threshold.[29]

This report raises questions about whether a number of the members of the pool could be relied upon to provide wholly objective scientific advice.

Critically, this process differs from the usual expert panel review process. This panel of consultants was directed to only interact with CASAC in writing, rather than to respond in real-time and deliberate with the committee. This undermines the mechanisms of peer review central to a strong evaluation of science-based information. Even if Administrator Wheeler had populated his pool with the experts CASAC needed to complete its review, the limitations he placed on the pool's members would have made it difficult for them to offer meaningful contributions to the process. While members of review panels typically participate in CASAC's public meetings, Administrator Wheeler's pool was not allowed to join the committee's meetings or to deliberate with the committee's members.[30] As one of CASAC's members has said, the Administrator's requirement that the pool's members only communicate with the committee in writing "'adversely affect[ed]' CASAC's ability to advise EPA[.]"[31] The Administrator's expedited process further prevented the pool's members from offering useful comments. As a professor at Texas A&M University explained after resigning from the pool, "'I simply did not have as much time to devote to the tasks as the tasks would have required[.]'"[32]

All told, the pool of consultants selected by Administrator Wheeler failed to remedy the arbitrary and unlawful deficiencies in CASAC's expertise as applied to this NAAQS review. Instead, the pool made the Administrator's reliance on CASAC's advice all the more arbitrary, for even with the consultants, CASAC lacked the necessary expertise to comment on the standards.

EPA has failed to recognize and consider the impact of these arbitrary decisions on the CASAC's ability to perform its duties and on the quality of the recommendations produced by

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[29] *See* Expert Panel Article, *supra* n. 24.
[30] Former CASAC Advice Letter, *supra* n. 7, at 4. Members of the public are regularly invited to join CASAC meetings and speak to CASAC members directly. *See, e.g.,* Notification of a Public Meeting of the Chartered Clean Air Scientific Advisory Committee (CASAC), 84 Fed. Reg. 58,713 (Nov. 1, 2019) (public notice of hearing on CASAC Draft Report on Policy Assessment for Ozone, inviting public comment and participation).
[31] *See* Expert Panel Article, *supra* n. 24.
[32] *Id.* (quoting Professor Brent Auvermann).

the CASAC. Rushing through the external review process, without the typical subject matter experts and a shorthanded CASAC, was particularly egregious and undermined the CASAC's ability to conduct the required review, make recommendations, and advise the Administrator, as required by the Clean Air Act. The above factors and "exceptional nature" of this NAAQS review indicate that the current CASAC was simply unable to fulfill its role in this process under these challenging circumstances, and the Administrator's reliance on this broken process is arbitrary and unlawful.[33]

C. The development of the Proposal conflated science and policy assessment steps.

Not only did EPA lack the necessary expertise for the review process underlying this Proposal, that review process was also flawed because of the simultaneous assessment of both science and policy issues. EPA has collapsed what has normally been three sequential stages of review for this Proposal—the ISA, REA, and PA—into a single review, with overlapping comment periods. This is contrary to four decades of past practice for NAAQS reviews, wherein EPA has first completed its review of the latest scientific assessment, and only after that, drafted its policy assessment. This process allows for the most recent, relevant science to provide the basis for policy decisions. By drafting and reviewing the ISA and the PA concurrently, the necessary clarity in available science is not available for the PA. As former members of CASAC describe, this "risks commingling policy issues prematurely before the science issues are adequately vetted and settled, which in turn creates the potential for policy choices to be made irrespective of the science" and harms the integrity of the process.[34] As the Independent Particulate Matter Review Panel noted, "the integrity of the process is harmed when policy issues are addressed before the science issues are adequately settled." As the IRP explained, the PA is "intended to 'bridge the gap' between EPA's scientific assessments and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS."[35] But here, that bridge was built for the purpose of connecting to a pre-determined result, without setting an adequate foundation to support that result.

The ISA was finalized on April 1, 2020, months after the comment period for the draft PA closed in December of 2019.[36] This contrasts with the prior review, for which a full review period for the PA was completed after the final ISA was published. For this review, now that the

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[33] Clean Air Scientific Advisory Committee, *CASAC Review of the EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Ozone (External Review Draft – October 2019) (*EPA-CASAC-20-003*)*, at 1-2 (Dec. 16, 2019), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/4713D217BC07103485258515006359BA/$File/EPA-CASAC-20-003.pdf [hereinafter, "CASAC review of PA"]

[34] Former CASAC Advice Letter, at 5.

[35] U.S. Environmental Protection Agency, "Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards." August 2019. Accessed at: https://www.epa.gov/sites/production/files/2019-08/documents/o3-irp-aug27-2019_final.pdf, at 6-1.

[36] *See* 84 Fed. Reg. 58,711 (noting end of comment period on December 16, 2019).

ISA is finalized, EPA must re-open the PA for the opportunity for review by CASAC and the public. This will help to prevent the conflation of science and policy and ensure that the findings in the PA are based on the best available science.

D. EPA failed to consider the "latest scientific knowledge" as required by section 108.

Section 108 requires that the NAAQS "accurately reflect the latest scientific knowledge" on public health and welfare.[37] In prior NAAQS reviews, EPA has properly considered a reassessment of studies past the initial ISA cutoff date to be necessary. But EPA has not conducted any such assessment for this review, nor established any other procedure for ensuring more recent studies have been taken into account.

Instead, EPA has only committed to considering studies published through March 30, 2018. This early cutoff date was six months before the first draft of the ISA was available, and more than a year before the final ISA was completed. Without a post-ISA assessment of more recent studies, EPA has failed to ensure the proposed standard accurately reflects the latest scientific knowledge.

Here, EPA states that later-published studies were considered only "if they were submitted in response to the Call for Information or identified in subsequent phases of ISA development[.]"[38] However, the Clean Air Act charges the Administrator to conduct a thorough review of the latest science.[39] It is EPA's job, with support of expert staff, to evaluate the science. This early cutoff date for EPA review unreasonably and unlawfully shifts the burden to the public to identify and evaluate relevant studies. We cite numerous examples of such studies in section IV.B of these comments.

EPA's failure to analyze more recent studies through a post-ISA assessment is arbitrary. Additionally, given the longstanding prior policy, EPA's failure to acknowledge or explain this change in approach is also arbitrary.[40]

At the very least, EPA should have considered all studies published as of December 3, 2018, the final date for accepting comments on the ISA,[41] or as of April 2020, when the ISA was finalized, before beginning the review period for the PA.

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[37] 42 U.S.C. § 7408(a)(2).
[38] 85 Fed. Reg. at 49,838 n.17.
[39] 42 U.S.C. §§ 7409(d)(1), 7408(a)(2).
[40] *See, e.g.*, *Physicians for Soc. Responsibility*, 956 F.3d at 644 ("Reasoned decision-making requires that when departing from precedents or practices, an agency must offer a reason to distinguish them or explain its apparent rejection of their approach.").
[41] Release of Draft Integrated Review Plan for the Ozone National Ambient Air Quality Standards, 83 Fed. Reg. 55,163 (Nov. 2, 2018).

E. The review process left inadequate time and opportunity for scientific review and public participation.

Both the process for the scientific review that underlies this Proposal and the comment period for this rulemaking have been dramatically and arbitrarily accelerated compared to prior NAAQS reviews, leaving insufficient time for adequate scientific review and public participation.

The Clean Air Act requires EPA to review, and if necessary, revise, the NAAQS every five years in light of the latest scientific knowledge. 42 U.S.C. §§ 7408, 7409. It is possible to meet those statutory deadlines without sacrificing the integrity of the scientific review process outlined by the statute. Though the 2018 Pruitt NAAQS Memo was purportedly driven by this desire to adhere to the statutory deadline of October 2020, the memo only announced this desire after years of Agency inaction and delay with respect to the standards.[42] In order to complete a review that meets its statutory obligations, the Agency review is required to be "thorough", and "accurately reflect the latest scientific knowledge."[43]

EPA's professed concern about meeting statutory deadlines for this rulemaking are belied by the other national standards that are much further behind in reviews—for carbon monoxide, nitrogen oxides, and sulfur dioxide—but about which EPA has done nothing. Rather, the evidence points to a process designed to arrive at a pre-determined result, delaying any increase in stringency of the standard. This process has all the hallmarks of being driven by the desired outcome to maintain the current standard, and forego the proper evaluation of scientific advancements in the name of public health protections.

1. The scientific review process was arbitrarily accelerated.

In the IRP, EPA initially anticipated review of two drafts of the ISA,[44] but only provided one. This departs from the past practice for multiple ISA drafts; e.g., the three drafts of the ozone ISA for the 2009–2015 review, each with at least a 60-day comment period.[45] The ISA for this review was especially rushed because, as described above, the ISA review period overlapped with the review period for the PA. The draft PA was released just two months after the IRP was finalized, compared to over a year and a half during the previous ozone review.

Significant prior experience shows that these complex and technical documents often require substantial revisions. Failing to issue second drafts of these documents severely undermines the opportunities for CASAC, public, and other expert comment on EPA's scientific and policy analyses, which are foundational to subsequent regulatory processes. Moreover, and

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[42] 80 Fed. Reg. 65,291 (Oct. 26, 2015).
[43] 42 U.S.C. §§ 7409(d)(1), 7408(a)(2).
[44] *See* IRP, *supra* n. 35, at 4-3.
[45] 76 Fed. Reg. 10,893 (Feb. 28, 2011); 76 Fed. Reg. 60,820 (Sep. 30, 2011); 77 Fed. Reg. 36,534 (June 19, 2012).

critically, a second draft ISA (as contemplated by the IRP) would have allowed for consideration and inclusion of important additional studies, in keeping with the directives in Clean Air Act sections 108(a)(2) and 109(d)(1) to consider the "latest" "useful" science, as part of the "thorough review" of the air quality criteria and existing standards.[46] The truncated review undertaken by EPA, coupled with selective inclusion of some post-ISA studies but the exclusion of others without adequate explanation (see section IV.B) has led to a record that does not fully satisfy these requirements. Even without the improperly excluded studies, the record compels revision of the primary standards. In all these respects, the Proposal is unlawful, arbitrary and capricious, and an abuse of discretion.

Comment deadlines throughout the review have prevented the public from meaningfully engaging in the review process. The ozone PA was released on November 1, 2019 with a 45-day comment period. Within this same period, comments on the particulate matter PA and ozone ISA were also due (on November 12 and December 2, respectively). This 45-day comment period is remarkably short given both the simultaneous review of two other major NAAQS review documents, as well as the broad scope of the draft PA, which covered the same scope as three assessment documents—the policy assessment, the welfare risk and exposure assessment, and the health risk and exposure assessment—that were reviewed separately in the prior review cycle. The 45-day comment period on the PA did not leave enough time for a thorough review of this extensive and technical document. In comparison, the 2015 review had two drafts of the PA, each with a longer comment period than that provided during this review.[47]

The shortened drafting period for these review documents placed extreme pressure on EPA staff, which has led to some critical omissions simply due to time constraints. For example, the PA failed to consider the health effects of ozone on outdoor workers, a particularly at-risk group.[48] CASAC's review of the PA also criticized EPA's failure to simulate impacts on outdoor workers.[49]

Former ozone expert panel members agree that this process "did not provide sufficient time to complete the 'thorough review' of the 'latest scientific information' of the 'kind and extent' of 'all identifiable effects' mandated by the Clean Air Act for the review of NAAQS," adding that "[t]his would be true even if the committee were supported by a robust panel of experts in the multiple disciplines involved."[50]

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[46] 42 U.S.C. §§ 7408(a)(2),7409(d)(1).
[47] 77 Fed. Reg. 42,495 (July 19, 2012) (first draft notice of availability); 77 Fed. Reg. 51,798 (Aug. 27, 2012) (extending comment period); 79 Fed. Reg. 4,694 (Jan. 29, 2014) (second draft notice of availability).
[48] Comment made by EPA staff during the EPA Presentation - Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, December 5, 2019 at the Clean Air Scientific Advisory Committee meeting; *see also Am. Trucking Ass'ns*, 283 F.3d at 375 (citing EPA's discussion of ozone exposure risks for outdoor workers and children in setting the 1997 ozone standard at 62 Fed. Reg. 38,856, 38,60).
[49] *See* CASAC Review of PA, *supra,* n. 33, at A-5 (comments of Dr. James Boylan).
[50] *See* Former CASAC Advice Letter, *supra,* n. 7, at 2, 5.

These flaws underscore that the requirements of section 108 have not been met in this review. EPA's rushed process may well have deprived even a lawfully constituted CASAC of adequate time to provide expert advice. To be certain, the inexpert CASAC, even assisted by the ad hoc consultant pool, failed to remedy these issues. Individually and in combination, the process flaws resulted in a Proposal that cannot be lawfully finalized without major revisions to the review process.

2. This Proposal has been arbitrarily accelerated.

Like the process for reviewing the foundational documents for this Proposal, the current comment period has also been arbitrarily accelerated. The 48 days that EPA has provided, in total, for public comment on the Proposal is a remarkably short comment period for such a consequential and scientifically complex rulemaking. EPA routinely provides longer comment periods on nationwide rules of this importance, including a 90-day comment period on the proposed ground-level ozone NAAQS in 2014.[51] Here, EPA offers no reason for why a comment period of about half that length would be sufficient. Even EPA's recent—and significantly shorter—Proposal regarding the particulate matter NAAQS afforded commenters 60 days. It is irrational to provide a shorter comment period for a longer Proposal of similar complexity.

And the mere 18-day lead time for public hearings also burdened the public by not providing them adequate opportunity to prepare to testify or to make arrangements that would allow them to testify, if, for example, they had work, school, or care-giving responsibilities that precluded their participation during a weekday. Limiting public participation in hearings is not consistent with the Act and is thus also arbitrary. *See* 42 U.S.C. § 7607(h) (EPA "shall ensure a reasonable period for public participation" in rulemaking).

The unreasonably short time period EPA has provided is all the more egregious due to the current public health crisis. The ozone review is being finalized during a global pandemic caused by a respiratory virus, meaning that the very respiratory health experts who are most relevant and best situated to provide detailed comments are necessarily preoccupied with the COVID-19 crisis. The 48-day public comment period would be a remarkably short comment period for such a consequential, highly technical and scientific rulemaking notwithstanding the extent of the current crisis. But the pandemic exacerbates barriers to public participation, with the closure of the docket room, and the closure of public reading areas—like libraries and schools that afford internet access to those who do not have it at home—coupled with the requirement that comments be submitted electronically. Although some changes may be warranted by the pandemic, they restrict opportunities for public input and may silence important feedback, particularly from the most vulnerable individuals in the population. Pushing through this incredibly important review despite the current circumstances and changes to the process

[51] 79 Fed. Reg. 75,234 (Dec. 17, 2014).

that further restrict public input is unacceptable, and must be remedied before the rule is finalized.

Without any explanation at all, EPA denied our organizations' request for an extension of the comment deadline expressing the above concerns.[52] These factors raise serious concerns about the adequacy of the opportunity for public comment and other issues with statutory requirements under the Clean Air Act. Given the current public health crisis, and the lack of expert panel support for CASAC, the public should have far more than the customary 90-day comment period, not substantially less.

IV. THE ADMINISTRATOR'S PROPOSED DECISION TO RETAIN THE PRIMARY STANDARD FOR OZONE IS UNLAWFUL AND ARBITRARY ON ITS MERITS.

The Administrator's proposed decision to retain the primary standard for ozone at 70 ppb is fundamentally at odds with the Clean Air Act's essential purpose and requirements. Ignoring precedent and the statutory directive to set standards at a precautionary level—one "allowing an adequate margin of safety"—the Administrator proposes to leave the primary standard unrevised because he contends that the "currently available evidence does not substantially differ from that which was available in the 2015 review when the current standard was established." 85 Fed. Reg. 49,830, 49,869 (Aug. 14, 2020). As noted at length in our comments both here and on the 2015 standards, a level of 70 ppb was then, and remains now, insufficiently protective of public health. The Administrator's decision to retain the standard is arbitrary, capricious and an abuse of discretion.

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

The scientific evidence described in the ISA shows that ozone harms human health and that significant harms occur at levels lower than what the current standard allows. Scientific evidence across various lines of evidence—including controlled human exposure studies, animal toxicology, and epidemiology—confirm these harms and coherence of adverse health effects. Importantly, the ISA identifies new health harms, including links to metabolic disease, that are linked to ozone exposures.

The epidemiology literature synthesis presented in the ISA indicates that a stronger standard (below 70 ppb) is merited, given robust evidence of health harms at lower exposure

[52] Environmental Defense Fund, Earthjustice, Clean Air Task Force, National Parks Conservation Association, Moms Clean Air Force, Appalachian Mountain Club, Sierra Club, Natural Resources Defense Council, and Physicians for Social Responsibility, "Request to Extend Public Comment Deadline for *Review of Ozone National Ambient Air Quality Standards*, 85 Fed. Reg. 49,830" (August 14, 2020), regulations.gov ID EPA-HQ-OAR-2018-0279-0321.

levels. At an 8-hour maximum level of 60 ppb, the ISA finds evidence of lung function impairments, pulmonary inflammation, injury, oxidative stress and other respiratory symptoms in children and adults exposed to ozone concentrations at that level or lower. Controlled human exposure studies showed ozone-induced decreases in lung function and inflammation in exercising adults at levels as low as 60 ppb. Risks of hospital admissions, emergency department visits, and physician visits for respiratory ailments were found to be elevated at 8-hour maximum levels of 31-55 ppb, with the lower threshold of those findings at a concentration that is less than half of the current standard. Collectively, these findings are coherent in their determinations of adverse health effects well below the level of the current standard. EPA must consider a more stringent primary NAAQS for ozone given the body of studies examining short-term ozone exposure and respiratory effects.

B. A long-term exposure ozone standard is necessary, and EPA arbitrarily fails to consider establishing one

EPA agrees long-term ozone exposure likely causes harms and notes in the ISA that within epidemiology studies of long-term exposure risks "it is much more common for the association to be underestimated because near-road ozone scavenging can result in greater spatial variability due to a reduction in ozone concentration compared with ambient ozone measured at a fixed-site monitor." ISA at 3-1; 2-1.

Within the final ISA, EPA has arbitrarily included a small number of studies published after March 2018 and not explained why certain studies, including several that identify health harms at currently permissible levels, were excluded from the final ISA. These include a 2019 study analyzing air pollution concentrations (including ozone) and asthma incidence in children.[53] While that study identified reduced asthma incidence as ozone concentrations fell over time (IRR for asthma was 0.85 (95% CI, 0.71–1.02) for a median reduction of 8.9 parts per billion, with an absolute incidence rate decrease of 0.78 cases per 100 person-years), the effect was not statistically significant. A number of studies published after March 2018, the cut-off period for study consideration in the current ozone ISA, confirm statistically significant health harms from both short- and long-term exposures to ozone.[54,55,56] For example, while there were

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

[54] Dominici, Francesca, Joel Schwartz, Qian Di, Danielle Braun, Christine Choirat, and Antonella Zanobetti. "Assessing Adverse Health Effects of Long-Term Exposure to Low Levels of Ambient Air Pollution: Phase 1." Research Reports: Health Effects Institute 2019 (November 1, 2019). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7300216/.

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

[56] Dedoussi, Irene C., Sebastian D. Eastham, Erwan Monier, and Steven R. H. Barrett. "Premature Mortality Related to United States Cross-State Air Pollution." Nature 578, no. 7794 (February 2020): 261–65. https://doi.org/10.1038/s41586-020-1983-8.

no epidemiologic studies examining the association between long-term exposure to ozone and COPD available for inclusion in the 2013 Ozone ISA, a recent study by Paulin et al. (2019) of smokers with or at-risk for COPD found that long-term exposure is associated with worse respiratory outcomes and increased emphysema and gas trapping. As noted in Limaye and Knowlton (2019),[57] the adverse respiratory health outcomes identified in this study were found to be potentially independent of smoking intensity or exposures to air pollution on the job, underscoring the health risks that ozone air pollution poses to tens of millions of individuals who currently smoke or formerly smoked. Additional studies published after March 2018 demonstrate causal links between long-term exposures and adverse health outcomes. Lim et al. (2019)[58] investigated associations of long-term (annual or warm season average of daily 8-h maximum concentrations) exposure with all-cause and cause-specific mortality in the NIH-AARP Diet and Health Study, a large prospective cohort of U.S. adults with 17 years of follow-up from 1995 to 2011. That study found that long-term annual average exposure was significantly associated with deaths caused by cardiovascular disease (per 10 ppb; hazard ratio [HR], 1.03; 95% confidence interval [CI], 1.01–1.06), ischemic heart disease (HR, 1.06; 95% CI, 1.02–1.09), respiratory disease (HR, 1.04; 95% CI, 1.00–1.09), and chronic obstructive pulmonary disease (HR, 1.09; 95% CI, 1.03–1.15) in single-pollutant models. The results were robust to alternative models and adjustment for co-pollutants (fine particulate matter and nitrogen dioxide).

Rhee et al. (2019)[59] analyzed air pollution exposures at the ZIP code level in the U.S. and hospital admissions with acute respiratory distress syndrome (ARDS) among nearly 1.2 million Medicare beneficiaries aged >65 years from 2000 to 2012 and found that an increase of 1 ppb in annual average ozone was associated with statistically significant increases in annual hospital admission rates for ARDS of 0.72% (95% CI, 0.62–0.82) and 0.15% (95% CI, 0.08–0.22), respectively. Importantly, this effect remained in low-pollution regions meeting the current NAAQS (annual average PM2.5 level < 12 $\mu g/m^3$ and annual average ozone level < 45 ppb). In those areas, the 1 ppb annual increase in ozone was associated with an increase in annual hospital admission rates for ARDS of 0.27% (95% CI, 0.16–0.38).

As noted by Nassikas et al. (2020),[60] the meteorological conditions that govern ozone concentration are projected to be more favorable to ozone formation over much of the United

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[57] Limaye, Vijay S, and Kim Knowlton. "Shining New Light on Long-Term Ozone Harms." JAMA Internal Medicine, 2019, 2. https://doi.org/10.1001/jamainternmed.2019.5967.

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

[59] Rhee, Jongeun, Francesca Dominici, Antonella Zanobetti, Joel Schwartz, Yun Wang, Qian Di, John Balmes, and David C. Christiani. "Impact of Long-Term Exposures to Ambient PM2.5 and Ozone on ARDS Risk for Older Adults in the United States." Chest 156, no. 1 (July 2019): 71–79. https://doi.org/10.1016/j.chest.2019.03.017.

[60] Nassikas, Nicholas, Keith Spangler, Neal Fann, Christopher G. Nolte, Patrick Dolwick, Tanya L. Spero, Perry Sheffield, and Gregory A. Wellenius. "Ozone-Related Asthma Emergency Department Visits in the U.S. in a

States due to continued climate change, even as emissions of anthropogenic ozone precursors are expected to decrease by 2050. In particular, as noted by Archer et al. (2019),[61] in the mid-Atlantic region of the United States, warmer temperatures caused by climate change threaten to heighten long-term ozone levels and chronic exposures to ozone.

Strosnider et al. (2019)[62] conducted an analysis of respiratory emergency department visits in 894 counties, the largest U.S. multicity study of impacts among all ages. Linking daily respiratory emergency department visits with estimated ozone concentrations during the week before the date of the visit, per 20-ppb increase in ozone, rate ratios were statistically significant at 1.017 (1.011–1.023) among children, 1.051 (1.046–1.056) among adults younger than 65, and 1.033 (1.026–1.040) among adults 65 and older.

Collectively, these studies build upon the existing body of evidence and coherently demonstrate significant causal links between long-term exposure to ozone and adverse health outcomes. Moreover, they show that long-term exposures at levels well below 70 ppb contribute to widespread population health harms. EPA has not considered establishing a long-term exposure standard despite robust evidence that doing so would benefit human health. EPA's failure to so consider is arbitrary, capricious and an abuse of discretion, for it allows unquestionably adverse effects—like death, hospitalization, emergency room visits, and disease worsening or incidence—to persist, contrary to the Clean Air Act.

In so failing, EPA also departs without explanation from CASAC's recommendation. As CASAC recognized, there's a mismatch between the short-term averaging period of the current standard and the long-term exposures that also cause harms: lowering the short-term peaks doesn't necessarily lower the long-term levels that harm people.[63] At most, the PA includes a footnote about how the 2014 HREA found that reductions to meet an 8-hour standard "would be expected to reduce O_3 concentrations in terms of the metrics reported in epidemiologic studies to be associated with respiratory mortality and morbidity,"[64] but "expected" is different from reality, and CASAC's comments were about reality. The Proposal is silent. Even if EPA's buried speculation in the PA were enough to constitute addressing CASAC's recommendation, it does so without rational explanation.

Warming Climate." Environmental Research 183 (April 2020): 109206. https://doi.org/10.1016/j.envres.2020.109206.

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

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

[63] *See* CASAC review of PA, *supra* n. 33, at 4-5.

[64] U.S. EPA, Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, External Review Draft, EPA-452/P-19-002 (October 2019), at 3-12 n.18. [hereinafter "2020 Policy Assessment"]

C. EPA cannot rely on claimed "uncertainties" and other impermissible factors to avoid strengthening the standard

EPA must set standards to protect public health even if there are scientific uncertainties, as stated by the Clean Air Act and reaffirmed by the federal courts.[65] The Administrator's proposed decision to retain the primary ozone standard is fundamentally at odds with the Clean Air Act's essential purpose and requirements. Ignoring precedent and the statutory directive to set standards at a precautionary level—one "allowing an adequate margin of safety"—the Administrator proposes not to revise the primary standard based on purported "uncertainties" in the science – even though there is coherent and powerful evidence of serious harm, including hospitalization; and more than ample epidemiological evidence of dire harm, at human exposure levels well below those allowed by the current NAAQS; corroborating clinical evidence showing the biological plausibility of those effects; and accountability and similar related studies showing reductions in health effects when ozone levels are reduced.

EPA also proposes to arbitrarily rely on purportedly similar evidence regarding the level of protection EPA projects here and what it projected in the 2015 standard as a basis for retaining the current standard. *See, e.g.*, 85 Fed. Reg. at 49,860/2, 49,866/1; *see also id.* at 49,869/1-2 (similar, regarding "overall health effects evidence base" and conclusions drawn therefrom), 49,870/1-2 (similar, regarding chamber and epidemiologic studies and relevant exposure levels), 49,871/2-3 (proposing to "consider the exposure and risk analyses for this review" "similarly" to how EPA considered them in the 2015 review, and claiming "the current analyses update and improve upon" the prior ones), 49,873/1-3 (similar, regarding proposed conclusions regarding exposure analysis results); *see also id.* at 49,870/2 ("the Administrator notes that the evidence base in this review does not include new evidence of respiratory effects associated with appreciably different exposure circumstances than the evidence available in the last review, including particularly any circumstances that would also be expected to be associated with air quality conditions likely to occur under the current standard."). Even if that were true, and even if it were permissible and rational to rely on the exposure assessment as EPA proposes to, the purported similarities just aren't relevant. The D.C. Circuit firmly rejected the notion that "the initial assessment is sacrosanct and remains the governing standard until every aspect of it is undermined." *Mississippi*, 744 F.3d at 1343 ("It would … make no sense to give prior NAAQS the sort of presumptive validity Mississippi insists upon."). The analytical similarities do not support retaining the standard, for privileging EPA's prior approach "would bind EPA to potential deficiencies in past reviews because discrepancies between past and current judgments as easily reflect problems in the past as in the present." *Id.* And, to the extent the evidence

[65] Comments of Christopher Frey. Regarding the CASAC's Review of the U.S. EPA's External Review Draft of the PA for Ozone (2019). December 5, 2019. Pg. 27-28. *Available at* https://yosemite.epa.gov/sab/sabproduct.nsf/9FB1491880D2E312852584C70060F33D/$File/Written+Statement+H+Christopher+Frey+CASAC+O3+Draft+PA+191205+Submitted.pdf [hereinafter "Frey PA Comments"].

regarding ozone's harms has grown stronger—as it has—that supports a stronger standard, for evidence that bolsters prior conclusions can justify a stronger standard. *Id.* at 1344 ("additional certainty about what was merely a thesis might very well support a determination that the line marked by the term 'requisite' has shifted.").

D. The proposed decision to retain the current NAAQS does not even purport to comply with the Act's requirements

The Administrator proposes to conclude only that the current standard "provides a strong degree of protection to at-risk populations such as children with asthma" or "a high level of protection, including for at-risk populations, from O_3-related effects of exposures that might be expected with air quality conditions that just meet the current standard." 85 Fed. Reg. at 49,873/1. This does not even claim to meet the Act's requirements: "NAAQS must protect not only average healthy individuals, but also sensitive citizens such as children, and if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *Coal. of Ass'n of Battery Recyclers*, 604 F.3d at 618 (cleaned up); *accord American Lung*, 134 F.3d at 389 ("NAAQS 'must be set at a level at which there is "an absence of adverse effect" on [] sensitive individuals'" (alteration in original; quoting *Lead Indus.*, 647 F.2d at 1153). Whatever "a strong degree of protection" or "a high level of protection" mean, it is not the same as assuring the "absence of adverse effect," as required.

E. EPA arbitrarily fails to consider ozone's impacts on important populations of concern

Exposure to ozone poses risks to the health of key vulnerable sub-populations, but EPA does not adequately consider these impacts within the Proposal, or the final ISA and PA. For example, numerous commenters[66] noted at CASAC meetings in December 2019 and February 2020 that the committee and EPA should consider at-risk populations (including outdoor workers, communities of color, and communities of lower socioeconomic status), but the Agency failed to do so in its draft ISA and PA review documents. Commenters noted that an approach favored by one CASAC member failed to consider scientific evidence of impact on specific at-risk populations including the elderly, children, and those with diseases by discounting

[66] Comments of California Air Resources Board and Office of Environmental Health Hazard Assessment. Regarding the U.S. EPA's External Review Draft of the ISA for Ozone and Related Photochemical Oxidants (2019). December 2, 2019. *Available at* https://yosemite.epa.gov/sab/sabproduct.nsf/E5D4E292A9FC0D39852584C5006A8C01/$File/FINAL+Ozone+ISA+ARB+OEHHA+comment+letter+2dec19+signed+v2.pdf [hereinafter "CARB and OEHHA ISA Comments"]; Frey PA Comments pg. 5, 33; Comments of Gretchen T. Goldman. Regarding the U.S. EPA ISA for Ozone (2019). February 3, 2020. Pg. 3. *Available at* https://yosemite.epa.gov/sab/sabproduct.nsf/6A65E491F6F2671E8525850300556483/$File/GTGoldman-O3-Feb11.pdf [hereinafter "Goldman ISA Comments"].

epidemiology evidence and favoring manipulative causation studies and thus would not allow CASAC to provide the advice the statute requires for EPA to fulfill its charge.[67]

In its failure to consider impacts on these populations of concern within the ISA, PA, and the Proposal itself, EPA has departed from past practice. For example, the 2013 ISA devoted an entire chapter to a discussion of increased-risk populations; to rationally protect such populations, EPA needs to complete a similar review for this ISA, or at least discuss at-risk populations for each health outcome. This concern[68] was presented to EPA and CASAC in December 2019, months before the recent ISA was finalized. This concern also relates to EPA and CASAC consideration of vulnerable groups within specific sections of the ISA. For example, as it relates to the relationship between short-term ozone and cardiovascular disease effects and total mortality, CASAC gave insufficient consideration of effects on the more vulnerable segments of the population.[69]

In addition to its failure to robustly consider the health harms inflicted by ozone air pollution on vulnerable groups broadly within the ISA and PA, EPA also failed to include at least one relevant study published within the initial ISA review period. A comprehensive systematic review and meta-analyses published by Bell et al. (2014)[70] synthesized evidence across 167 peer-reviewed studies meeting strict inclusion criteria (73 on mortality and 96 on hospitalizations and emergency department visits, including 2 examining both mortality and hospitalizations) in order to identify populations at heightened risk of health harms from ozone. That study found a significant positive relationship between short-term ozone exposure and mortality risks among older populations. In that study, per 10-ppb increase in daily 8-hour ozone concentration, mortality risk for younger persons, at 0.60% (95% CI): 0.40, 0.80), was statistically lower than that for older persons, at 1.27% (95% CI: 0.76, 1.78). Findings adjusted for publication bias were similar. Limited/suggestive evidence was found for higher associations among women; mortality risks were 0.39% (95% CI: −0.22, 1.00) higher than those for men. It also identified strong evidence for higher associations with unemployment or lower occupational status.

Recently, an epidemiological study examining the effects of air pollution and other meteorological factors on COVID-19 confirmed cases and deaths in Queens, New York found that increases in the daily maximum eight-hour ozone concentration was "…statistically and positively associated with new confirmed cases related to COVID-19…".[71] The study was

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[67] *See* Goldman ISA Comments, *supra* n. 66, pg. 3.
[68] *See* CARB and OEHHA ISA Comments, *supra* n. 66, pg. 9.
[69] *Id.,* pg. 5.
[70] Bell, Michelle L., Antonella Zanobetti, and Francesca Dominici. "Who Is More Affected by Ozone Pollution? A Systematic Review and Meta-Analysis." *American Journal of Epidemiology* 180, no. 1 (July 1, 2014): 15–28. https://doi.org/10.1093/aje/kwu115.
[71] Adhikari, Atin and Yin, Jingjing. "Short-Term Effects of Ambient Ozone, PM2.5, and Meteorological Factors on COVID-19 Confirmed Cases and Deaths in Queens, New York." *International Journal of Environmental Research and Public Health 17 (June 5, 2020).* https://doi.org/10.3390/ijerph17114047.

conducted in response to recently published studies from China that reported short-term exposures of pollutants like ozone and other meteorological factors were significantly associated with COVID-19 cases.[72] The Queens study found that a one-unit increase in the moving average of ozone was associated with a 10.51% in daily new COVID-19 cases.[73] Notably, authors state that "[a]lthough ozone levels were found to be increasing during the COVID-19 outbreak in Queens, none of the data points for the height-hour max ozone exceeded the EPA health-related regulatory standard of 0.07-0.085 ppm (unhealthy for sensitive groups)." The author's observation that the height-hour max ozone level was not exceeded suggests the current standard may not be protective when accounting for impacts to individuals exposed to the SARS-CoV-2 virus. Given the emerging evidence linking air pollution and COVID-19 infections, EPA should consider how air pollutants, like ozone, would impact public health in the near and long term.

Moreover, in its current review EPA has not considered particular risks of ozone exposures to outdoor workers, whose patterns in exposure, underlying health conditions, income distribution, and other underlying health determinants can at times differ from those of the general population.[74]

As explained above, the Clean Air Act requires EPA to protect these vulnerable subpopulations from ozone's adverse effects. EPA ignores its statutory obligation and acts arbitrarily in failing to do so.

F. EPA's near-exclusive focus on lung function decrements demonstrated in controlled human experiments on healthy young adults arbitrarily overlooks important factors and sensitive populations for whom the standards must be protective with an adequate margin of safety

In proposing to retain the current primary standard, the Administrator proposes to "give[] particular attention to the longstanding evidence of respiratory effects causally related to short-term O_3 exposures." 85 Fed. Reg. at 49,869/1. EPA thus repeats its exceedingly well-founded, long-standing conclusion that short-term ozone exposure causes respiratory effects. *Id.* at 49,844/2-46/3, 49,869/2; *accord, e.g.*, PA at 3-23 to -28; ISA at ES-8, IS-24 to -31 & tbl.IS-4. Among those respiratory effects are lung function decrements (measured as decreases in FEV_1), respiratory symptoms, and airway inflammation. *E.g.*, 85 Fed. Reg. at 49,845/1-2. EPA notes repeatedly that highly probative, controlled human experiments on healthy young adults have

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[72] Yongjian, Z.; Jingu, X.; Fengming, H.; Liqing, C. "Association between short-term exposure to air pollution and COVID-19 infection: Evidence from China." *Science of the Total Environment,* (April 13, 2020). https://doi.org/10.1016/j.scitotenv.2020.138704

[73] *Id* at 71.

[74] Moda, Filho, and Minhas. "Impacts of Climate Change on Outdoor Workers and Their Safety: Some Research Priorities." *International Journal of Environmental Research and Public Health* 16, no. 18 (September 17, 2019): 3458. https://doi.org/10.3390/ijerph16183458.

shown statistically significant increases in lung function decrement and respiratory symptoms occur just above 70 ppb and statistically significant increases in inflammation occur at 60 ppb. *Id.* at 49,842/3, 49,851/2, 49,870/2. EPA also notes that more sensitive populations, such as people with asthma, are more vulnerable to experiencing harms from the same level of ozone than healthy young adults are. *Id.* at 49,846/1, 49,848/1, 49,857/3; *see also id.* at 49,869/2-3, 49,870/3. Yet, the Administrator's proposed conclusions hardly mention inflammation at all, and puts significantly less weight on harmful exposures to at least 60 ppb ozone levels, instead almost entirely addressing lung function decrement and respiratory symptoms at the 70 ppb benchmark exposure level. *See id.* at 49,868/3-74/1. Further, in proposing to retain the current standard's level, the Administrator fails to explain how his reliance on controlled human experiments on exclusively healthy young adults protects more sensitive populations. Understanding the level of ozone at which sensitive populations experience effects and which effects are adverse is fundamental to assessing whether this Proposal rationally satisfies the Clean Air Act's health-protective mandate. As explained below, the Administrator's Proposal is arbitrary.

1. EPA failed to rationally consider new information regarding adversity of effects

In numerous past NAAQS reviews, EPA has given significant weight to the American Thoracic Society's expertise regarding what constitutes an adverse effect of air pollution. *See, e.g.*, *Murray Energy*, 936 F.3d at 612 (EPA "chose to adopt the ATS definition of adversity"); *ATA III*, 283 F.3d at 375-76 ("in deciding when certain observed physiological effects of ozone 'become so significant that they should be regarded as adverse' to individuals' health, EPA looked to guidelines published by the American Thoracic Society."); 84 Fed. Reg. 9866, 9878/2, 9883/3, 9892/2, 9900/2-3 (Mar. 18, 2019); 73 Fed. Reg. 37,818, 37,849/2-50/3, 37,868/1, 37,871/2 (July 11, 2007); *see also* 85 Fed. Reg. at 49,840/2 (noting that in 2015 review, EPA considered, in determining adversity of effects, "commonly accepted guidelines or criteria within the public health community, including statements of the American Thoracic Society (ATS), an organization of respiratory disease specialists"). Indeed, in the 2015 review, EPA departed from its 2008 approach to determining how lung function decrement changes can amount to an adverse effect, and the D.C. Circuit relied on EPA's purported adherence to the then-current ATS guidelines about what constitutes an adverse effect of air pollution in upholding the change. *Murray Energy*, 936 F.3d at 612.

Since the 2015 NAAQS, ATS has updated its guidelines.[75] Importantly, in the newly updated guidelines, ATS expressly stated that "small lung function changes should be considered adverse in individuals with extant compromised function, such as that resulting from asthma, even without accompanying respiratory symptoms," a change from its prior guidelines, which

[75] Thurston et al., A Joint ERS/ATS Policy Statement: What Constitutes an Adverse Health Effect of Air Pollution? An Analytical Framework, 49 Eur. Respiratory J. 1600419 (2017) [hereinafter "ATS Guidelines"].

did not expressly address this circumstance.[76] The newly updated guidelines also emphasize the importance of considering impacts on especially susceptible subpopulations, and discuss how a focus on broad group-level average effects can mask more substantial (harmful) effects experienced by a subset of the group.[77]

In this Proposal, EPA has not rationally considered the new ATS guidelines. It notes the new ATS statement that "'small lung function changes' in individuals with preexisting compromised function, such as asthma, 'should be considered adverse…even without accompanying respiratory symptoms,'" and that the ATS guidelines emphasize the importance of examining effects in subsets of broader populations (including a population like "study subjects"). 85 Fed. Reg. at 49,848/3. But EPA fails to rationally discuss or otherwise implement these guidelines. Instead, EPA examines the number of study subjects in chamber studies who experience FEV_1 decrements of at least 15%. *Id.* at 49,851/2-3; *see also id.* at 49,863/1-2 (similarly highlighting the 15% FEV_1 decrement threshold). EPA nowhere offers any explanation as to why it is solely considering the number who experience 15% FEV_1 decrement. The PA acknowledges that, in prior reviews, "the CASAC concurred with the EPA's use in the 2014 HREA of estimated FEV_1 decrements of ≥15% as a scientifically relevant surrogate for adverse health outcomes in active healthy adults, and an FEV_1 decrement of ≥10% as a scientifically relevant surrogate for adverse health outcomes for people with asthma and lung disease," and that, in the risk assessment, "mid- to upper-end of the range of moderate levels of functional responses and higher (i.e., FEV_1 decrements ≥15% and ≥20%) are included to generally represent potentially adverse lung function decrements in active healthy adults, while for people with asthma or lung disease, a focus on moderate functional responses (FEV_1 decrements down to 10%) may be appropriate." PA app.3D at 3D-73, 3D-76. EPA's lack of any explanation for fixing exclusively on 15% decrement, rather than 10% decrement, in its analysis

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[76] *Id.,* ATS Guidelines, at 7; see also ATS, Samet et al., What Constitutes an Adverse Health Effect of Air Pollution?, 161 Am. J. Respir. Crit. Care Med. 665, 670-71 (2000). Notably, in its 2008 review of the ozone NAAQS, EPA took an approach that is consistent with the newly updated ATS guidelines. It found that lung function decrement of 10% or greater was "harmful (or 'adverse') to asthmatics." *Mississippi*, 744 F.3d at 1349 (citing 73 Fed. Reg. at 16,454-55). Indeed, EPA in the 2008 final rule "strongly" rejected comments suggesting that "transient decreases in FEV_1 of 10-20% are not by themselves significant or meaningful to asthmatics," explaining that for such people, this level of lung function decrease "would likely interfere with the normal activities for many individuals, and would likely result in more frequent medication use." 73 Fed. Reg. at 16,463/2-3.

[77] ATS Guidelines, at 3 tbl.1 ("[s]usceptibility" is one of the "[c]onsiderations for assessing adversity of clinical or pathological effects"), 5 (discussing study and noting that for "young healthy subjects, individual risk of a clinical event is minimal, but population risk, including that of susceptible subpopulations, such as the elderly, is probably substantial"), 5 ("considerations of health equity and environmental justice (e.g. socioeconomically disadvantaged populations being more exposed to air pollutants) are also similarly relevant to an assessment of adversity at the population level, with a similar shift in exposure and risk being of greater adversity to such vulnerable populations."), 7 (warning that "a small but statistically significant mean reduction in FEV_1 in a population means that some people had larger reductions, with the likelihood that reductions in a subset of susceptible subjects can have passed a threshold for clinical importance"), 8 (reaffirming discussion on preceding page regarding FEV_1 decrement).

in the Proposal of the chamber study results is arbitrary, particularly as the 15% decrement threshold has no apparent tie to the sensitive subjects who the standard must protect.

Beyond its arbitrary use solely of a 15% FEV_1 threshold, EPA also does not rationally consider effects on a subset of study subjects. It discusses just the raw number of subjects who experienced such a decrement. The raw number alone provides no information about how results might be generalized to a broader population—which is a key consideration in determining the public health importance of an effect caused by air pollution. Further, to the extent the Administrator examines effects on a subset of study subject in proposing conclusions, he merely uses the subset results to conclude that the higher the level of ozone, the more people who experience effects. *See* 85 Fed. Reg. at 49,863/1-2. Such an analysis just says that at a higher level, more effects occur, which leaves unexamined and unanswered the question of whether effects occur at a particular level (or whether those effects are adverse).

That the ATS guidelines do not generally expressly establish numerical thresholds and often avoid specificity does not free EPA from its heavy burden under the Clean Air Act and Administrative Procedure Act to explain its decision-making process, especially in the tremendously important context of protecting public health. Moreover, EPA's interpretation of the ATS guidelines regarding numerical criteria in this arena is overstated. First, in context, the guidelines' statement that "[t]here cannot be precise numerical criteria, as broad clinical knowledge and scientific judgments, which can change over time, must be factors in determining adversity," relates to authors' concerns that, as knowledge develops, we may find new effects and need to be able to apply new knowledge to say whether they're adverse. Thurston et al., *ATS Guidelines*, at 4. Second, in discussing precisely the issue of interpreting FEV_1 decrements observed in chamber studies of ozone exposure, the guidelines expressly mention the 10% FEV_1 decrement threshold, *id.* at 7-8, indicating that, like EPA historically has, the guidelines regard the 10% threshold as worthy of consideration. Thus, EPA's failure to discuss the clinical significance of such a level—particularly for people with existing lung disease—is arbitrary. *See also infra* § IV.F.3.

Further confirmation of EPA's arbitrary approach toward the newly updated ATS guidelines comes from CASAC. CASAC highlighted the newly updated guidelines in recommending to EPA that lung function decrement in the absence of respiratory symptoms should be considered adverse for children with asthma. CASAC Consensus Responses on PA 8-9; *see also id.* at A-15 (comments of Dr. Frampton[78] similarly raising point). Contrary to

[78] Notably, current CASAC member Dr. Mark W. Frampton is also one of the co-authors of the updated ATS guidelines. CASAC Consensus Responses on PA at ii (listing as one CASAC member "Dr. Mark W. Frampton, Professor Emeritus of Medicine, Pulmonary and Critical Care, University of Rochester Medical Center, Rochester, NY"); Thurson et al., *ATS Guidelines*, at 1-2 & n.11 (listing as author "Mark W. Frampton," and giving his affiliation as "Pulmonary and Critical Care, Depts of Medicine and Environmental Medicine, University of Rochester Medical Center, Rochester, NY, USA").

CASAC's express recommendation, as explained above, EPA fails to rationally discuss this point.

2. EPA arbitrarily focuses on lung function decrements and respiratory symptoms ahead of lung inflammation

As corroborated by studies cited in the ISA, exposure to ozone causes lung inflammation, emphysema, and interstitial fibrosis with progressive loss of lung function. Chronic lung inflammation is a characteristic feature of lung diseases as chronic obstructive pulmonary disease and asthma.[79] Systemic inflammation has been linked to a number of cardiovascular disease-related outcomes and is an important indicator of disease development. For example, circulating cytokines such as IL-6 can stimulate the liver to release inflammatory proteins (e.g., CRP) and coagulation factors that can ultimately increase the risk of thrombosis and embolism (ISA at 4-27). Importantly, Tables 4-28 and 4-29 of the ISA (beginning at page 4-108) demonstrate that evidence of inflammation is apparent after short-term exposures ranging from 12-35 ppb.

The 2011 Kim study showed a statistically significant increase in inflammation for healthy young adults exposed to 60 ppb of ozone over 6.6 hours of moderate exercise. 85 Fed. Reg. at 49,851-52 tbl.1, 49,870/2. This is important because respiratory inflammation is a well-documented harm resulting from short-term ozone exposure. *E.g.*, ISA at IS-25 tbl.IS-4, IS-17, app.3 at 3-28 to -39. Over time, even with lower levels of exposure than the current standard targets, ozone can result in inflammation that can cause permanent lung damage and development of severe lung disease. ISA at IS-35, app.3 at 3-90 to -94, 3-102 to -104. It is particularly concerning for people with lung disease like asthma, which is an "inflammatory lung disease," *id.* app.3 at 3-39, as "airway inflammation…is a primary feature in the clinical definition and characterization of asthma severity," and people with asthma may be particularly prone to experiencing inflammation from ozone exposure. *Id.* app.3 at 3-49, 3-53 to -54. As well as being harmful in itself, it also provides coherence for epidemiologic studies tying ozone exposure to other serious health harms, like emergency room visits. ISA at IS-29 to -31, app.3 at 3-2, 3-4, 3-8 to -10, 3-81 to -83, 3-85 tbl.3-2.

Consistent with inflammation's serious consequences, CASAC highlighted how inflammation is "a key component in the pathophysiology of asthma," and that it and other ozone-induced effects "likely contribute to the risk of an asthma exacerbation." CASAC Consensus Responses on PA 8; *accord id.* at A-14 (comments of Dr. Frampton). And, as mentioned above, CASAC explained,

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[79] Groves, Angela M., Andrew J. Gow, Christopher B. Massa, Jeffrey D. Laskin, and Debra L. Laskin. "Prolonged Injury and Altered Lung Function after Ozone Inhalation in Mice with Chronic Lung Inflammation." *American Journal of Respiratory Cell and Molecular Biology* 47, no. 6 (December 2012): 776–83. https://doi.org/10.1165/rcmb.2011-0433OC.

> It is reasonable to expect that, in people with asthma, any increase in airway inflammation is an adverse effect, with the potential to increase the risk for an asthma exacerbation. Repeated episodes of airway inflammation may enhance airway remodeling, which occurs in asthma, and leads to irreversible reductions in lung function.

Id. at 8 (emphasis added); *accord id.* at A-14 (comments of Dr. Frampton).

But in proposing to retain the 2015 ozone standard, the Administrator focuses on study results regarding lung function decrement and respiratory symptoms, an EPA-acknowledged adverse combination of effects that occurred with statistical significance in a study of exposure to ozone levels just above 70 ppb. *See* 85 Fed. Reg. at 49,868/3-74/1; *see also, e.g.*, *id.* at 49,866/2-3 (acknowledging combination of lung function decrements and respiratory symptoms is adverse). Accordingly, the Administrator proposes to once again emphasize the 70 ppb level of ozone, giving lesser weight to exposures to 60 ppb, a level at which ozone causes inflammation, with even less weight going to single such exposures. *Id.* at 49,872/2-3. The Administrator fails to rationally explain how this approach protects against the harms inflammation causes. Indeed, CASAC found that EPA was putting too much weight on lung function decrement, and instead highlighted the importance of lung inflammation as an adverse effect for people with asthma. CASAC Consensus Responses on PA 8-9; *accord id.* at A-13 to -14 (comments of Dr. Frampton); *see also* 85 Fed. Reg. at 49,845/3 (describing concerns 2013 ISA described about inflammation and lung function decrement and symptoms).

The Administrator's failure to explain his deprecation of inflammation is particularly important. He proposes to ultimately rely largely on the results of the exposure assessment to purportedly justify retaining the existing standard.[80] 85 Fed. Reg. at 49,871/1 ("As at the time of the last review, the exposure and risk estimates developed from modeling exposures to O_3 in ambient air are critically important to consideration of the potential for exposures and risks of concern under air quality conditions of interest, and consequently are critically important to judgments on the adequacy of public health protection provided by the current standard."); *see also id.* at 49,871/1-73/1 (discussing exposure analysis). Specifically, he proposes to heavily rely on the exposure assessment's finding that there would be no more than 1% of children with asthma (and all children), experiencing at least one dangerous 7-hour exposure to 70 ppb of ozone in a year. *Id.* at 49,872/2, 49,873/1; *see also id.* at 49,860 tbl.2. By contrast, the Administrator proposes that such exposures to 60 ppb of ozone are "of lesser concern than occurrences for the next higher benchmark of 70 ppb," and to give even less weight to single such exposures to 60 ppb of ozone (as opposed to multiple such exposures). *Id.* at 49,872/2-3. His Proposal allows exposures to 60 ppb, measured as a percent of children with asthma (and all children), approximately an order of magnitude greater than exposures to 70 ppb. *See id.* at

[80] For this paragraph's purposes, we assume for the sake of argument that the Administrator's reliance on the exposure assessment were rational and lawful.

49,860 tbl.2 (maximum percent of children with asthma and all children with at least one exposure to 70 ppb benchmark is 1.0% and 0.9%, respectively; to 60 ppb benchmark is 11.2% and 10.6%, respectively). Even if the Administrator's proposed greater weight on multiple exposures to the 60 ppb benchmark (as opposed to single such exposures) were rational, the percentage of children so exposed would still be meaningfully different from the percentage exposed to the 70 ppb benchmark at least once per year. *See id.* (up to 4.9% of children with asthma and 4.3% of all children would experience multiple exposures to 60 ppb benchmark). The Administrator must strengthen the standard to prevent such a large percentage of children—particularly especially vulnerable children—from experiencing such dangerous exposures. *See Coal. of Ass'n of Battery Recyclers*, 604 F.3d at 618 ("this court has held that NAAQS must protect not only average healthy individuals, but also sensitive citizens such as children, and if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." (cleaned up)). At the very least, the Administrator must rationally explain (as he thus far has not) how the standard provides requisite protection for sensitive populations. *American Lung*, 134 F.3d at 392-93.

3. EPA fails to rationally explain how its approach protects more sensitive populations who are not subjects in controlled human experiments

Of the scientific evidence underlying the Administrator's Proposal to retain the current standard, the Administrator relies most heavily on chamber studies whose participants are solely healthy young adults. *See, e.g.*, 85 Fed. Reg. at 49,869/3-70/3. The Administrator notes EPA's prior identification of adverse effects demonstrated in chamber studies, which includes the adverse combination of lung function decrement and respiratory symptoms demonstrated to occur in healthy young adults at 72 ppb (or, EPA now contends, 73 ppb, *e.g.*, 85 Fed. Reg. at 49,856/2 n.80, 49,870/2, 49,872/1-2).[81] *See* 85 Fed. Reg. at 49,871/1-2; *e.g.*, 80 Fed. Reg. at 65,325/2, 65,330/2-31/2, 65,346/3, 65,363/1-2, 65,364/1. But, as explained above, the NAAQS must protect sensitive subpopulations, not merely healthy young adults. EPA acknowledges that people with asthma are more vulnerable to ozone. *E.g.*, 85 Fed. Reg. at 49,846/1, 49,848/1-49/1, 49,857/3-58/1, 49,863/3, 49,869/2-3. Yet the Administrator does not explain how he accounts for this greater vulnerability.

The consideration the Administrator gives to children with asthma focuses on curbing (but not eliminating) exposures to at least 70 ppb of ozone and, to a lesser degree, exposures to at least 60 ppb of ozone. *E.g.*, *id.* at 49,871/1-73/1. Nowhere does EPA explain what the results of chamber studies on healthy young adults mean for more sensitive populations exposed at similar levels: what do these studies mean for lung function decrement in such populations exposed at that level? What is the clinical significance of such lung function decrement? What about other

[81] This study accounts for the Administrator's focus on exposures to 70 ppb. *See, e.g.*, 85 Fed. Reg. at 49,856/2 & n.80, 49,870/2, 49,872/1-2.

effects that healthy young adults may not experience, but more sensitive populations would as a result of exposure at that level? It is possible to answer these questions. For example, in the prior review, CASAC expressly found that the chamber studies (which EPA agrees have not changed) showed that "in healthy subjects, decreases in lung function and respiratory symptoms occur at concentrations as low as 72 ppb and that these effects almost certainly occur in some people, including asthmatics and others with low lung function who are less tolerant of such effects, at levels of 70 ppb and below." EPA-HQ-OAR-2008-0699-0190 at 6 (discussing effects of 8-hour exposures to ozone). But without addressing such questions, EPA cannot rationally explain how it meets the statutory test of assuring the absence of adverse effect in sensitive populations. *See American Lung*, 134 F.3d at 392-93.

To be sure, EPA points to a few additional studies of people with asthma that EPA thinks means lung function response between people with asthma and people without asthma is similar, *id.* at 49,849/1, but, as CASAC notes, those studies do not look at people with more severe asthma or children. CASAC Consensus Responses on PA 8; *accord id.* at A-13, A-15 (comments of Dr. Frampton). Nor does EPA address what the significance of such lung function decrement is for sensitive populations, like children with asthma. *See id.* at 8 (warning that "suggest[ion] that lung function decrements in the absence of symptoms do not represent an adverse health effect…should not apply to children with asthma"); *id.* at A-15 (comments of Dr. Frampton).

EPA thus assumes that the level of lung function impairment—and the significance of such impairment—is similar for people who can bear it the least. There is no basis for that assumption. Moreover, as explained above, NAAQS are supposed to be protective and precautionary, including for sensitive populations. EPA's assumption is thus not just unexplained but also inconsistent with the Act and the controlling judicial interpretations of it.

4. Not strengthening the standard in view of this evidence would be arbitrary and unlawful

For the reasons given above, EPA's proposed decision not to strengthen the standards is arbitrary. Further, given the evidence available to it, its proposed decision is unlawful under the Clean Air Act.

As discussed above, the D.C. Circuit has made clear that NAAQS must protect against adverse effects in sensitive population—"[i]f a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard." *American Lung*, 134 F.3d at 389; *accord Coal. of Ass'n of Battery Recyclers*, 604 F.3d at 618; *see Lead Indus.*, 647 F.2d at 1153 ("the Administrator is to set standards which ensure that there is 'an absence of adverse effects.'"). In these binding decisions, the D.C. Circuit relied on, among other things, the Senate Report on the Clean Air Act Amendments of 1970. *See Coal. of Ass'n of Battery Recyclers*, 604 F.3d at 618 (quoting *American Lung* and noting that *American Lung* quotes S. Rep. No. 91-1196, at 10 (1970)); *American Lung*, 134 F.3d at 389 (quoting S. Rep. No. 91-1196,

at 10, and citing *Lead Industries* and noting that *Lead Industries* quotes S. Rep. No. 91-1196, at 10); *Lead Indus.*, 647 F.2d at 1152-53 (quoting S. Rep. No. 91-1196, at 10). That same Senate Report provides important additional detail about when "air quality is sufficient to protect the health of [sensitive individuals]":

> [W]henever there is an absence of adverse effect on the health of a statistically related sample of persons in sensitive groups from exposure to the ambient air. An ambient air quality standard, therefore, should be the maximum permissible ambient air level of an air pollution agent or class of such agents (related to a period of time) which will protect the health of any group of the population.
>
> For purposes of this description, a statistically related sample is the number of persons necessary to test in order to detect a deviation in the health of any person within such sensitive group which is attributable to the condition of the ambient air.

S. Rep. No. 91-1196, at 10. This test is fully consistent with the same portion of the same Senate Report that EPA cites, which explains that "[i]n establishing an ambient standard necessary to protect the health of these persons, reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group." *Id.*; *see also, e.g.*, 85 Fed. Reg. at 49,833/2 n.1 (citing and quoting same).

As mentioned above, the prior CASAC found that an 8-hour exposure to 70 ppb of ozone "almost certainly" causes the adverse combination of lung function decrements and respiratory symptoms in people with asthma. EPA-HQ-OAR-2008-0699-0190 at 6. This conclusion was based on the statistically significant results of the Schlegle study. Accordingly, under the Act, the NAAQS cannot lawfully be at the 70 ppb level, for such a level allows 70 ppb of ozone to occur every day, and EPA accepts the scientific evidence that shows adverse effects will occur for people with asthma when they are exposed to ozone at that level. And, to the extent EPA finds adverse effects occur at or below that level—as it must, per the preceding sections—the standard must be lower still.

G. Scientific studies compel strengthening the standard

1. Evidence of harms at levels that occur under the standard

EPA's own review of epidemiological studies mandates strengthening the standard. The epidemiology literature synthesis presented in the ISA indicates that a stronger standard (below 70 ppb) is merited, given robust evidence of health harms at lower exposure levels. An 8-hour maximum limit of 60 ppb aligns with the draft ISA finding evidence of lung function impairments, pulmonary inflammation, injury, oxidative stress and other respiratory symptoms

in children and adults exposed to ozone concentrations at that level or lower.[82] Many studies, including Kim et al. (2011), Schelegle et al. (2009), Adams (2006), and Brown et al. (2008), and Korrick et al. (1998)[83] provided the basis for EPA's conclusion that 60 ppb ozone concentrations can cause lung function decrements.[84] Studies published since March 2019 further confirm this link. For example, Dominici et al. (2019) analyzed data from 61 million Medicare enrollees, between the years 2000 and 2012, using exposure estimates based on sophisticated hybrid models with a resolution of 1 km^2 which included populations living in less well monitored areas. That study identified an association between all-cause mortality in a two pollutant analysis – including at levels below the current ozone NAAQS. Another study by Rhee et al. (2019), detailed earlier, also found that an increase 1 ppb in annual average ozone levels was associated with statistically significant increases in annual hospital admission rates for ARDS of 0.72% (95% CI, 0.62-0.82) and 0.15% (95% CI, 0.08-0.22), respectively. Importantly, this effect remained in in low-pollution regions meeting the current NAAQS (annual average PM2.5 level < 12 $\mu g/m^3$ and annual average ozone level < 45 ppb). In those areas, the 1 ppb annual increase in ozone was associated with an increase in annual hospital admission rates for ARDS of 0.27% (95% CI, 0.16-0.38).

2. EPA arbitrarily discounts scientific studies

In its Proposal, EPA distorts the available epidemiology studies by discounting those that analyzed health impacts in areas that met the current standard for some (but not all) of the study duration or those with mixed findings across several cities, some of which in exceedance of the standard. It notes that "[t]he extent to which reported associations with health outcomes in the resident populations in these studies are influenced by the periods of higher concentrations during times that did not meet the current standard is unknown", and asserted that multicity study findings "complicat[e] interpretations regarding the contribution of concentrations in the small subset of locations that would have met the current standard compared to that from the larger number of locations that would have violated the standard." However, elsewhere in the Proposal EPA taken steps to further analyze reported findings from Schelegle et al. (2009) that showed reduced lung function and increased pulmonary inflammation at levels below the current NAAQS to argue that no further strengthening of the standard is needed because, in its interpretation, average during the entire study period did not meet the current NAAQS. Elsewhere, EPA has used the fact that short- and long-term exposures occur concurrently to

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[82] Draft ISA at IS-24 to IS-25.

[83] Korrick S A, Neas L M, Dockery D W, Gold D R, Allen G A, Hill L B, Kimball K D, Rosner B A, and Speizer F E. "Effects of Ozone and Other Pollutants on the Pulmonary Function of Adult Hikers." Environmental Health Perspectives 106, no. 2 (February 1, 1998): 93–99. https://doi.org/10.1289/ehp.9810693

[84] Comments of Peter Valberg and Julie Goodman. Regarding the U.S. EPA's ISA for Ozone (External Review Draft) (2019). November 25, 2019. Pg. 6. *Available at* https://yosemite.epa.gov/sab/sabproduct.nsf//23AC2DE8637E771F852584BE006CD0D7/$File/Gradient_Ozone_ISA_Testimony.pdf

avoid adequate consideration of both single and multicity studies. EPA asserts in the Proposal that "[t]he quantitative exposure and risk analyses completed in this review update and in many ways improve upon analyses completed in the last review" when it has not conducted appropriate analyses of the scientific studies that inform these analyses. EPA has therefore inconsistently weighed the evidence, conducted biased analyses, and arbitrarily dismissed the findings of specific studies without justification.

Importantly, §109(b)(1) of the Clean Air Act calls for creation of NAAQS that are 'requisite to protect the public health' with 'an adequate margin of safety'. This suggests that we are not limited by evidence where a model unequivocally shows an effect with no ambiguity whatsoever, nor is EPA limited to consideration of studies in areas meeting the current NAAQS when considering whether to revise the standard.

EPA and some CASAC members insists on prioritizing evidence from "manipulative or interventional causation" studies and discounts other forms of causation (e.g., epidemiological causation, but-for causation, mechanistic causation, etc.). Epidemiological studies are not the sole determinant of causality; rather, they provide supplemental support to evidence obtained from other disciplines and demonstrate a coherence of information across studies.[85]

Lastly, the Administrator makes note of "uncertainty" that remains because there are few observations available at concentrations levels substantially below the current standard.[86] This lack of information, rather than a reason to maintain the weak 2015 standard, should motivate a strengthened ozone standard, because of the likelihood of adverse health effects at levels substantially lower than current federal limits. The very multicity domestic epidemiologic studies that would provide the studies the Administrator claims would help resolve uncertainty for him will continue to be difficult to execute without further declines in ambient ozone concentrations mandated by the Agency.

H. EPA's treatment of the exposure and risk analysis is arbitrary

EPA relies on its updated exposure assessment to support its proposed retention of the primary standard. Specifically, EPA points to the exposure assessment to claim that small percentages of key populations (including children and asthmatic children) would experience multiple exposures of concern in areas just meeting the current 70 ppb standard.[87] EPA's approach is inconsistent with the Clean Air Act, which promises air in which people can engage in their normal range of activity free from adverse effects. Moreover, due to critical limitations

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[85] Comment of Jennifer Richmond-Bryant. Regarding the U.S. EPA's Draft Ozone ISA (2019). December 3, 2019. Pg. 2. *Available at* https://yosemite.epa.gov/sab/sabproduct.nsf/81594E33A5C673CE852584BD0078F919/$File/O3+ISA+Public+Comments+WRITTEN.pdf

[86] *See*, *e.g.*, 85 Fed. Reg. at 49,871-2.

[87] 85 Fed. Reg. at 49860, Tbl. 2.

of the APEX model discussed below, EPA's exposure assessment provides no support for EPA's population-level claims. First, APEX uses high-level demographic variables like age and gender to establish activity profiles. But EPA has failed to establish that these high-level demographic variables are predictive of time spent outdoors with elevated ventilation rates, the critical metric for predicting exposures of concern. Second, APEX's modeling of individuals is flawed and systematically underestimates the likelihood of multiple exposures of concern for simulated individuals, thereby overstating the protectiveness of the modeled air quality standards. Critically, EPA's assessment provides no relevant information for key groups, including outdoor workers and summer camp attendees, who are most likely to experience harmful effects due to prolonged and repeated harmful ozone exposure. For all the reasons that follow, EPA's approach is unlawful and arbitrary.

1. The Clean Air Act requires NAAQS to be set without consideration of how often people will intersect with unsafe air

EPA's reliance on its exposure assessment is unlawful and inconsistent with the Act. Section 109 of the Act mandates that EPA set the NAAQS at a level that allows the public to spend time outdoors engaged in their normal activities and that the air will be clean enough to "protect the public's health with an adequate margin of safety." This mandate "carries the promise that ambient air in all parts of the country shall have no adverse effects upon any American's health." 116 Cong. Rec. 81 (Dec. 18, 1970) (remarks of Senator Muskie, floor manager of the conference agreement). Indeed, EPA has previously recognized this to be the case:

> Standards must be based on a judgment of a safe air quality level and not on an estimate of how many persons will intersect given concentration levels. EPA interprets the Clean Air Act as providing citizens the opportunity to pursue their normal activities in a healthy environment.

44 Fed. Reg. at 8,210.

Here, EPA is unlawfully using its exposure assessment to subvert this mandate. EPA relies on the exposure assessment to support a standard that results in levels of air quality that are unsafe for people engaging in normal outdoor activity based on EPA's projection that only a small percentage of people will experience multiple exposures of concern. As set forth below, EPA's methodology for projecting exposures of concern is flawed and systematically understates the fraction of people who will experience harmful exposures. Especially in light of these deficits in EPA's model, a precautionary and protective approach must be applied. When such uncertainties suggest that it might be unsafe to be active outside, or that some at-risk groups could experience more frequent exposures of concern than indicated by the modeling, EPA must act in favor of protecting sensitive groups.

2. EPA's has failed to rationally explain the basis for limiting its exposure assessment to eight cities or for the eight cities chosen

EPA's exposure assessment accompanying the current Proposal is far more limited than for the 2015 standard. Whereas in 2015 EPA evaluated 15 urban areas, accounting for 19 million school age children and 85 million people aged 5 to 95,[88] the "streamlined"[89] list of eight study areas in the present exposure assessment represent less than half (42 million people) of the prior analysis.[90] While EPA acknowledges that "the exposure and risk analyses are not intended to provide a comprehensive national assessment,"[91] it fails to provide a rational basis for limiting the assessment to the degree and in the manner it did. This restricted assessment is arbitrary, capricious, and an abuse of the Agency's discretion.

EPA's criteria for selection of urban study areas are inadequately explained. In the Policy Assessment, EPA states that it "developed criteria" for selection of urban areas for the exposure and risk analysis.[92] Yet the Agency provides no information on how those criteria were developed or why they are appropriate. EPA simply asserts—without explanation—that the set of areas "was chosen to ensure it reflects the full range of air quality and exposure variation expected in major urban areas in the U.S. with air quality that just meets the current standard."[93] It is not clear how (or whether) most of the identified criteria bear on whether the set of chosen areas reflects the full range of air quality and exposure variation expected in major U.S. urban areas. Among other things:

- EPA fails to explain why the urban study areas used in this analysis should be a subset of those from the 2014 Health Risk and Exposure Assessment.[94]
- EPA fails to provide any basis for either its lower bound Combined Statistical Area/Metropolitan Statistical Area population of 2 million or its upper bound of 10 million.[95] Instead, EPA irrationally claims that those arbitrarily-selected bounds demonstrate that "[t]he eight study areas represent a variety of circumstances with regard to population exposure to short-term concentrations of O_3 in ambient air."[96] To the contrary, they merely demonstrate that EPA selected urban areas within apparently arbitrary population bounds.

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[88] 2014 Final HREA at 5-10, Tbl. 5-1 (Aug. 29, 2014).
[89] 85 Fed. Reg. at 49854/2.
[90] *See* 2020 Policy Assessment, *supra*, n. 64, at 3C-14, Tbl. 3C-1.
[91] *Id.,* at 3-61.
[92] *Id.,* at 3D-16.
[93] 85 Fed. Reg. at 49854/2.
[94] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-16.
[95] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-17.
[96] 85 Fed. Reg. at 49854/2.

- EPA fails to explain why the urban study areas must have at least 10 ambient air monitors.[97] Beyond the fact that the number 10 itself is arbitrary, eliminating urban areas with fewer than 10 monitors makes little sense because EPA's modeling does not have an accurate way of modeling people's movement around the study area. Other than having the ability to model commuting behavior, the model presumes that activity occurs within a given air district. EPA provides no indication of why APEX modeling of an urban area with fewer than 10 ambient air monitors would be less accurate than one with 10 or more.

Ultimately, EPA's selection of study cities is arbitrary because EPA did not even adhere strictly to its own criteria. For example, EPA included Sacramento even though its 2015-2017 DV was 86 ppb, a concern that CASAC flagged in its consensus letter.[98] And EPA excluded cities from the prior review that meet its criteria, including Cleveland, OH, Washington, DC, and Houston, TX,[99] without adequate explanation.

3. EPA fails to show that the APEX model provides meaningful estimates of population-level exposures for the urban areas analyzed

Even if EPA's selected urban areas were representative in all the ways that EPA claims[100]—which it has not established—EPA fails to demonstrate that APEX provides data that meaningfully reflect population-level exposures. This is because the demographic data that APEX uses to establish user profiles have not been shown to reflect the variables that correlate with whether people are likely to spend extended periods of time outdoors at moderate levels of physical activity—the preconditions for exposures of concern. While acknowledging that "a single profile does not, in isolation, provide information about the study population," EPA claims that "a distribution of profiles represents a random sample drawn from the study area population" and, "[a]s such, the statistical properties of the distribution of simulated profiles are meant to reflect statistical properties of the population in the study area."[101] But EPA fails to establish that this is so.

APEX functions by "[c]onstruct[ing] an activity event sequence (a minute-by-minute time-series) by selecting a sequence of appropriate daily activity diaries for the simulated individual (using demographic and other influential variables)."[102] "**[A]ctivity patterns of the sampled individuals** (e.g., the specification of indoor and other microenvironments, the duration of time spent in each) **are assumed by the model to be similar to individuals with similar demographic characteristics**, according to activity data such as diaries compiled in EPA's

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[97] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-17.
[98] *See* CASAC Review of PA, *supra* n. 33 at 10.
[99] The 2015-2017 design value for Houston is 81 ppb, which is just outside EPA's range of 60 to 80 ppb, but notably much closer to that range than Sacramento (DV of 86 ppb).
[100] 85 Fed. Reg. at 49854/2.
[101] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-20.
[102] *Id.,* at 3D-16.

Consolidated Human Activities Database (CHAD)."[103] According to the model's documentation, these demographic characteristics are: age, gender, race, and work status.[104] But EPA provides no regression analysis (R^2 value) or other quantitative or qualitative analysis to establish that these variables alone or in combination reasonably and accurately explain the amount of time an individual spends outdoors engaging in moderate (or higher) levels of exertion. If these variables do not capture the relevant variability in this metric, then an extrapolation of behavior from thousands of simulated individuals based exclusively on their demographic characteristics provides no meaningful information about how many people would experience exposures of concern.[105]

4. EPA fails to show that the APEX model provides meaningful estimates of individual exposures

The population-level problems with APEX are compounded by equally profound individual-level issues with the model. EPA acknowledges that "exposures could be underestimated for some population groups that are frequently and routinely outdoors during the summer (e.g., outdoor workers, children)."[106] In particular, "longitudinal activity patterns do not exist for these and other important population groups (e.g., those having respiratory conditions other than asthma), thus limiting the extent to which the exposure model outputs reflect these groups that might routinely experience high exposure concentrations."[107] Given EPA's focus on assessing multiple exposures of concern, this reliance on modeling that fails to accurately represent the groups most likely to experience such multiple exposures is fatal to EPA's reliance on its exposure modeling, and is arbitrary, capricious, and an abuse of discretion.

APEX models exposures in a way that homogenizes individuals based on demographic characteristics and mutes important variability. As the model's documentation explains, "APEX creates seasonal or year-long sequences of activities for a simulated individual by sampling human activity data from more than one subject in CHAD," resulting in "uncertainty . . . about season-long exposure event sequences."[108] EPA acknowledges that "[t]his approach **can tend to underestimate the variability from person to person because each simulated person**

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[103] APEX, Version 5.2: Volume I: User's Guide (Oct. 2019), at 3, *available at* https://www.epa.gov/sites/production/files/2019-12/documents/apex52_usersguide_vol1_october2019.pdf (hereinafter APEX Documentation, Vol. I).
[104] APEX Documentation Vol. I at 21.
[105] There are other limitations with APEX as well, including the fact that "The population activity pattern data supplied with APEX (CHAD activity data) are compiled from a number of studies in different areas and for different seasons and years. Therefore, the combined data set may not constitute a representative sample." APEX Documentation, Vol. I at 5.
[106] *See* 2020 Policy Assessment, *supra*, n. 64, at 3-72.
[107] *Id.,* at 3-72.
[108] APEX Documentation Vol. I, at 5.

essentially becomes a composite or an "average" of several actual people in the underlying activity data (which tends to dampen the variability)."[109]

For example, "[s]imulated individuals are assigned activity diaries longitudinally without regard to occupation or school schedule . . . ."[110] Rather, "[o]nce APEX identifies the basic personal attributes of a simulated individual . . . and daily air temperatures . . ., activity pattern data obtained from CHAD . . . are then selected based on age, sex, temperature category, and day of the week."[111] The model does recognize the need for autocorrelation in developing longitudinal activity pattern sequences,[112] but EPA selected a method for autocorrelating (the diversity & autocorrelation method) that produces lower estimates of multiple exposures of concern than, for example, the Markov-chain clustering method it considered.[113] And EPA has not shown that any of the autocorrelation methods it evaluated provides a reasonable simulation of groups such as outdoor workers or children attending summer camp that consistently spent long periods of time outdoors with elevated levels of respiration.

5. Key groups are not appropriately modeled or considered in the exposure assessment

Due at least in part to the limitations discussed above, key groups that are most likely to experience multiple exposures of concern or are particularly vulnerable are not appropriately modeled or considered in EPA's exposure assessment. This is arbitrary.

i. Children attending outdoor summer camps

Every year more than 14 million children, and adults, attend camps in the United States, in addition to over 1.5 million camp workers.[114] Most camps last for at least a week,[115] and many

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[109] APEX Documentation Vol. I at 5.
[110] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-92.
[111] *Id.,* at 3D-54.
[112] With regard to the three alternate methods for longitudinal activity pattern sequences that EPA considered, EPA explains that Che et al. (2014) found: "little difference was observed across the methods with regard to estimates of the mean exposures of simulated individuals. Differences were observed, however, in the number of multiday exposures exceeding a selected benchmark concentration." 2020 Policy Assessment at 3D-60. Those differences were substantial, about 12-14%. *Id.*
[113] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-60.
[114] American Camp Association, ACA Facts and Trends, *available at* http://www.acacamps.org/media/aca-facts-trends (accessed Sept. 9, 2020).
[115] American Camp Ass'n, Camper Enrollment Report 2017, at 4, available at https://www.acacamps.org/sites/default/files/resource_library/2017_CamperEnrollmentReport.pdf.

for a month or two,[116] frequently offering overnight camps. The most popular camper age is 9-12 years old,[117] and most camp activities take place outdoors. According to one survey, over 75 percent of both overnight and day camps said campers spent more than seven hours a day outside in the open air and only one camp reported less than two hours a day spent in the open air.[118] Studies of children at summer camps, where they experience sustained outdoor activity, show that short-term ozone exposure is associated with decreased respiratory function,[119] even when restricted for levels above 60 ppb.[120] Studies of children at summer camp with asthma have also shown increased risk of respiratory symptoms on high pollution days as well as decreases in lung function.[121]

EPA's exposure assessment does not meaningfully address summer camp attendees. As noted above, in APEX "[s]imulated individuals are assigned activity diaries longitudinally without regard to occupation or school schedule . . . ."[122] The model does not attempt to simulate children whose summer days are primarily spent engaging in outdoor activity. Epidemiological studies looking at active children who spend significant time outdoors call into question the representativeness of EPA's modeling. For example, McConnell et al. showed that active children who played three or more sports growing up in communities with eight-hour ozone levels ranging from 55.8 ppb to a maximum of 69 ppb were three times more likely to develop asthma than their peers in communities with lower ozone levels, ranging from 30.6 to 50.9 ppb.[123] EPA's exposure assessment provides no meaningful information about these regularly active children.

ii. Outdoor workers

There are millions of outdoor workers in the United States. According to the Bureau of Labor Statistics, in 2014 there were approximately 29 million workers in industries with outdoor work including agriculture, forestry, fishing, and hunting (2.1 million), construction (7.0 million), leisure and hospitality (12.5 million), mining, quarrying, and oil and gas extraction (0.5

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[116] *Id.*
[117] *Id.* at 16.
[118] P.A. James & K.A. Henderson, Camps and Nature Report (2007), *available at* http://www.acacamps.org/sites/default/files/images/research/understand/camps_nature_report.pdf.
[119] *See e.g.*, P.L. Kinney, G.D. Thurston, M. & Raizenne (1996). The effects of ambient ozone on lung function in children: A reanalysis of six summer camp studies, *Env. Health Perspect.*, 104(2): 170-174; .D. Thurston, M. Lippmann, M.B. Scott, & J.M. Fine (1997). Summertime haze air pollution and children with asthma, *Am. J. of Resp. and Crit. Care Med.*, 155(2): 654-660.
[120] Spektor, D.M., et al. (1988). Effects of ambient ozone on respiratory function in active, normal children, *Am. Rev. of Resp. Disease*, 137(2): 313-320.
[121] D. Thurston, M. Lippmann, M.B. Scott, & J.M. Fine (1997). Summertime haze air pollution and children with asthma, *Am. J. of Resp. and Crit. Care Med.*, 155(2): 654-660.
[122] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-92.
[123] R. McConnell et al. (2002). Asthma in exercising children exposed to ozone: A cohort study, Lancet, 359(9304): 386-391.

million), transportation and warehousing (4.2 million), and utilities (0.6 million).[124] By EPA's own admission, "[a]bout one third of workers were required to perform outdoor work in 2018." 85. Fed. Reg. 49,850.

EPA acknowledges that it did not attempt to simulate outdoor workers in its present review of the primary standard.[125] Instead it points back to the "targeted analysis" (single study area, single year) that was conducted in the 2014 Health Risk and Exposure Assessment (HREA)[126] and asserts that if a similar approach were used for this assessment, the results would be "expected" to be "similar" to 2014.[127] Assuming this is correct, the results of the 2014 analysis confirm that outdoor workers face outsize risks of adverse effects in areas just meeting a range of standards, including the current 70 ppb standard. As EPA explained in the 2014 HREA:

> The percentages of people experiencing one or more FEV1 decrements ≥ 15% during the 2006 O_3 season in Atlanta are 3.6 times higher for outdoor workers than for the general population (ages 19-35) under the existing [75 ppb] standard, and range up to 5.3 times higher for the alternative standards [down to 60 ppb]. The percents of people experiencing six or more FEV1 decrements ≥ 15% during the 2006 O3 season in Atlanta are 24 times higher for outdoor workers than for the general population under the existing [75 ppb] standard, and range up to 150 times higher for the alternative standards [down to 60 ppb].[128]

For the now-current 70 ppb standard, EPA's modeling found that 3.2 percent of outdoor workers would experience at least one FEV1 decrement of 15 percent or greater and nearly 1 percent (0.93%) would experience six or more such FEV1 decrements. The present 70 ppb standard is plainly inadequate to protect this vulnerable group.

EPA's basis for its "expect[ation]" is also unexplained and thus arbitrary. To the extent it relies on the overall output of the 2014 HREA being "similar" to the overall output of the new exposure estimate, EPA fails to explain how an overall similarity implies that all the subgroups that go into making up that overall result are also similar, rather than where the results for one subgroup have shown higher impacts, but are canceled out by lower impacts on another group. Further, EPA goes into great detail describing the underlying dissimilarities between the 2014 HREA and the current exposure assessment. These include significant changes in the areas studied. The overall output of the two studies may be similar, but, given the difference in input, EPA fails to provide any rational basis for concluding that this targeted analysis is also similar.

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[124] Bureau of Labor Statistics, Jobs for People Who Love Being Outdoors (July 2017), at Chart 1, available at https://www.bls.gov/careeroutlook/2017/article/outdoor-careers.htm.
[125] *See* 2020 Policy Assessment, *supra*, n. 64, at 3-62.
[126] *Id.,* at 3-62, n.78.
[127] 85 Fed. Reg. at 49859 n.89.
[128] 2014 Health Risk and Exposure Assessment at 6-28.

iii. People with asthma

Despite its recognition that, under similar exposure circumstances, the health risk to people with asthma is "greater . . . relative to other population groups,"[129] EPA's exposure assessment irrationally and arbitrarily presumes people with asthma will experience identical lung function decrements to healthy individuals when confronted with the same exposures of concern.

EPA acknowledges that controlled human exposure studies are conducted using healthy young adults[130] and "recognize[s] the lack of evidence from controlled human exposure studies at the lower concentrations of greatest interest (e.g., 60, 70 and 80 ppb) for children and for people of any age with asthma."[131] Thus, EPA concludes, "the health effects documented in controlled human exposure studies of healthy adults may [] contribute to more severe outcomes when occurring in people with asthma."[132]

Irrationally, in its exposure assessment, EPA nevertheless presumes people with asthma will experience the same lung function decrements as healthy people for a given exposure, extrapolating FEV decrements for people with asthma based on the same susceptibility as healthy individuals.[133] EPA even caveats that: "there is uncertainty regarding the interpretation of the exposure and risk estimates and the extent to which they represent the populations at greatest risk of O3-related respiratory effects."[134] But EPA still plows forward undaunted with its reliance on the exposure assessment to purportedly show exposure risks to people with asthma are acceptable. This is arbitrary.

6. EPA arbitrarily fails to acknowledge or account for averting behavior

The exposure assessment irrationally ignores the possibility that the results are influenced by averting behavior, a possibility EPA analyzed and discussed in 2015, but entirely failed to address in this review. In 2015, EPA recognized that many people, including children, avert outdoor activity and that its exposure estimates may be inaccurate due to their failure to capture averting behavior. In discussing activity diaries in that review, EPA noted that "we do not know if any diary day represents the activities of an individual who averted,"[135] and EPA conducted a "no averting" simulation to address this possibility.

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[129] *See* 2020 Policy Assessment, *supra*, n. 64, at 3-71.
[130] *Id.,* at 3-71.
[131] 85 Fed. Reg. at 49857.
[132] 85 Fed. Reg. at 49857; 2020 Policy Assessment at 3-71.
[133] 2020 Policy Assessment at 3-66.
[134] *Id.*, at 3-72; *see also* 85 Fed. Reg. at 49857-58.
[135] 2014 Health Risk and Exposure Assessment at 5-53, n. 27.

In the present review, averting is nowhere discussed.[136] Yet, EPA fails to offer any explanation why the possibility that averting behavior influenced the activity diaries relied on in the APEX modeling is no longer an issue in this review. If the activities documented in the activity diaries were influenced by averting and reflect the actions of people who chose to stay inside due to poor air quality, this further undercuts the representativeness of EPA's exposure modeling by understating the amount of time people would spend outdoors with healthier air. This is arbitrary.

7. Other issues with the exposure assessment

There are several additional problems with EPA's exposure assessment that further render the Agency's reliance on it arbitrary and unlawful. These include:

- Inadequate consideration of environmental justice: While EPA acknowledges in numerous places that there are strong correlations between asthma prevalence and race, EPA did not address correlations between asthma and race in attributing asthma prevalence to simulated study populations.[137]
- Failure to follow CASAC advice regarding quantitative uncertainty analysis: CASAC commented in its consensus letter that EPA failed to provide uncertainty bounds on its exposure and risk estimates, explaining that the ranges presented "represent variability between cities, not uncertainty."[138] CASAC noted that "this type of uncertainty is a prime candidate for a quantitative uncertainty analysis because there are estimates on the uncertainties associated with the air quality estimates."[139] Yet EPA has not addressed this in its final Policy Assessment nor proposed rule.
- Failure to adequately address CASAC advice regarding model performance evaluation: In its consensus letter on the policy assessment, CASAC urged that, "[i]n addition to the ozone [model performance evaluation] MPE, it would be useful to perform an MPE for the ozone precursors (NOx and VOCs)."[140] CASAC explained that, "[i]f the precursor concentrations don't match the observations, the HDDM sensitivity results may not be accurate even if the ozone concentrations match observations."[141] Nevertheless, EPA did not provide a model performance evaluation for ozone precursors in its final Policy Assessment or proposed rule.
- Failure to address EPA's own analysis showing a lower standard would significantly reduce exposures of concern for sensitive groups: Even if EPA's reliance on its exposure assessment were not arbitrary, EPA fails to articulate a rational basis for rejecting lower standards, which (per EPA's modeling) substantially reduce and nearly eliminate

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[136] There is no discussion of averting behavior and the possibility that activity diaries were influenced by averting behavior in the proposed rule or the final Policy Assessment.
[137] *See* 2020 Policy Assessment, *supra*, n. 64, at 3D-25.
[138] *See,* CASAC Review of PA, *supra* n. 33, at 10.
[139] *Id*.
[140] *Id*., at 11.
[141] *Id*.

exposures of concern for children and children with asthma—two important sensitive groups.[142]

8. EPA arbitrarily limited and dismisses the risk assessment

EPA unlawfully and arbitrarily proposes to dismiss the risk assessment. At base, EPA rejects it because the risk assessment extrapolates in an effort to address sensitive populations. *See* 85 Fed. Reg. at 49,858-59 & n.87; *see also id.* at 49,857. But EPA's statutory responsibility is to protect sensitive populations based on the information available to EPA. As explained above, EPA has limited the information it chiefly relies on to studies solely of healthy young adults. Those studies cannot ethically test the most sensitive populations. EPA has thus positioned itself to never be able to comply with the statute: the studies it relies on cannot test the populations it must protect, and EPA rejects extrapolation to address those populations. EPA's position is unlawful under the Act and arbitrary.

The draft ISA incorporates content that would normally be published separately as the draft HREA and WREA. "Combining assessment steps in this manner such that they are reviewed concurrently and without sequencing or iteration undermines the integrity of the review process."[143]This is especially concerning as the HREA is important to setting the primary ozone standard.

I. To the extent the CASAC's recommendations have any validity, EPA has unlawfully and arbitrarily departed from some of them

As explained above, EPA's CASAC was illegally constituted and failed to meet its obligations during the ozone review. Despite these enumerated failings, the Agency itself must fulfil certain obligations in responding to and incorporating the advice of the CASAC. However, just like CASAC failed to fulfill its obligations to the Agency, so too did the Agency fail to meet its statutory obligations with respect to the committee. These obligations are separate and distinct from those of the committee itself, and EPA must fulfil its statutory obligations to consider the advice of CASAC.

The Act expressly requires EPA, in developing standards, to consider the advice of the statutorily created CASAC and rationally explain any important departure from CASAC's recommendations. 42 U.S.C. §§ 7409(d)(2)(B), 7607(d)(3). When CASAC makes a scientific finding, it is not enough for EPA merely to "disagree" with CASAC's findings on policy grounds: "to the extent that CASAC has exercised scientific judgment, EPA must respond in kind." *Mississippi*, 744 F.3d at 1358. Nor can EPA rotely invoke "uncertainty" to justify

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[142] *Cf.* 2020 Policy Assessment, *supra* n. 33, at 3-66, Tbl. 3-4 *with id.* at 3-69, Tbl. 3-5.
[143] *See* Former CASAC Advice Letter, *supra,* n.7, pg. 7).

disagreeing with CASAC's scientific judgment. *Id.* at 1357. Instead, "EPA must explain why the evidence on which CASAC relied cannot support the degree of confidence CASAC placed in it. This is especially true given the added layer of stringency imposed by EPA's obligations under section 307(d)(6)." *Id.* Even if CASAC makes a policy, rather than scientific, recommendation that EPA departs from, EPA must explain its reasoning for not accepting the recommendations of CASAC. *Am. Farm Bureau Fed'n*, 559 F.3d at 521. Even if the Act did not so require, settled principles of administrative law would require EPA to reconcile any disparity between its standards and those recommended by CASAC. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Under the Act, EPA's Proposal must "set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by [CASAC]," and "if the Proposal differs in any important respect from any of these recommendations," must set forth "an explanation of the reasons for such differences." 42 U.S.C. § 7607(d)(3). Thus, EPA "must fully explain" its reasons for any departure from CASAC's recommendation. *Mississippi v. EPA*. 744 F.3d 1334, 1354 (D.C. Cir. 2013). EPA must also provide such an explanation in the final rule. Id. 1355. Further, "EPA must be precise in describing the basis for its disagreement with CASAC. If EPA's quarrel is with CASAC's scientific analysis, then in order to preserve the integrity of CASAC's scientific role, EPA must give a sound scientific reason for its disagreement." *Id.* As an example—and others are given throughout these comments—though the Proposal reaffirms many times that EPA agrees with CASAC that the current review does not "substantially differ"[144] from the 2015 review, unlike the 2015 review, the Administrator only proposes a standard set at 70, as opposed to, at minimum, exploring a full range of standards between 60 and 70 ppb, and specifically, a standard below 70, to account for CASAC's previous finding, reiterated by a part of the committee during this review, that a standard set at 70 would not include an adequate margin of safety.[145]

The Proposal does not directly discuss proposing a range of standards to below 70 to consider, like the 2015 standard. Instead, the Administrator points to the "slight differences of the current exposure and risk estimates from the 2014 HREA estimates for the lowest benchmark" that he notes are in part due to "the use of air quality data reflecting concentrations much closer to the now-current standard than was the case in the 2015 review" as a reason to maintain the standard at 70 ppb and "a more stringent standard is not needed." 85 Fed. Reg. 49,873. Much like background ozone levels and their purported impact on the standards' attainability in setting the standard cannot inform the NAAQS-setting process, so too does the

[144] *See, e.g,* "the Administrator considers the advice and conclusions of the CASAC, including particularly its overall agreement that the currently available evidence does not substantially differ from that which was available in the 2015 review when the current standard was established. 85 Fed. Reg. 49,869,

[145] *See, e.g.,* "[The Administrator] also notes that another part of the CASAC indicated its agreement with the prior CASAC comments on the 2014 draft PA, in which the prior CASAC opined that a standard set at 70 ppb may not provide an adequate margin of safety (Cox, 2020, p. 1)"

fact that air quality is improving due to progress meeting legally required standards seem irrelevant to the inquiry of whether or not a lower standard is appropriate. EPA has failed to fulfil its statutory obligations to fully explain its departures from CASAC's advice, an obligation that it must meet regardless of any procedural or substantive flaws with CASAC's review.

V. THE ADMINISTRATOR'S PROPOSED DECISION TO RETAIN THE SECONDARY STANDARD FOR OZONE IS UNLAWFUL AND ARBITRARY ON ITS MERITS.

It is well-established that ozone harms growing plants, and that it harms them in a different way from how it harms humans. For humans, EPA has long focused on short-term peak ozone levels, whether over a 1- or 8-hour period, for such exposures cause a welter of well-documented adverse effects on human health, especially when people breathe at elevated rates. By contrast, ozone harms plants over the course of a growing season as the amount of ozone they are exposed to accumulates. Thus, scientists have developed the W126 metric, which looks at weighted, cumulative ozone levels, over an extended time period. EPA has recognized this W126 metric over the last 15 years as the most biologically relevant form for protecting vegetation. These two ways of looking at ozone levels do not overlap perfectly: a community without harmful short-term peaks may have persistent ozone levels that can cumulatively harm plants, and vice versa.

Yet EPA has repeatedly declined to set the standard in this biologically relevant form, instead reverse engineering its reasoning on the secondary standard to justify adopting the primary standard as the secondary standard. Unsurprisingly, EPA's decisions regarding the secondary standard have been repeatedly rejected by the D.C. Circuit because EPA ignored the Act's requirements and made irrational decisions. *See Murray Energy*, 936 F.3d at 617-20 (EPA arbitrarily departed from the science and failed to specify a level of air quality requisite to protect public welfare); *Mississippi*, 744 F.3d at 1358-62 (EPA illegally and arbitrarily failed to specify a level of air quality requisite to protect public welfare). EPA proposes to once again override the science and keep the secondary standard as the biologically ill-fit primary standard. Just like its two prior final actions, this Proposal is arbitrary and unlawful for the reasons given below.

A. EPA's legal obligations in setting and reviewing the secondary standard

The Act requires EPA to set and periodically revise secondary ambient air quality standards that protect public welfare, 42 U.S.C. §§ 7408(a), 7409(a)-(b), and

> [S]pecify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, 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.

Id. § 7409(b)(2).

Under the Act, "[t]o ensure that the NAAQS take account of the current science," EPA must complete a thorough review of the standards "at least once every five years." *Id.* § 7409(d)(1); *Nat'l Ass'n of Mfrs. v. EPA*, 750 F.3d 921, 923 (D.C. Cir. 2014) ("To ensure that the NAAQS take account of current science, the Clean Air Act directs EPA to review the standards at least once every five years.") (citation omitted). During this review, EPA must revise the criteria and standards or promulgate new standards as appropriate. 42 U.S.C. § 7409(d)(1). The secondary ("welfare") standards "shall specify a level of air quality the attainment and maintenance of which…is requisite to protect the public welfare from any known or anticipated adverse effects." 42 U.S.C. § 7409(b)(2); *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 530 (D.C. Cir. 2009). Effects on welfare include impacts on "soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants." 42 U.S.C. § 7602(h). Senator Muskie, one of the prime architects of the Act, in speaking about the amendments for public welfare during the Senate debates, noted that the protections for public welfare "are especially important because some pollutants may have serious effects on the environment at levels below those where health effects may occur" and will be set to be "protective against any know[n] or adverse environmental effects."[146] The congressionally mandated "ongoing, periodic review and revision process set up by Congress…ensure[s] that regulatory guidelines and standards which protect human safety and welfare are kept abreast of rapid scientific and technological developments," *American Lung Ass'n v. Browner*, 884 F. Supp. 345, 347 (D. Ariz. 1994), and that "as the contours and texture of scientific knowledge change…EPA's NAAQS review necessarily changes as well." *Mississippi*, 744 F.3d at 1344; *see also* discussion and caselaw cited above. The CASAC is chartered to offer recommendations on the secondary as well as the primary NAAQS.

B. EPA's repeated failures to obey the Act's requirements when it establishes secondary standards means it is acting here on remand of two NAAQS, as well as a fresh review.

In 2008, EPA revised the ozone NAAQS, setting the secondary ozone standard once more equal to the primary standard. 73 Fed. Reg. 16,436. EPA had proposed to set a standard with W126 form, but, after the Office of Management and Budget and then-President Bush noted their extra-statutory preference for a secondary standard equal to the primary, EPA ultimately

[146] Legislative History of Clean Air Act Amendments of 1970 at 227 (Senate Debate on S. 4358, Sept. 21, 1970).

decided not to. *Id.* at 16,497/2-3; *see also* Final Opening Br. of State Pet'rs 32-36, *Mississippi v. EPA*, No. 08-1200 (DC. Cir. Aug. 27, 2012) (#1391391) (detailing history). EPA's 2008 decision was unlawful because EPA failed to specify the requisite level of air quality to protect against adverse effects. *Mississippi*, 744 F.3d at 1361-62 ("Because EPA failed to determine what level of protection was 'requisite to protect the public welfare,' EPA's explanation for the secondary standard violates the Act.").

EPA incorporated its response to the *Mississippi* remand into the 2015 ozone NAAQS. 80 Fed. Reg. at 65,369/2. But the 2015 secondary ozone NAAQS was itself arbitrary. CASAC provided clear scientific advice that EPA's proposed three-year averaging approach lacked scientific grounding, and that, if EPA insisted on pursuing it anyhow, EPA should set the three-year average to prevent damaging single-year exposures that a three-year average "obscure[s]." *Murray Energy*, 936 F.3d at 617. But real-world data showed that the 3-year W126 benchmark EPA relied on did not prevent those harmful levels, and EPA had no rational response. *Id.* Nor had EPA rationally shown that "single-year effects matter less than a three-year average." *Id.* Because of its holding about the irrationality of EPA's three-year averaging, the Court expressly declined to reach the question of whether EPA had rationally refused to use the W126 index because, purportedly, the existing form of the standard was "'highly correlated' to a three-year average of the W126 index." *Id.* at 618. Further, EPA had received expert scientific advice regarding levels of air quality requisite to protect against visible leaf damage but refused to specify such a level by relying on purported "uncertainties." *Id.* at 619. The *Murray Energy* Court held that EPA's refusal was arbitrary. *Id.* at 618-20. Accordingly, the Court remanded the secondary standard to EPA. *Id.* at 627-28.

EPA has now proposed to respond to the *Murray Energy* remand. 85 Fed. Reg. 49,830, 49,879/3 (Aug. 14, 2020) ("This review of the secondary O_3 standard also considers the August 2019 decision by the D.C. Circuit on the secondary standard established in 2015 and issues raised by the court in its remand of that standard to the EPA such that the decision in this review will incorporate the EPA's response to this remand."). Thus, this Proposal represents EPA's response not just to the *Murray Energy* remand, which addressed EPA's response to the *Mississippi* remand, but also the *Mississippi* remand. Accordingly, the records of the 2008 and 2015 secondary standards are relevant here, and EPA must rationally address CASAC's advice given in those records. *See BNSF Ry. v. Surface Transp. Bd.*, 741 F.3d 163, 166-67 (D.C. Cir. 2014) (reviewing agency action on remand and looking to pre-remand record); *West Virginia v. EPA*, 362 F.3d 861, 872 (D.C. Cir. 2004) (reviewing EPA action on remand and looking to pre-remand record).

C. The welfare harms caused by ozone are extensive and well-established.

1. Adverse effects to vegetation and ecosystems

Ozone adversely affects public welfare by harming vegetation and ecosystems. Ozone has long been known to be highly phytotoxic. It disrupts the normal storage of nutrients and carbon and visibly damages foliage. Ozone exposure has adverse effects on public welfare in the form of harm to crop and forest productivity, resilience, scenic beauty, and ecosystem functioning. Ecosystem-service impacts include, but are not limited to, cultural (e.g. recreation) and product (e.g. agriculture) related services.

In this review EPA is clear that harm to vegetation and ecosystems from ozone exposure is pervasive and serious. EPA identifies four new specific ecological effects in addition to the eight identified in the last review and changes its determination regarding ozone's effects on "Alteration of terrestrial community composition" from "Likely to be causal" to "causal." The final 2020 ozone ISA documents the ecosystem effects that the Agency considers causal and likely casual,[147] including:

- Visible injury to plants and tree foliage effects- Causal
- Reduced vegetation growth- Causal
- Reduced plant reproduction- Causal/New
- Increased tree mortality- Likely to be causal/New
- Reduced yield and quality of agricultural crops - Causal
- Alteration of herbivore growth and reproduction - Likely to be causal/New
- Alteration of plant-insect signaling - Likely to be causal/New
- Reduced productivity in terrestrial ecosystems - Causal
- Reduced carbon sequestration in terrestrial ecosystems - Likely to be causal
- Alteration of belowground biogeochemical cycles - Causal
- Alteration of terrestrial community composition-Causal/New
- Alteration of terrestrial ecosystem water cycling - Likely to be causal

The current review incorporates the latest science, which has advanced our understanding around ozone's specific role in adversely impacting plant reproduction and contributing to plant mortality, and also adversely impacting the insects and other animals that rely on plants. Previously EPA had treated decreased plant reproduction and increased mortality as an aspect of reduction in vegetative growth; but new studies included in this review more clearly characterize these impacts and demonstrate that they are adverse ecological effects in their own right. Fruit number and fruit weight reductions were fairly consistent in a synthesis of 123 studies and

[147] 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, 2020 at ES-13, Table ES-2.[hereinafter "2020 ISA"]

occurred at ozone levels from 40 ppb to >100 ppb. Plant-insect signaling can be disrupted at ozone levels >=50 ppb, changing and reducing the volatile compounds that enable plant signaling.[148]

Additionally, this review includes science that strengthens the conclusion that ozone has a causal impact of altering terrestrial community composition by harming a large number of species. The breadth of impact of ozone is demonstrated by Agathokleous et al. (2015)[149], a meta-analysis of 195 published papers which EPA cites as evidence, with 80% of the wild plant species experiencing negative effects of ozone exposure, representing 210 genera and 85 families.[150] Ozone can also harm other terrestrial organisms such as fungi, bacteria, and soil invertebrates.

Evidence for the causal relationship between ozone exposure and foliar injury has become even stronger with the addition of field studies in National Parks and Forests.[151] A new study by Neufeld et al. looked at foliar damage and other adverse impacts from ozone on two Coneflower species from Great Smoky Mountain and Rocky Mountain (ROMO) National Parks.[152] While one species was well known to be sensitive to ozone, this work, and that of Kohut et al. (2012), confirmed that the ROMO species can also be injured, and both species had reductions in photosynthetic rate and stomatal conductance with elevated ozone. Neufeld et al. (2018) detected statistically significant ozone injury on both plants, in pots at a North Carolina facility, at an ambient 12-hr W126 level of 9.3 ppm-hr, accumulated from April 1 - Aug 4, 2011, and a corresponding maximum 3-month 12-hr W126 value of 6.4 ppm-hr over this timeframe (calculated from data provide by H. Neufeld).

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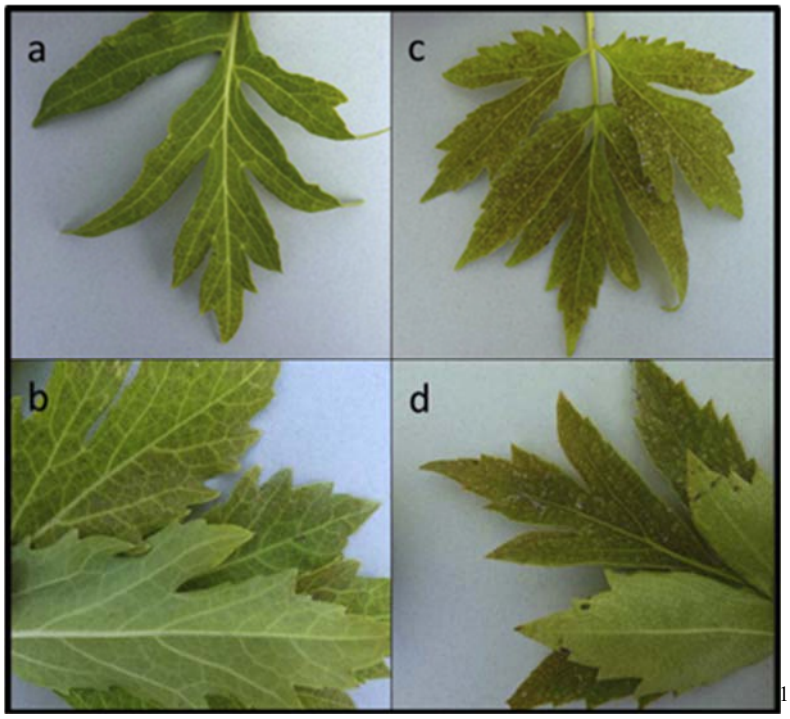
[148] *Id.,* at 8-89

[149] Agathokleous, E; Saitanis, CJ; Koike, T. (2015). Tropospheric O-3, the nightmare of wild plants: a review study. Journal of Agricultural Meteorology 71: 142-152, *available at* http://dx.doi.org/10.2480/agrmet.D-14-00008.

[150] *See* 2020 ISA, *supra,* n. 147, at 8-143-160, Table 8-20; Agathokleous, et al. (2015).

[151] Smith, G. (2012). Ambient ozone injury to forest plants in Northeast and North Central USA: 16 years of biomonitoring. Environ Monit Assess 184: 4049-4065, *available at* http://dx.doi.org/10.1007/s10661-011-2243-z, Kohut, R; Flanagan, C; Cheatham, J; Porter, E. (2012). Foliar ozone injury on cutleaf coneflower at Rocky Mountain National Park, Colorado. West N Am Nat 72: 32-42, *available at* http://dx.doi.org/10.3398/064.072.0104.

[152] Neufeld, H. S., Sullins, A., Sive, B. C., & Lefohn, A. S. (2019). Spatial and temporal patterns of ozone at Great Smoky Mountains National Park and implications for plant responses. *Atmospheric Environment: X, 2*, 100023, *available at* https://doi.org/10.1016/j.aeaoa.2019.100023



[153]

Foliar stipple on cutleaf coneflower (*Rudbeckia laciniata L.)* var. *ampla* (a, b) and var. *digitata* (c, d) on August 10, 2011 after growing outdoors at Appalachian State University, Boone, NC USA. Both varieties have an absence of injury on abaxial surfaces, which is consistent with ozone exposure symptoms. Note blue/black stipple on var. *ampla*, characteristic of that seen on leaves of this variety in Rocky Mountain National Park, whereas stippling is initially purple/brown on var. *digitata* and then quickly coalesces into brown necrotic areas.

Ozone-sensitive species with documented ozone injury remain important bioindicators. Just as important is that foliar injury from ozone is recognized as a deleterious ecological effect by EPA and one that can impact plant health, timing of leaf senescence, and scenic beauty.

Biomass loss is a known causal impact of ozone exposure that is damaging to forest health and plant survival. A recent synthesis of global studies documents hundreds of species that are known to experience growth loss with ozone exposure, of which 57 are native to the U.S..[154] EPA presented a number of new studies in the 2020 ISA that continue to support that ozone causes biomass loss at the individual tree level as well as across landscapes. Gustafson et al. (2013) used a model to scale results from the Aspen FACE study to the landscape level and found ozone significantly reduced landscape biomass and reduced net carbon storage so much that it essentially eliminated the increased carbon storage observed in the study in the presence of

[153] Neufeld, et al.

[154] *See* 2020 ISA, *supra,* n. 147, at 8-31; Bergmann, E., Bender, J., & Weigel, H.-J, Impact of tropospheric ozone on terrestrial biodiversity: A literature analysis to identify ozone sensitive taxa. Journal of Applied Botany and Food Quality, Vol 90 (2017): Journal of Applied Botany and Food Quality, *available at* https://doi.org/10.5073/JABFQ.2017.090.012.

elevated CO2 for this species.[155] Biomass loss from ozone exposure has also been shown in other scaling up studies for silver birch, quaking aspen,[156] Ponderosa pine and aspen,[157]and eastern cottonwood, black cherry, aspen, and tulip poplar.[158]The impact of decreased biomass storage across forests is highly significant in scientific and policy terms because carbon sequestration by trees is an important removal mechanism of atmospheric carbon dioxide.

Ecosystem services should be considered as a key construct to assess the relationships between ozone impacts to vegetation and other harms to public welfare. Ozone pollution has both direct ecological impacts, such as the damage that happens to plant and tree foliage when exposed to ozone, as well as the resulting impacts to cultural (e.g., recreation) and product (e.g., agriculture) related services. EPA retains the 2013 Ozone ISA affected ecosystem services of:

Decreased productivity

Decreased carbon sequestration

Decreased crop yield

Altered water cycling

Altered community composition

Altered pollination

Altered forest products

While this list clearly overlaps with the ecological effects determination identified, ecosystem services provide another, independently viable method of consideration of these impacts. By using ecosystem services to characterize the impact to public welfare, EPA can develop methods to assess what might be expected to change under air quality scenarios representing varying alternatives for a secondary standard. As EPA recognizes, in addition to the many benefits of reduced ozone pollution that EPA can readily evaluate, there are additional benefits that are difficult to quantify but are extremely important to the public welfare

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[155] Gustafson, EJ; Kubiske, ME; Sturtevant, BR; Miranda, BR. (2013), Scaling Aspen-FACE experimental results to century and landscape scales. Landsc Ecol 28: 1785-1800, *available at* http://dx.doi.org/10.1007/s10980-013-9921-x.

[156] Resco de Dios, V; Mereed, TE; Ferrio, JP; Tissue, DT; Voltas, J., Intraspecific variation in juvenile tree growth under elevated CO2 alone and with O3: A meta-analysis, *Tree Physiology*, *36*:6 (2016), 682–693, *available at* http://dx.doi.org/10.1093/treephys/tpw026.

[157] Lapina, K; Henze, DK; Milford, JB; Travis, K., Impacts of Foreign, Domestic, and State-Level Emissions on Ozone-Induced Vegetation Loss in the United States. Environ Sci Technol 50, 2 (2016), 806-813, *available at* https://pubs.acs.org/doi/10.1021/acs.est.5b04887.

[158] Capps, S. L., Driscoll, C. T., Fakhraei, H., Templer, P. H., Craig, K. J., Milford, J. B., & Lambert, K. F. (2016). Estimating potential productivity cobenefits for crops and trees from reduced ozone with U.S. coal power plant carbon standards. Journal of Geophysical Research: Atmospheres, 121(24), 14,679-14,690, *available at* https://doi.org/10.1002/2016JD025141.

nonetheless. EPA appears to provide little to no update on the latest ecosystem services literature and it is unclear if it is because this work is lacking or EPA was deficient.

The causal effects defined above clearly show that when ozone is present in the ambient air there are significant and multiple costs to vegetation, and while some species are more sensitive than others, ozone impacts happen across numerous *Plantea* taxa, and that there are consequential and cumulative impacts for the ecosystems and landscapes, including damage to wildlife habitat. EPA is legally obligated to set the ozone standard at a level that prevents these adverse effects on public welfare.

2. Adverse effects to climate

Our groups are concerned that the proposed rule does not properly characterize the welfare impacts of radiative forcing from ozone. Ozone not only harms vegetation, but also is a potent greenhouse gas. Multiple ISAs state that there is a "relationship between the changes in tropospheric O_3 concentrations and effects on climate."[159] The proposed rule also states that "as in the last review, the current evidence, augmented since the 2013 ISA, continues to support a causal relationship between the global abundance of O_3 in the troposphere and radiative forcing, and a likely causal relationship between the global abundance of O_3 in the troposphere and effects on temperature, precipitation, and related climate variables." 85 Fed. Reg. at 49,882/3-83/1. The important facts about ozone's climate impacts are known. First, it is clear that ozone has a strong warming impact, especially in Northern mid-latitudes (where the United States is) and in the Arctic. Second, whatever its exact radiative forcing, ozone is the third strongest greenhouse gas. Third, it is well-established that ozone formation can be reduced through decreases in methane, nitrogen oxides, carbon monoxide and VOCs. As EPA acknowledges, reducing these precursors would significantly benefit public health as well as climate. Consequently, Administrator Wheeler must consider the direct as well as indirect climate impacts of ozone as he makes his judgment about setting the level of the secondary standard.

The Arctic region deserves special consideration both due to the Class I areas located within Alaska[160] near the Arctic Circle and because ozone-mediated climate impacts in the Arctic have implications for the contiguous United States.

Ozone has a larger impact in the Arctic than in other regions.[161] This is so both because ozone remains in the atmosphere longer than average in the Arctic winter and spring[162], and

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[159] U.S. EPA. Integrated Science Assessment (ISA) of Ozone and Related Photochemical Oxidants (Final Report, Feb 2013). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-10/076F, 2013, at 2-47 [hereinafter "2013 ISA"]; 2020 ISA, *supra,* n. 147 at IS-82.

[160] The Class I areas within Alaska are: Denali National Park, Bering Sea Wilderness Area, Simeonof Wilderness Area, and Tuxedni Wilderness Area. 40 CFR Part 81, Subpart D.

[161] 2013 ISA, *supra* n. 159, at 10-13,14,18.

[162] *Id.* at 10-18.

because ozone is most effective at absorbing shortwave radiation, such as that reflected from snow and ice, in the Arctic.[163] In fact, ozone is estimated to exert a radiative forcing of approximately 1 W/m^2 during the Arctic summer[164] and to have increased temperatures as much as 0.5 °C in the winter and spring in the Arctic in the last century.[165]

The Arctic is a unique region that hosts an intricate and highly specialized ecosystem. Many of the species in the region are the last survivors from the last ice age. Because the environment is harsh, species in the Arctic are highly adapted to survive in a narrow range of conditions. Furthermore, the inhabitants of the Arctic have no options for migration in the face of a warming environment; they are already as far north as possible and there is no higher elevation to which these species can climb. Arctic species rely upon fundamental features of the Arctic landscape, such as sea ice, permafrost, and seasonal snowpack. Yet, these features are already declining or disappearing, and the region is teetering on the brink of various climatic "tipping points."

The Arctic is currently experiencing climate changes of a magnitude not experienced anywhere else on Earth. For instance, the Arctic is warming at twice the rate of the rest of the world.[166] Furthermore, sea ice is melting at precipitous and unprecedented rates.[167] Greenland ice sheets are contracting at accelerating rates and permafrost is experiencing deeper and more frequent freeze/thaw cycles.

Adverse impacts resulting from the accelerated loss of Arctic sea ice extend well beyond the Arctic Ocean and its coast. By reflecting the sun's energy back into space, sea ice is an effective insulator, preventing heat in the Arctic Ocean from escaping upward and warming the lower atmosphere.[168] The decline of sea ice amplifies warming in the Arctic, which in turn has major implications for temperature patterns over adjacent, permafrost-dominated land areas and for weather patterns across the Northern Hemisphere.[169] Higher temperatures will thaw out extensive expanses of permafrost, resulting in the potential release of methane and carbon dioxide currently frozen in Arctic soils, thereby accelerating further warming.[170] Additional warming in the Arctic resulting from the loss of sea ice will also affect weather patterns by altering atmospheric circulation patterns, leading to more extreme weather events and affecting

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[163] *Id.* at 10-13.
[164] *Id.*
[165] *Id.* at 10-18.
[166] IPCC, CLIMATE CHANGE 2007: SYNTHESIS REPORT at 30 (2007).
[167] *See, e.g.*, Stroeve, J. et al., *Arctic Sea Ice Extent Plummets in 2007*, 89 EOS 2 (January 8, 2008); R. Kwok and D.A. Rothrock, *Decline in Arctic sea ice thickness from submarine and ICESat records: 1958-2008*, 36 GEOPHYS. RESEARCH LETT L15501 (2009).
[168] World Wildlife Fund, Martin Sommerkorn & Susan Joy Hassol, eds., Int'l, ARCTIC CLIMATE FEEDBACKS: GLOBAL IMPLICATIONS (2009), 19-20, *available at* https://www.worldwildlife.org/publications/arctic-climate-feedbacks-global-implications-report.
[169] *Id.* at 18.
[170] *Id.*

transportation, agriculture, forestry and water supplies.[171] Loss of sea ice in the Arctic Ocean will therefore have serious repercussions as climactic feedbacks resulting from higher temperature increases accelerate, the timing of the seasons is altered, and shifting circulation patterns cascade through the Arctic and beyond.

These climate impacts will directly affect proximate Class I areas within Alaska. In addition, a strong secondary standard for ozone is a critical part of the overall effort to avoid cascading catastrophic consequences for the lower 48 states.

3. Adverse effects to public lands

Class I areas under the Act (National Parks, Wildernesses, Forests, and Refuges) hold special value and context to the public and therefore warrant strong protection. Air pollution that harms ecosystems and scenic beauty in these national public lands adversely affects public welfare because, among other things, these special places were set aside for conservation of their natural values, for use and enjoyment by the public, and under the Clean Air Act, as places to have the most pristine air quality. 42 U.S.C. § 7472. EPA must limit the impacts from ozone pollution to Class I areas to fulfill, and act consistently with, the Congressional mandates to protect and preserve these places for the foregoing purposes. Advancing protections to safeguard the air and resources in these areas is critical to meeting the Clean Air Act objective.

In giving priority to these areas, the Administrator must consider that Class I areas include many mountain systems that can have high background ozone with little change in diurnal concentrations, even during the daylight hours. Consequently, when ozone pollution events occur, they build upon these high background levels and therefore exacerbate overall cumulative impacts. Class I areas also include many wetland ecosystems, which support significant diverse wildlife, and where foliar injury from ozone can be more severe.

In addition to the ozone impacts to vegetation, EPA must consider the climate change impacts of ozone in Class I areas. Ozone increases radiative forcing, which in turn exacerbates climate harms in national parks and other Class I areas. National parks are significantly threatened by a rapidly warming planet. Impacts range in degree and breadth and include coastal areas affected by rising oceans, deserts experiencing extreme heat events, and alpine regions beleaguered by extended drought.

For example, rising sea levels in Florida's Everglades National Park threaten the mangrove ecosystem that filters saltwater and thereby preserves freshwater wetlands. Rising temperatures and drought in New Mexico's Bandelier National Monument have driven bark beetles to higher elevations, causing high mortality rates to the piñon pines. Rising temperatures

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[171] Francis, J. and Stephen Vavrus, *Evidence Linking Arctic Amplification to Extreme Weather in Mid Latitudes*, 39 GEOPHYS. RES. LETT. L06801 (2012), *available at* https://agupubs.onlinelibrary.wiley.com/doi/full/10.1029/2012GL051000.

in Yellowstone National Park are also killing whitebark pine trees, which translates to reduced chances of grizzly bear survival in Yellowstone because grizzlies rely heavily on whitebark pine seeds as a critical source of nutrition. Warmer temperatures in Great Smoky Mountains National Park could increase ozone levels, further damaging critical tree and plant species. Scientists have linked these and other changes occurring in our national parks directly to climate change.

In 2014, NPS published a study that examined the extent to which 289 parks are experiencing extreme climate changes when compared to the historical records from 1901–2012.[172] Results show that parks are overwhelmingly at the extreme warm end of historical temperatures. The 2014 Parks Study also points to changes in precipitation patterns since 1901. These findings are supported by previous scientific research. Parks that have been experiencing extremely warm and dry climates include Kalaupapa National Historical Park in Hawaii, Mojave National Preserve in southern California, and Lake Mead National Recreation Area in Nevada and Arizona. Parks that have become extremely warm and wet include Cape Lookout National Seashore in North Carolina, Florissant Fossil Beds National Monument in Colorado, and Delaware Water Gap National Recreation Area in New Jersey and Pennsylvania.

The Appalachian National Scenic Trail (ANST) was designated as a unit of the National Park System and the first National Scenic Trail in 1968. The Appalachian Trail follows the hills and valleys of the Appalachian mountain range in the eastern United States. The 2014 Parks Study found the recent mean temperatures on the ANST were ranked as "extreme warm" compared to the historical data set. Further, climate data collected at a northern ANST mid-elevation site in the White Mountain National Forest, where winter recreation is very important to local economies, show that snowpack is disappearing 15 days earlier in the spring and annual snowfall has declined by 69 inches over the time period of 1935–2012.[173]

According to the 2014 Parks Study, species within national parks are experiencing extreme climates, causing changes to plant and animal behavior. For example, temperate tree species in the Great Lakes region appear most sensitive to higher summer temperatures, while white-tailed deer are more sensitive to winter conditions.

There is a growing body of evidence that links recent increases in drought and wildfire frequency and intensity to climate change.[174] Climate change has resulted in increasing temperatures, decreases in total precipitation and snow accumulation, increases in insect and

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[172] Monahan & Fisichelli, Climate Exposure of U.S. National Parks in a New Era of Change (2014), *available at* https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0101302.

[173] Appalachian Mountain Club unpublished data.

[174] *See* Sommers et al., Wildland Fire Emissions, Carbon, and Climate: Science Overview and Knowledge Needs, 317 Forest Ecology and Mgmt. 1, 1–8 (2014); Climate Science Special Report (CSSR), Fourth National Climate Assessment, Chapter 8: Droughts, Floods and Wildfire at 8.1-8.1.2, *available at* https://science2017.globalchange.gov/chapter/8/; David L. Peterson, Climate Change Intensifying Wildfire on National Forests, U.S. Forest Service Blog, (June 2, 2016), https://www.fs.fed.us/blogs/climate-change-intensifying-wildfire-national-forests.

disease outbreaks, and an extended growing season; all factors that increase the risks of drought and wildfire.

A 2018 NPJ Climate and Atmospheric Science study found that "the declines in western snowpack represent a substantial loss of snow storage… [and] that since 1915 western U.S. snowpack has declined by 21% or 36 km, greater than the volume of water stored in the West's largest reservoir, Lake Mead."[175]

Likewise, according to a 2015 U.S. Forest Service report: "Climate change has led to fire seasons that are now on average 78 days longer than in 1970. The U.S. burns twice as many acres as compared to three decades ago and Forest Service scientists believe the acreage burned may double again by mid-century."[176]

Finally, the National Climate Assessment from 2017 concludes: "Given the larger projected increases in temperature at high altitudes compared to adjacent lower altitudes and the resulting changes in both snowpack depth and melt timing in very warm future scenarios…, and assuming no change to water resource management practices, several important western U.S. snowpack reservoirs effectively disappear by 2100 in this dynamical projection, resulting in chronic, long-lasting hydrological drought."[177]

The increased risk of wildfire and more frequent, sustained droughts from a changing climate is overlaid on other human-related stressors and activities including land development, disturbance, and use; and fuel build up from past fire suppression. While some ecosystems, particularly in the western U.S., are naturally fire prone and have evolved around periodic fire, many of these areas are already seeing even more extreme drought and the typical fire regime and revegetation cycle may not be sustainable as the fires become too frequent and severe. For example, climate change could exacerbate the amount of land burned by wildfires at Yellowstone National Park three to ten times from 1990–2100.[178] Future fire regimes will also be impacted by changes in revegetation patterns and fuel loads, which interact with climate conditions.

We note that, though Class I areas merit particular protection, other public lands, including those owned by states, are similarly treasured, important, and vulnerable to ozone-caused harms. All these lands are especially important in the time of COVID-19, when we are encouraging people to spend time outdoors, and in view of the Great American Outdoors Act's

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[175] Mote et al., Dramatic Dec lines in Snowpack in the Western US, Climate and Atmospheric Science, 1(2) NPJ Climate and Atmospheric Sci. 1, 2 (2018), 4, *available at* http://www.nature.com/articles/s41612-018-0012-1.pdf.
[176] United States Dept. of Agriculture (USDA), *The Rising Costs of Wildfire Operations: Effects of the Forest Service's Non-Fire Work*, 2–3, *available* at https://www.fs.fed.us/sites/default/files/2015-Fire-Budget-Report.pdf.
[177] CSSR, Fourth National Climate Assessment, Chapter 8: Droughts, Floods, and Wildfire, *available at* https://science2017.globalchange.gov/chapter/8/.
[178] Gonzalez et al., Disproportionate magnitude of climate change in United States national parks, Environ. Res. Lett. 13 (2018) 104001, 9. (citing Westerling et al. 2011), *available at* https://iopscience.iop.org/article/10.1088/1748-9326/aade09/pdf.

commitment to investing in maintaining public lands and permanent funding of the Land and Water Conservation Fund. EPA must also protect those lands.

i. Intense wildfires are not all natural

Wildfires in heavily forested areas are of particular concern in the context of climate change because of their role in annual sequestration of carbon dioxide and as long-term sinks for storing terrestrial carbon. Lightning strikes, which are expected to increase with warmer weather, are the more common ignition source in remote wildlands, while human-caused ignition of wildfires is more common in more populated areas. In mountain systems, the early arrival of spring means temperatures rise sooner and snow melts occur earlier, significantly increasing the risk for wildfires at mid-elevations in Colorado.[179] According to the National Climate Assessment, "by the latter half of the century, as temperature continues to increase, it will be too warm to snow in many current snow-producing situations and precipitation will mostly be rainfall."[180] The loss of snow packs will dramatically change how quickly and routinely certain areas run out of sustained melting that historically have prevented drought and are essential to keep areas moist throughout the summer. Drier and warmer conditions also limit forest recovery from fire. A recent study in the U.S. Rocky Mountains found post-fire tree regeneration was significantly lower in 2000–2011 compared to 1988–1999, attributing it to climate-induced changes.[181]

The toll on human health and outdoor recreation from massive wildland fires was demonstrated in the summer of 2017 in the western U.S., where numerous air quality action days were called due to fire. This is only expected to worsen in our future climate as one study predicts: "Under future climate change, we estimate that more than 82 million individuals will experience a 57% and 31% increase in the frequency and intensity, respectively, of Smoke Waves."[182] They define Smoke Waves as two or more days with elevated fine particulate levels. This summer and fall's wave of fires across the West Coast further shows the harmful impacts of

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[179] Westerling, et al., Warming and Earlier Spring Increase Western U.S. Forest Wildfire Activity, 313 Sci. 940, 940–43 (2006).

[180] CSSR, Fourth National Climate Assessment, Volume 1 Chapter 7: Precipitation Change in the United States, at 7.1.1 (2017), *available at* https://science2017.globalchange.gov/chapter/7/.

[181] Stevens-Rumann et al., Evidence for declining forest resilience to wildfire under climate change. Ecology Letters (2017). doi: 10.1111/ele.12889, *available at* http://files.cfc.umt.edu/phiguera/publications/Stevens-Rumann_et_al_2018_Ecology_Letters.pdf.

[182] Liu et al., Particulate Air Pollution from Wildfires in the Western U.S. Under Climate Change, 138 Climatic Change 655, 655–66 (2016); *see also* Adam J.P. Smith et al., *Climate Change Increases the Risk of Wildfires*, ScienceBrief (Sept. 2020 update), *available at* https://sciencebrief.org/uploads/reviews/ScienceBrief_Review_WILDFIRES_Sep2020.pdf.

wildland fires.[183] Distressingly, there is evidence that the number of fires in 2020 is not at all exceptional, notwithstanding their striking and severe impacts.[184]

At specific parks, climate change is a driving force behind wildfire related concerns across the nation. For instance, drought and hotter temperatures have led an increase in buffelgrass, an invasive species, in Saguaro National Park.[185] Buffelgrass is changing the desert ecosystem by making it susceptible to wildfire for the first time.[186] Furthermore, "[w]hen ignited, buffelgrass burns at very high temperatures and promotes rapidly spreading fires; it also re-grows quickly after fires." The introduction of buffelgrass, along with hotter and drier temperatures will increase occurrences of wildfire in desert ecosystems, such as Saguaro National Park.[187] Fires can cause other impacts to the ecosystems of National Parks, such as the changing of the dominant tree species at Isle Royale National Park.[188] In the last 50 years, temperatures at Mesa Verde have risen "at a much faster rate than they did over the preceding century."[189] These higher temperatures may cause much larger fires across the Southwest as "forests across the western mountains are drier more often and for longer periods, more wildfires are ignited and they spread more easily."[190] Furthermore, "the average number of large wildfires of more than 1,000 acres across the western United States has increased from 140 per year in the 1980s to 250 per year between 2000 and 2012."[191] These fires have devastating impacts at Mesa Verde, beyond burning forests and vegetation, including "spalling, the peeling away of the rock face as the water in the sandstone evaporates, which can destroy ancient rock carvings."[192] Intense fires can also dry out the soil making the area susceptible to flooding.[193]

ii. The impacts of wildfires

As the intensity and frequency of wildfires continue to grow, in part because of anthropogenic climate change, so will the burden these fires place on the federal government and

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[183] *E.g.*, *Ore. grieves for natural places wiped out by blazes*, Greenwire (Sept. 23, 2020), https://www.eenews.net/greenwire/stories/1063714479/; *Seeping under doors, bad air won't ease up in the West*, Greenwire (Sept. 16, 2020), https://www.eenews.net/greenwire/stories/1063713847/.
[184] Thomas Frank, *U.S. watches wildfires in horror. But it's an average year*, Climatewire (Sept. 17, 2020), https://www.eenews.net/climatewire/stories/1063713927/.
[185] Saunders et al., National Parks in Peril: The Threats Of Climate Disruption (Oct. 2009), 22, *available at* http://www.rockymountainclimate.org/website%20pictures/National-Parks-In-Peril-final.pdf.
[186] *Id.*
[187] *Id.*
[188] Fisichelli et al., *Climate, Trees, Pests, and Weeds: Change, Uncertainty, and Biotic Stressors in Eastern U.S. National Park Forests*, Forest Ecology and Management 327 (2014), 32.
[189] Holtz et al., Union of Concerned Scientists, National Landmarks at Risk: How Rising Seas, Floods, and Wildfires are Threatening the United States' Most Cherished Historic Sites (May 2014), 36, *available at* https://www.ucsusa.org/sites/default/files/2019-09/National-Landmarks-at-Risk-Full-Report.pdf.
[190] *Id.*
[191] *Id.*
[192] *Id.* at 37.
[193] *Id.*

local communities. *See* 42 U.S.C. §7602(h) (welfare effects include "effects on…damage to and deterioration of property … as well as effects on economic values"). For instance, in the latter part of the 20th century, from 1986–1999, federal firefighting suppression costs split between the Department of Interior and U.S. Forest Service ranged from a low of around $203 million in 1986 to a high of $918 million in 1994–95.[194] From 2000–2016, there were only four years in which federal firefighting cost fell below $1 billion, and in 2015 those costs exceeded $2.13 billion.[195] For the U.S. Forest Service, fire operations made up only 16 percent of its annual appropriated budget in 1995. By 2015, fire operations exceeded over 50 percent of their annual budget.[196] Without a clear path forward to address climate change, the costs of fighting fires on federal lands will likely continue to rise, resulting in more federal money being spent on fire suppression as opposed to other essential national park budgetary needs.

Taken together, these data show that welfare effects from climate change—including contributing effect from tropospheric ozone—not only can be "anticipated," but in fact are already occurring in the nation's National Parks and other Class I areas. EPA must address the dire need to reduce direct and indirect climate impacts from ozone, in addition to addressing vegetation effects, when setting the standard.

All publicly protected lands are visited for recreation and rejuvenation and are often important wildlife habitat areas. This nexus of sensitive ecological systems with the significant ecosystem services must be weighted in the context of the public welfare.

D. EPA's proposed re-adoption of the arbitrary 2015 secondary ozone standard is arbitrary and unlawful.

1. EPA's reliance on the advice of this CASAC, which was improperly convened, and which lacks the expertise necessary to review the standard, is arbitrary.

As discussed in section III, the Administrator's reliance on recommendations from the current CASAC during this NAAQS review is unlawful and arbitrary because the Agency illegally and arbitrarily limited the pool of potential appointees when selecting most of the members based on the Pruitt directive.

Particularly relevant here, as EPA has heard already in this review, this CASAC lacks expertise on ozone's effects on vegetation, whereas the prior CASAC had it. EPA-HQ-OAR-2018-0279-0329 (Oral Comment of H. Christopher Frey, Ph.D.) 5 ("In the last review, there were multiple experts for effects on plants, but there were none in this review."). Indeed, none of

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[194] *See* National Interagency Fire Center, Federal Firefighting Costs (Suppression Only), https://www.nifc.gov/fireInfo/fireInfo_documents/SuppCosts.pdf.
[195] *Id.*
[196] USDA, *The Rising Cost of Fire Operations: Effects on the Forest Service's Non-Fire Work* (2015), 2, *available at* https://www.fs.fed.us/sites/default/files/2015-Fire-Budget-Report.pdf.

the members of the current CASAC have the expertise necessary to evaluate the public welfare impacts of ozone. Per their own self-reported biographies, none of the CASAC members has any specific expertise on the types of welfare harms ozone causes.[197] The closest a member comes appears to be Dr. Ronald J. Kendall, who is a wildlife toxicologist.[198] But ozone's welfare effects land most directly on plants or climate, not on wildlife.

By contrast, the previous CASAC had a 20-member ozone review panel that included scientists with directly relevant expertise, such as Dr. Kathleen Weathers (also a member of the chartered CASAC), who "studies ecosystem processes within and among aquatic, airborne, and terrestrial systems;"[199] Dr. David A. Grantz, whose academic research and work focuses directly on the impacts of ozone on growing plants;[200] Dr. Howard S. Neufeld, whose academic research and work focuses directly on the impacts of "ozone on plants native to Great Smoky Mountains National Park;"[201] and Dr. Peter Woodbury, whose academic work focuses on "agricultural and forest ecosystems," including how ozone affects them.[202]

Despite this CASAC's lack of relevant, meaningful expertise, the Administrator proposes to rely on its ill-informed advice as a basis for retaining the current secondary standard. The Administrator expressly says that "[i]n reaching [his proposed conclusions 'that the current secondary O_3 standard provides the requisite protection against known or anticipated adverse effects to the public welfare, and should therefore be retained, without revision'], the Administrator has carefully considered…the advice and recommendations from the CASAC." 85 Fed. Reg. at 49,907/1; *see id.* at 49,907/2, 49,913/2 (noting that CASAC recommended retaining current secondary standard); *see also id.* at 49,906/2-07/1 (providing a summary of CASAC's advice). Further, in "draw[ing] on the considerations and conclusions in the PA," including the "rationale presented for those conclusions," the Administrator "notes the CASAC" positively assessed the PA's discussion of the secondary standard. *Id.* at 49,907/2. Even more granularly, the Administrator cites this CASAC as support for his proposed conclusions regarding visible leaf damage, *id.* at 49,908/2, for his focus on relative biomass loss, *id.* at 49,910/1; for his "focus on a 3-year average W126," *id.* at 49,910/3; for his reaffirming the same conclusion EPA

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[197] *See* EPA, *Members of the Clean Air Scientific Advisory Committee*, https://yosemite.epa.gov/sab/sabpeople.nsf/WebExternalCommitteeRosters?OpenView&committee=CASAC&secondname=Clean Air Scientific Advisory Committee .

[198] EPA, *Ronald J. Kendall*, https://yosemite.epa.gov/sab/sabpeople.nsf/WebPeople/KendallRonald%20J.?OpenDocument; *see also* CASAC 2020 Policy Assessment Letter at A-18 ("Ronald J. Kendall was assigned" to review draft policy assessment's chapter on secondary standard).

[199] *See* Cary Institute of Ecosystem Studies, *Dr. Kathleen C. Weathers*, https://www.caryinstitute.org/science/our-scientists/dr-kathleen-c-weathers.

[200] *See* Kearney Agricultural Research and Extension Center, *Dr. David A. Grantz*, http://kare.ucanr.edu/About_us/Staff_Directory/?facultyid=850.

[201] *See* Appalachian State University, *Dr. Howard S. Neufeld*, https://biology.appstate.edu/directory/dr-howard-s-neufeld.

[202] *See* Cornell School of Integrative Plant Science, *Peter Woodbury*, https://scs.cals.cornell.edu/people/peter-woodbury/

reached in 2015 that a 17 ppm-hrs benchmark, measured as a 3-year W126 average, would be "'effective in particularly protecting the public welfare in light of vegetation impacts form [*sic*] ozone,'" *id.* at 49,911/2 (quoting this CASAC's written advice); and for his overall judgments regarding welfare effects and how to assess ozone's impacts on them (which includes the decisions summarized in this sentence), *id.* at 49,911/1. All of these determinations are arbitrary because CASAC lacked the expertise required to provide meaningful, independent, scientific review of the secondary standard and thus its advice and recommendations on the secondary standard cannot bear any weight.

Instead, the only legally operative CASAC advice at issue here is the advice given by the actually expert panels in the past. Those panels have repeatedly made clear that the secondary standard must be (1) biologically relevant to the harms ozone causes (i.e., in a cumulative form, rather than the 8-hour form EPA prefers); (2) a single-year average to protect against the harms ozone causes even in just a single growing seasons (i.e., not the 3-year average that allows single-year levels that exceed the scientifically based threshold for unacceptable relative biomass loss, even though EPA prefers such a 3-year average); and (3) one that protects against adverse effects from visible leaf damage (i.e., is set lower than the 17 ppm-hrs level EPA prefers).[203] The Administrator must rationally explain his departures from those recommendations and that advice. As the D.C. Circuit has held, EPA has not done so in the past, and, as explained below, the Administrator has once again failed.

2. EPA arbitrarily and unlawfully relies on purported uncertainty to justify an under-protective approach.

In proposing to reject alternatives (like establishing a single-year W126 benchmark or setting a lower threshold for protecting against visible leaf damage) or decline to analyze important impacts of ozone (like on climate change) that could or would support a more protective standard, EPA repeatedly emphasizes purported uncertainty, *e.g.*, 85 Fed. Reg. at 49,910/3, variability, *e.g.*, *id.*, and lack of precision, *e.g.*, *id.* at 49,900/3, 49,901/2-02/2, 49,910/1-3, or known quantitative relationships, *e.g.*, *id.* at 49,908/1-2, 49,909/2-3. As to many of the harmful effects of ozone, which EPA agrees are causal or likely to be causal, EPA fails

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[203] *E.g.*, CASAC Letter 2014a at iii-iv, 11-16; EPA-HQ-OAR-2018-0279-0315 at 2, 17 (2012 CASAC letter on first draft policy assessment for 2015 ozone NAAQS); EPA-HQ-OAR-2018-0279-0071 at 1-2 (2010 CASAC letter on proposed reconsideration of 2008 ozone NAAQS); https://yosemite.epa.gov/sab/sabproduct.nsf/4AF876432433128885257425006 9E494/$File/EPA-CASAC-08-009-unsigned.pdf at 2-3 (2008 CASAC letter on final 2008 ozone NAAQS); https://yosemite.epa.gov/sab/sabproduct.nsf/FE915E916333D776852572AC007397B5/$File/casac-07-002.pdf at 3 (2007 CASAC letter on final policy assessment (then called staff paper) for 2008 ozone NAAQS); EPA-HQ-OAR-2018-0279-0256 at 2, 5-7 (2006 CASAC letter on second draft policy assessment (then called staff paper) for 2008 ozone NAAQS); *see also* EPA-HQ-OAR-2018-0279-0070 (2014 CASAC letter on second draft welfare risk and exposure assessment for 2015 ozone NAAQS).

even to reach a conclusion as to whether the effects are adverse or at what level of ozone the effects become adverse. This is inconsistent with the statutory requirement to "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, 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), and arbitrary. EPA's reliance on uncertainty is likewise unlawful and arbitrary. The D.C. Circuit has rejected the notion that EPA must "wait until it has perfect information before adopting a protective secondary NAAQS. Rather, the Act mandates promulgation of secondary standards requisite to protect public welfare from any 'anticipated adverse effects associated with' regulated pollutants, suggesting that EPA must act as soon as it has enough information (even if crude) to 'anticipate[]' such effects." *ATA III*, 283 F.3d at 380 (quoting 42 U.S.C. § 7409(b)(2); emphasis and alteration in original). By requiring refined information, EPA thus violates the Act.

Further, it is well-established that EPA cannot rotely point to "uncertainty" to justify its actions. *See, e.g.*, *State Farm*, 463 U.S. at 52. Nor can EPA justify a refusal to rely on certain data by saying that those data are less certain than other data. *See, e.g.*, *Tripoli Rocketry Ass'n v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 437 F.3d 75, 81-83 (D.C. Cir. 2006). Rather, what actually matters is whether EPA can rationally say that it is rejecting data or alternatives as too uncertain. EPA fails to do so here, instead irrationally rejecting options based solely on their being less certain than other options.

3. EPA arbitrarily and unlawfully fails to specify a level of air quality that is requisite to protect against several known and anticipated adverse welfare effects caused by ozone.

i. EPA unlawfully and arbitrarily treats tree growth loss as a surrogate for all vegetation-related adverse welfare impacts.

EPA proposes to use the relative biomass loss (RBL) functions for trees as a proxy for "the broad array of O3 vegetation-related effects." 85 Fed. Reg. at 49,899. EPA's approach is unjustified, irrational, and arbitrary. Further, by relying on an unjustified surrogate, EPA fails to comply with its statutory obligation to specify a standard that protects the public welfare from "any known or anticipated adverse effects." 42 U.S.C. § 7409(b)(2).

EPA has a statutory obligation to "specify 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. *Id.* (emphasis added). EPA may not use surrogates in a manner inconsistent with this statutory obligation. *See Sierra Club v. EPA*, 353 F.3d 976, 985 (D.C. Cir. 2004) (recognizing limits on EPA's discretion to use surrogates to ensure that EPA still complies with its statutory obligation to set standards that reflect the performance of the best performing

sources and what they can achieve with regard to hazardous air pollutants when setting technology-based standards for hazardous pollution under Clean Air Act section 112). Here, EPA contravenes its statutory obligation by using one adverse effect as a surrogate for another without showing that prevention of the former will prevent the latter. EPA does not even claim, let alone establish with evidence, that the prevention of adverse relative biomass loss will protect the public welfare against other vegetation-related adverse effects. EPA does not even claim that tree growth loss is reliably correlated with other vegetation-related effects, like crop loss, visible leaf damage, and alteration of plant-insect signaling.

EPA also does not claim that W126 levels that will prevent adverse welfare effects from tree growth loss will also prevent these other adverse effects. Crop loss, for example, is observed mainly in annual plants, not trees, and EPA has developed different E-R functions to characterize the response of crops to ozone, confirming that tree growth loss does not predict crop loss. Likewise, visible leaf damage does not necessarily correspond to tree growth loss. It is measured differently, and EPA claims (see below) that it lacks sufficiently reliable data to predict visible leaf injury. *E.g.*, 85 Fed. Reg. at 49,899 ("With regard to foliar injury, the lack of clear quantitative relationships that would support predictive E–R functions was recognized."). A fortiori, EPA cannot claim that prevention of tree growth loss will prevent adverse levels of visible leaf injury. Nor can EPA rationally claim that tree growth loss is a valid surrogate for other vegetation-related adverse effects that it claims to lack sufficient data to quantify and predict, such as disruption of plant-insect communication. Moreover, the expert CASAC has instructed EPA that visible leaf damage is a more sensitive adverse welfare effect than tree growth loss.[204] In fact, CASAC has instructed EPA that W126 values would have to be reduced below levels that limit tree growth loss to 2% to protect adequately against visible leaf damage.[205] EPA proposes to adopt a secondary standard that allows tree growth loss far above 2%, and therefore cannot possibly claim that such a standard will protect against visible leaf injury.

Another fatal flaw in EPA's reliance on tree growth loss as a surrogate for all other vegetation-related effects is that EPA proposes to retain a three-year average as the form and averaging period of the standard, on the ground that, in light of year-to-year variations "that influence the occurrence and magnitude of O_3-related effects in any year," EPA allegedly "has greater confidence" in a three-year average. 85 Fed. Reg. at 49,900. Even if this approach were justified as to tree growth effects, the effect of which builds up from year to year (which it is not, as explained below), it would not be justified as to effects like visible leaf injury and annual crop loss, the welfare effects of which are felt in a single growing season, and for which the public welfare therefore requires protection from high levels that may occur in a single year.

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[204] CASAC Letter 2014a at 14 (emphasis added).
[205] *Id.* ("Visible foliar injury is even more sensitive than RBL of 2%.").

EPA claims that this surrogacy approach was approved by the expert CASAC, citing the 2014 CASAC letter on the second draft PA for the last review. 85 Fed. Reg. at 49,899 n. 176. The CASAC's conclusions do not support EPA's approach, and in fact are inconsistent with it. As the CASAC letter makes clear, the CASAC endorsed RBL as a surrogate for other welfare effects that result from tree growth loss. *Id*. (quoting CASAC letter) ("The CASAC concurs that biomass loss in trees is a relevant surrogate for damage to tree growth that affects ecosystem services such as habitat provision for wildlife, carbon storage, provision of food and fiber, and pollution removal."). CASAC does not suggest, as EPA now claims, that tree growth loss is a surrogate for all vegetation-related effects, such as crop loss, visible leaf damage, or disruption of plant-insect communication. Indeed, if CASAC had agreed that tree growth loss is a surrogate for all vegetation-related adverse effects, it would not have identified benchmarks for other adverse effects that differ from the tree-growth loss benchmarks and advised EPA to set a standard protective of those other benchmarks. Yet that is what CASAC did. *See Murray Energy*, 936 F.3d at 618 (quoting CASAC letter advising that a level of 10 ppm-hrs is required to protect against visible leaf damage); CASAC Letter 2014a at 14 (advising that a level of 7 to 15 ppm-hours is required to protect against unacceptable crop loss).

ii. EPA's analysis of visible leaf damage—a distinct and well-established adverse welfare impact—is arbitrary and unlawful.

EPA proposes to conclude that the current secondary standard "provides sufficient protection" against visible foliar injury. 85 Fed. Reg. at 49,909. But the agency does not specify the target level necessary to protect against foliar injury. Instead, it points to putative "important uncertainties" in the "understanding of the O_3 exposure conditions that will elicit visible foliar injury." 85 Fed. Reg. at 49,908. EPA's action is arbitrary and unlawful. First, EPA offers no rational explanation as to why it disregarded the 10 ppm-hrs target recommended by the 2015 CASAC and thus fails to respond to the *Murray Energy* remand. Second, the Agency's conclusion about the sufficiency of the current standard is based on flawed analyses.

In *Murray Energy v. EPA*, the D.C. Circuit held that EPA's decision not to set a target level to protect against visible leaf damage during the 2015 review was arbitrary and capricious. 936 F.3d at 620. CASAC had advised EPA of its "scientific judgment" that "a level of 10 ppm-hrs is required to reduce foliar injury." *Id*. at 618 (quoting CASAC). But EPA rejected this advice in the final rule and concluded instead that there were too many "uncertainties and complexities" in the evidence to specify a level of air quality to protect against foliar injury. 80 Fed. Reg. at 65,407-08. The court rejected EPA's reasoning, holding: (1) that EPA must explain what evidence is available and rationally explain how it reached the conclusion that this evidence leaves EPA "unable to choose a level at all"; and (2) that "[w]here CASAC has 'reached a scientific conclusion that adverse [welfare] effects [are] likely to occur,' EPA must, 'explain why the evidence on which CASAC relied cannot support the degree of confidence CASAC placed in it.'" 936 F.3d at 619 (*quoting Mississippi*, 744 F.3d at 1357).

To begin with CASAC's recommendation, as discussed above, this rulemaking is, in part, EPA's response to the *Murray Energy* remand. EPA must thus explain why it could not rely on the CASAC analysis. EPA does not engage with this question in the proposed rule. The Agency refers to the current CASAC's recent vague assertion that "uncertainties continue to hamper efforts to quantitatively characterize the relationship of [visible foliar injury] occurrence and relative severity with ozone exposures," 85 Fed. Reg. at 49,907, but nowhere addresses the actually expert CASAC's clear scientific judgment that a level of 10 ppm-hrs is required. Indeed, in the same breath that it points to "uncertainties," the current CASAC recognizes, as it must, that "[v]isible foliar injury from ozone exposure has been well characterized for decades," and that the documentation of these effects extends to a large cross-section of "many tree, shrub, herbaceous, and crop species."[206] Once again, EPA does not rationally explain why the available evidence prevents EPA from specifying a level of protection. Nor does EPA rationally explain "why the evidence on which CASAC relied cannot support the degree of confidence CASAC placed in it." 936 F.3d at 619.

EPA arbitrarily proposes to conclude that the current secondary ozone standard "provides sufficient protection of natural areas, including particularly protected areas such as Class I areas, from O_3 concentrations in the ambient air that might be expected to elicit visible foliar injury of such an incidence and severity as would reasonably be judged adverse to the public welfare." 85 Fed. Reg. at 49909. As an initial matter, EPA's proposed conclusion arbitrarily and unlawfully fails to comply with the requirement the Act gives it. Moreover, the evidence that EPA offers to support this conclusion is flawed and unconvincing for the reasons discussed below.

First, EPA's Proposal arbitrarily and unlawfully avoids identifying a level at which it finds ozone's effects on visible leaf damage to be adverse. (As explained below, such a level is well below 17 ppm-hrs.) Instead, EPA alludes generally to some level of ozone "that might be expected to elicit visible foliar injury of such an incidence and severity as would reasonably be judged adverse to the public welfare." 85 Fed. Reg. at 49909. As that phrasing makes apparent, EPA is disclaiming making any such judgment, instead using a doubly passive and conditional phrasing—"might be expected" and "would reasonably be judged." But the Act commands "the Administrator" to exercise "judgment" in setting a secondary NAAQS that "shall specify a level of air quality requisite…to protect the public welfare from any known or anticipated adverse effects." 42 U.S.C. § 7409(b)(2). The Proposal thus makes clear that the Administrator is not exercising any judgment of his own on this issue, which is unlawful and irrational. *See Johnson v. Copyright Royalty Bd.*, 969 F.3d 363, 391 (D.C. Cir. 2020) ("One thing is clear from that passive-voice phrasing: Whoever it is that might be 'consider[ing]' the decision a 'rehearing,' it is not the Board." (alteration in original)).

Second, as for the evidence EPA offers in support of its statement, the EPA provides an analysis of the USFS FHM/FIA ozone biomonitoring data set (see EPA 2020 Appendix 4C

[206] 2020 CASAC Letter on the Integrated Science Assessment at 22.

Policy Assessment). The data are a useful piece of evidence that documents ozone injury across multiple bioindicator plants, years, and sites. But this bioindex metric is averaged twice, across each species and then across all species, which can mute representation of highly injured individuals. Accordingly, to ensure EPA is providing protection for vulnerable species, this data must be considered in its entirety along with additional information in setting a level protective of foliar injury. EPA has neither looked fully at this data nor looked at additional information. In fact, EPA does not provide the foundational pieces of this same dataset in the 2020 PA that was presented in the EPA 2014 PA and WREA (*see* WREA Section 7.2, and Figure 7-9 below) identifying 10.46 ppm-hrs as a benchmark level for foliar injury and a level that 58% of National Parks were exceeding this level at least 3 years over the study period. This previous analysis was part of key evidence that led the expert CASAC to recommend a level below 10 ppm-hrs.

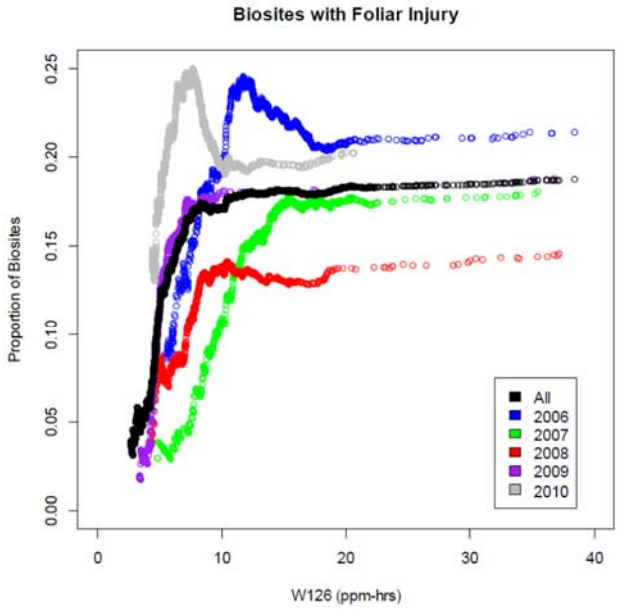

Figure 7-9 Cumulative Proportion of Sites with Foliar Injury Present, by Year

Instead of building on the previous evidence, EPA focuses on 25 ppm-hrs as an important point in its 2020 analysis of the biomonitoring data, based on the magnitude of increase in the rate of increase of biosite index scores of moderate to severe (Moderate BI = 15-25, heavy BI >25). There are at least three arbitrary aspects to this. First, EPA's focus on moderate to severe biosite index scores is arbitrary. The >0-4.9 and 5-15 biosite index score must be considered because, though the USFS method considers this as very light to light foliar injury, it also lists possible risk as "Visible injury to highly sensitive species, e.g., black cherry" and "Visible injury to moderately sensitive species, e.g., tulip poplar." Even if BI >15 is the focus, a third of biosites had an index greater than 15 with less than 7 ppm-hrs cumulative ozone exposure, which is significant. If all BI scores above zero are included, this lower threshold saw over 500 biosites with foliar injury. Second, in leaping on 25 ppm-hrs, EPA relies on the magnitude of increase in a rate of increase. It is hardly obvious why that particular derivative of a derivative is a

meaningful metric for determining the level at which ozone exposure has an adverse effect on visible leaf damage, and EPA nowhere explains why it is.

Third, more injury with higher ozone levels is expected, but it is arbitrary to use the higher percent of high BI scores in the > 25 ppm-hrs group for a threshold. That is because the mere fact that there's more injury at higher levels (measured as a percent of sites with high BI scores) doesn't say anything about whether there are adverse effects at lower levels, and the higher percentage at higher levels isn't necessarily meaningful, because there are fewer sites with any data at those levels. EPA must instead consider the overall number of sites that had injury, including those that had very light to moderate, as the purpose of the FIA data set is as indicators of damage, including very sensitive to less sensitive species. EPA must consider the expert CASAC's consideration of the FHM/FIA data, and that clearly shows injury is occurring at levels as low as 3 ppm-hrs and in the range of 5-10 ppm-hrs (Figure 7-9 above).

Additional data also point to a much lower threshold for foliar injury than 25 or 17 ppm-hrs. Foliar injury has been found at levels as low as a 12-hr W126 maximum 3-month value of 6.4 ppm-hrs in potted coneflower.[207] Lefohn and Musselman 2012 recommended a 24-hr W126 threshold of 6.37 ppm-hrs, with N100=4, for the Forest County Potawatomi Community. The authors based their recommendation on multiple sources including Davis 2007 who documented ozone injury on 4 indicator species. EPA references Davis 2007 and 3 other similar studies in the 2014 Policy Assessment in Table 5-7 (*see* page 5-57 of the EPA 2014 PA) re-created in Table 1 below. These studies used sum60 as an ozone metric, and EPA provided 12-hr W126 values; however, the number of months included in these values are not clear. We supplement EPA's table with the maximum 3-month 12-hr W126 sum calculated from the monthly 12-hr W126 sums provided in the Tropospheric Ozone Assessment Report (TOAR) database. In 2003 of the Davis 2007 survey, when all 4 indicators had ozone injury, the maximum 3-month 12-hour W126 was 7.7 ppm-hrs. Even if the W126 metric were not the relevant one and the 8-hour primary standard were, Myers et al. 2018, in chambers experiments, found injury in different species of milkweed that increased with the season, and occurred below 70 ppb.

Table 1. Visible foliar injury incidence in four National Wildlife Refuges, similar to EPA 2014 Policy Assessment Table 5-7 with updated maximum 3-month 12-hr W126 values [208]

Study	Site Name/EPA monitor ID #	Year	4th highest daily maximum	12 hr. W126	% Plants with visible injury	TOAR max. 3 month 12 hr W126	TOAR Months of max.

[207] Neufeld et al. 2018, calculated from 2011 data provided by H. Neufeld.

[208] *See* 2014 PA at 5-517, tbl. 5-7. Supplemented with maximum 3-month 12-hr W126 sums calculated from the monthly 12-hr W126 sums provided in the Troposhperic Ozone Assessment Report (TOAR) database.

			8-hr average	(number of months unknown)			
Davis, 2009	Cape Romain NWR, SC/ 450190046	2002	0.075	20	5-32	10.6	April-June
		2003	0.074	11	3-13	9.8	June-Aug.
Davis 2007a	Moosehorn NWR, ME/ 230090102 [209]	2002	0.1	24	0-17	11.9	June-Aug.
		2003	0.083	22	0-13	10.8	June-Aug.
		2004	0.082	14	3-10	7.0	June-Aug.
Davis 2007b	Seney NWR, MI/ 261530001	2002	0.083	11	0-13	6.1	April-June
		2003	0.076	15	1-6	7.7	May-July
		2004	0.074	10	2-6	3.8	May-July
Davis & Orendovici 2006	NWR, NJ/ 340010005 [210]	2001	0.095	39	0-45	No data	No data
		2002	0.092	53	0-4	No data	No data
		2003	0.085	36	0-4	No data	No data

The National Park Service also calculates exposures to evaluate ozone injury and damage as the running maximum 3-month, cumulative 12 one-hour (0800–1959) W126 and provides threshold values, see Table 2. In NPS field surveys to assess foliar injury caused by ozone, such as Kohut (2020),[211] they recognize EPA's 2010 draft review that identified a range for foliar injury, stating: "While EPA proposed a W126 3-mo standard in the range of 7–15 ppm-hr to protect vegetation, the threshold it identified for foliar injury is 5–9 ppm-hr."[212]

[209] Values are from Cadillac Mountain in Acadia National Park (the closest available data) and likely an overestimate of the values at Moosehorn NWR, which is north and inland.
[210] No data for this site are in the TOAR database.
[211] Kohut 2020. Field Surveys to Assess Foliar Ozone Injury on Plants in National Parks and Monuments on the Colorado Plateau, Natural Resource Report NPS/NRSS/ARD/NRR—2020/2112.
[212] *Id.*

Table 2. NPS Injury thresholds for the W126 3-mo index in cumulative ppm-hr [213]

Ecosystem component	W126 3-mo threshold	Response
Foliar injury in natural ecosystems	5–9 ppm-hr	Foliar injury
Tree Seedlings in natural ecosystems	7–13 ppm-hr	Growth reduction
Tree seedlings/saplings in plantations	9–14 ppm-hr	Growth reduction

The expert CASAC frames its overall recommendation of 7–15 ppm-hrs on the basis of all the evidence of casual effects to vegetation, including the foliar injury information. In CASAC's comments on the second draft Policy Assessment in 2014, they explicitly state: "A level below 10 ppm-hrs is required to reduce foliar injury."[214]

Notably, CASAC recognized the significance of the USFS FHM/FIA ozone biomonitor data, but did not limit its consideration of that data in the way that EPA now proposes to do. Further, CASAC's focus on the 10 ppm-hrs level is consistent with the CASAC committee's consensus comments on the draft WREA, where they clearly point to the level of 10 ppm-hrs as a point near which there is "a change in the E-R slope."[215] Noting "this slope change is not a threshold for no injury," CASAC explained that it was significant enough to make "10 ppm-hrs [be] a reasonable candidate level for consideration in the WREA, along with other levels."[216] EPA failed to examine that level before, and it continues to depart without rational explanation from CASAC's plain, science-based recommendation.

EPA's review of the FIA/FHM dataset provides a clear relationship between the W126 metric and foliar injury when sites that showed positive injury are sorted by soil moisture. This relationship is significant in that it allows land managers to recognize the W126 levels that can cause foliar damage that is not only unsightly to the public but also indicates plant stress. The high variability in foliar injury occurrence does not negate the positive findings because a robust relationship with W126 is still present, regardless of the presence of some variability. These positive findings necessitate action by EPA to protect the public welfare from the impacts that they represent.

While soil moisture at sites may be a factor in the level of injury observed, this environmental condition is just a risk factor that may or may not make a site and its plants at risk

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[213] *See* Kohut, Field Surveys to Assess Foliar Ozone Injury on Plants in National Parks and Monuments on the Colorado Plateau, Natural Resource Report NPS/NRSS/ARD/NRR--2020/2112 (2020), 5.

[214] CASAC Letter 2014a at iii.

[215] Letter from CASAC Chair Dr. H. Christopher Frey to U.S. EPA Administrator Gina McCarthy, re: CASAC Review of the EPA's Welfare Risk and Exposure Assessment for Ozone (Second External Review Draft) (EPACASAC-14-003), 15, June 18, 2014.

[216] *Id.*

but is not a determinant in the threshold. Soil moisture status does not cause the injury: ozone does. Even if soil moisture could be considered causal also, the mere fact that air pollution is one of many causes of an adverse impact does not relieve EPA of its obligation to protect the public welfare against adverse effects from air pollution. *See, e.g.*, 42 U.S.C. § 7408(a)(2)(A). EPA provides no valid reason for discarding or downplaying data showing particularly elevated levels of foliar injury at sites with moist soil conditions and higher W126 values. These results are completely consistent with other scientific evidence, and confirm that foliar injury occurs at ozone levels well below those EPA predicts occur under the current standard. Nor, given the robust data EPA has on foliar injury, does the contribution of soil moisture prevent EPA from specifying a level of protection. Thus, declining to specify a secondary standard protective against foliar injury based on soil moisture would be unlawful and arbitrary.

To the extent EPA is suggesting that it can deem visible foliar injury as not being an adverse effect on welfare, such a suggestion is unlawful and arbitrary. EPA itself has repeatedly identified foliar injury as adverse effects in prior reviews. In its 2010 reconsideration Proposal, EPA stated: "In an area such as a national park, where visitors come in part for the aesthetic quality of the landscape, the Administrator recognizes that visible foliar injury incidence is an important welfare effect which should be considered in determining an appropriately protective standard level. 75 Fed. Reg. 2938, 3025 (Jan. 19, 2010). On the same page, EPA also said the 1996 consensus workshop findings (which, among other things, recommended levels of protection against foliar injury) should be given substantial weight. *Id.* And the 2010 Proposal went on to say:

> The Administrator also believes that in order to preserve wilderness areas in an unimpaired state for future generations, she must consider a level that affords substantial protection from known adverse O_3-related effects of biomass loss and foliar injury on sensitive tree species, as well as a level that takes into account potential "anticipated" adverse O_3-related effects, including effects that result in continued impairment in the year following O_3 exposure (i.e., carryover effects).

Id. at 3025-26.

Further, the 2014 CASAC specifically identified visible foliar injury as an adverse welfare effect, a conclusion that CASAC has never altered or rescinded.[217] Indeed, CASAC confirmed that it has not departed from its advice on foliar injury by noting in its most recent review that EPA does not appear to have fully responded to the issues identified by the D.C. Circuit in *Murray Energy*,[218] which included EPA's failure to specify a level that would protect against adverse welfare effects associated with foliar injury. EPA offers no reasoned basis for rejecting these conclusions, or the Park Service analyses discussed above.

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[217] CASAC Letter 2014a at 10.
[218] 2020 CASAC Letter on Policy Assessment at 21.

iii. EPA unlawfully and arbitrarily fails to address ozone's adverse effects on climate.

As explained, EPA bears a heavy burden if it wants to be excused from carrying out its statutory obligations. It cannot merely assert uncertainty but rationally explain how the evidence supports the Agency's finding of such significant uncertainty that the agency cannot fully implement the statute. *See Murray Energy*, 936 F.3d at 618-20. Nor can EPA escape by making unsupported comparisons between the level of the primary standard and various levels of the secondary standard threshold. *See Am. Farm Bureau*, 559 F.3d at 530.

In this review, EPA finds once again that ozone plays a causal role in warming the atmosphere. *See* 85 Fed. Reg. at 49,882-83. Ozone's role in the greenhouse effect, climate forcing, and consequently climate change has been reinforced. However, EPA cites uncertainty around the amount of radiative forcing caused by tropospheric ozone and the extent to which changes in weather can be attributed to ozone as justification to not specify a level of air quality to protect against its adverse impacts. *See id*. at 49,883. EPA also presents uncertainties in its determination that ozone is likely causal in reducing carbon sequestration, a key mechanism to counter climate change. *See id*. at 49,900. Yet EPA does not claim that these uncertainties and evidence limitations are so profound that they render the agency unable to specify a protective standard, let alone explain such a conclusion. It is unlawful and arbitrary for EPA to decline to protect the public welfare from the climate impacts of ozone based on the mere existence of uncertainties and data limitations.

Further, EPA links biomass loss, which it also found to be causally related to ozone, to carbon sequestration. 85 Fed. Reg. at 49899. Although EPA points to uncertainty in quantifying the amount of carbon uptake due to avoided ozone damage, EPA compiles evidence of significant annual biomass loss in long lived perennial trees in the 2020 ISA, an impact that scales up to the landscape level.[219] EPA also recognizes that hundreds of species are documented to suffer biomass loss due to ozone exposure.[220]

In 2015, EPA specifically pointed to the fact that reduction of carbon storage is an important public welfare harm from ozone and considered it an important rationale for the need to revise the previous standard. *See* 80 Fed. Reg. at 65,370. This is further supported by the 2020 ISA that cites consistent findings of carbon storage loss with ozone damage.[221] In the 2014 WREA, EPA estimates that transitioning to a W126 of 7 ppm-hrs would increase carbon sequestration and produce carbon dioxide reductions equal to taking 11 million cars off the road.[222] Indeed, EPA qualifies this estimate as likely low, as EPA's analysis did not include the

[219] Gustafson et al. 2013; Lapina et al., 2016; and Capps et al. 2016.
[220] Bergmann et al., 2017.
[221] 2020 ISA at 8-103.
[222] 2014 WREA at 6-49.

forests on public lands, and therefore the climate benefits of reducing ozone exposure to 7 ppm-hrs would likely be much greater. EPA's do-nothing Proposal would forego this carbon sink. Increased atmospheric carbon on this scale qualifies as an adverse welfare effect. Yet EPA does not even attempt to protect against the degree of such effects predicted to occur at levels below 17 ppm-hrs.

EPA fails to rationally explain its failure to identify or provide requisite protection levels against this important welfare impact. It does not even try in this action. Further, in its last effort, where it actually attempted to confront the evidence, EPA's analysis was arbitrary. Specifically, at one point in its 2014 proposed rule, the agency sought to minimize the significance of additional carbon storage that would be provided with more protective W126 levels. EPA asserted that as a percent of the estimated carbon storage under the current standard, estimates of storage over 30 years under the 15, 11 and 7 ppm-hrs scenarios are less than 0.1% (13 MMtCO2e), just under 1% (593 MMtCO2e) and under 2% (1,600 MMtCO2e). 79 Fed. Reg. 75,234, 75,325 (Dec. 17, 2014). But by EPA's own measures, 1,600 MMt over 30 years (estimated at the 7 ppm-hrs level) is actually very significant. By comparison, EPA's past projections for its Clean Power Plan (i.e., setting standards of performance for carbon emissions from existing power plants under Clean Air Act §111(d) are that it will reduce CO2 emissions by roughly 300-500 MMt per year. *See* 79 Fed. Reg. 34,830, 34,931-33 (June 18, 2014). So, the carbon reduction benefits of a 7 ppm-hrs ozone standard over 30 years would be very roughly equal to about 4 years of the benefits from EPA's Clean Power Plan. EPA can hardly claim that such benefits are insignificant from a public welfare perspective.

In addition, EPA's failure to actually estimate, discuss, and assess the climate impacts of ozone pollution and its welfare implications is arbitrary and departs from the advice of CASAC without rational explanation. CASAC advises that EPA "should more thoroughly address the effects of ozone on climate change."[223] "At a minimum," CASAC instructs, "estimates of the change in warming caused by a change in ozone should be discussed and implications for human welfare in the United States should be evaluated."[224] EPA's departure from CASAC's advice is unlawful and arbitrary.

iv. EPA unlawfully and arbitrarily fails to protect the public welfare with regard to adverse effects on crop yields.

Though the quantitative relationship between ozone exposure and relative yield loss (RYL) in crops is well-established, EPA arbitrarily claims that it need not "separate[ly] consider[]" or "provide a more appropriate focus" on crop yield effects because of "complexities" in evaluating their public welfare impact. 85 Fed. Reg. at 49,912.

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[223] 2020 CASAC Letter on PA, *supra* n. 33, at 22.
[224] *Id.*

The ozone-related growth effects on agricultural and commodity crops have been "extensively studied," and "robust E-R functions" have been developed. 85 Fed. Reg. at 49,878. CASAC has, in fact, advised EPA of its judgment that 5% yield loss constitutes an adverse welfare impact and that a range of 7 ppm-hrs to 15 ppm-hrs is protective of median crop loss of 5% or less.[225] CASAC noted that, at a level of 7 ppm-hrs, all analyzed crop species would have a yield loss of less than 5%.[226]

EPA does not give effect to CASAC's recommendation, nor does it provide a reasonable explanation for failing to do so. EPA admits that its analysis of air quality at sites meeting the current standard shows that they are experiencing RYL of 5.1%, a level that CASAC has instructed constitutes an adverse welfare effect. This is arbitrary and unlawful. The Agency points to "complexities involved in interpreting the significance of such small RYL estimates" to support its decision not to set a standard that protects against crop loss, but offers no explanation for why RYL of 5.1% is "small." 85 Fed. Reg. at 49,906. According to EPA, these complexities stem from: the "extensive management of crops" that "may to some degree mitigate potential O_3-related effects," the use of "variable management practices" to achieve "optimal yields," and various other environmental conditions that may impact crop yield. *Id.* But EPA does not claim that these complexities prevent it from specifying ozone levels requisite to protect the public welfare from crop loss, let alone rationally explain such a claim, especially given that CASAC has proposed a benchmark. And the mere fact that factors other than ozone also affect crop health and productivity does not excuse EPA's failure to address the impact of ozone.

EPA also points to alleged uncertainty in the applicability of established E-R functions in current agricultural areas, 85 Fed. Reg. at 49,898, but gives no reason for that alleged uncertainty other than to repeat that agricultural management practices may influence the harm from ozone. The impact of ozone on crops is well-established by a large body of evidence across a wide range of crops, and EPA provides no rational reason why this data would not be applicable to current agricultural areas, regardless of the obvious fact that agricultural management will also affect the productivity of crops. Again, merely pointing to a potential complicating factor is insufficient to excuse EPA's failure to specify a level to protect against this well-established and well-characterized adverse effect.

EPA also claims that the "question of assessing overall public welfare impacts for such RYL estimates" is complicated by the fact that changes in yield of commercial crops and commodities "may affect producers and consumers differently." 85 Fed. Reg. at 49,906. EPA here seems to claim that reducing crop loss may actually be detrimental to the public welfare. But EPA fails to explain why this would be so and provides no record support for such a claim. The argument also doesn't square with EPA's acknowledgment that producers use variable

[225] CASAC Letter 2014a at 14.
[226] *Id*.

management practices to produce "optimal yields." For each of these reasons, EPA's refusal to specify a level to protect the public welfare against crop losses is unlawful and arbitrary.

4. EPA arbitrarily and unlawfully proposes a 3-year average, 17 ppm-hours general target level of protection.

EPA arbitrarily and unlawfully proposes to retain a three-year average, 17 ppm-hrs target level of protection, which is ill-suited to protect against adverse impacts to the public welfare caused by ozone. In reaffirming this target level, EPA fails to respond to the *Murray Energy* remand. Indeed, in its letter review of EPA's policy assessment, CASAC states that it is "not clear" that EPA has fully addressed the *Murray Energy* decision.[227] *Murray Energy* requires EPA to "either lower the standard to protect against unusually damaging cumulative seasonal exposures that will be obscured in its three-year average, or explain its conclusion that the unadjusted average is an appropriate benchmark notwithstanding CASAC's contrary advice." 936 F.3d at 618. EPA accomplishes neither in the proposed rule.

Instead, EPA retains the three-year average, 17 ppm-hrs benchmark, which based on the RBL data presented in Table 4A-3 allows for 5.3% biomass loss in the median of 11 species in a single year, with at least 6% biomass loss for 5 species, including as much as 35.6% in one tree species. A biomass loss of 6% has been found by the expert CASAC to be "unacceptably high." *Murray Energy*, 936 F.3d at 613 (quoting CASAC).

During the 2015 review, CASAC advised that, if EPA were to use a three-year average benchmark, "the level of the standard should be revised downward such that the level for the highest three-month summation in any given year of the three-year period would not exceed [its] scientifically recommended" range of single-year benchmarks. 936 F.3d at 617 (quoting CASAC). This would be necessary to "protect against single unusually damaging years that will be obscured in the average." *Id*. In the final rule, EPA proposed a three-year average, 17 ppm-hrs benchmark and argued that it was appropriate because it was below the 19 ppm-hrs that was associated with a median across 11 species of 6% annual growth loss. 80 Fed. Reg. at 65,406-07.

But, in *Murray Energy*, the D.C. Circuit concluded that EPA had not demonstrated "how its chosen benchmark protects against 'unusually damaging years.'" 936 F.3d at 617. The court also noted that "EPA's use of a benchmark that *averages out* to less than 6% biomass loss over three years does not accord with CASAC's advice." *Id.* Here, EPA once again arbitrarily proposes not to "revise downward" and instead to retain the same three-year average target.

i. EPA's analysis of relative biomass loss is arbitrary.

Even assuming relative biomass loss were the controlling effect for purposes of the secondary standard's stringency, the 6% annual relative biomass loss target EPA proposes to

[227] 2020 CASAC Letter on Policy Assessment, *supra* n. 33, at 21.

retain and therefore use is far too high to protect the public welfare.[228] Previous CASACs clearly established an ecological end point of 1-2% annual RBL as negatively impacting forest trees which are long lived perennials therefore experiencing cumulative loss year after year. A biomass loss of 2% per year compounds, adding up year after year in forests that should be thriving over 30-100 years. In this review EPA does not offer a scientifically based or otherwise rational basis for concluding otherwise. Further, CASAC found the level of 7 ppm-hrs is the only level analyzed for which the relative biomass loss for the median tree species is less than or equal to 2%. Accordingly, EPA must protect against tree biomass loss greater than 2% annually by adopting a W126 level of 7 ppm-hrs to protect forests and ecosystems, especially in Class I areas. The 2020 PA and other material in the record provides clear evidence that tree biomass loss increases with increasing W126 levels above 7 ppm-hrs based on concentrations exposure response curves. Further, sensitive tree species that experience significant biomass loss when exposed to ozone are integral to our nation's forest and even urban/suburban landscaping and greenways.

EPA has incorrectly reasoned that an upper level of the W126 for protecting tree biomass loss, as relative biomass loss, should be 17 ppm-hrs because this aligns with previous CASAC comment that >6% biomass is unacceptably high and because 17 and 15 (CASAC recommended upper limit) have the same median percent loss (5.3%).[229] Further, EPA claims that there is little difference from 17 down to 9 ppm-hrs because there is no change in the number of tree species at or below 2% biomass loss, e.g. 5 out of 11. EPA's rationale is arbitrary because it departs from the evidence and the expert CASAC's recommendation without rational explanation. Three facts make this clear:

1. expert CASAC percent loss judgments are based on an annual form of the W126 standard, yet EPA is proposing a 3-year averaging for the standard.

2. percent biomass loss values that DO CHANGE dramatically from the low end of expert CASAC's recommendation to the current standard as seen in PA Appendix 4A, Table 4A-3, which show the ranges here:

[228] Although *Murray Energy* rejected an argument that EPA's prior reliance on a 6% target was arbitrary based on the record in that case, 936 F.3d at 615-16, nothing in *Murray Energy* prevents EPA from revising its prior determination to better accord with the scientific evidence and the advice of the expert CASAC.

[229] The 2020 Policy Assessment reports a median value of 4.5% RBL at a level of 15 ppm-hrs, see Table 4A-3.

Species	W126 = 7	W126 = 10	W126 = 17
Red Alder	1.8%	2.8%	5.3%
Ponderosa Pine	2.4%	3.6%	6.7%
Aspen	3.4%	5.2%	9.8%
Tulip poplar	1.5%	3.2%	9.4%
Eastern White Pine	2.6%	4.6%	10.7%
Black Cherry	16.7%	22.9%	35.6%

3. The expert CASAC clearly supports 7 ppm-hrs as appropriate to protect trees from significant biomass loss, at no greater than 2%, while EPA wrongly construed CASAC comment to indicate that 2% biomass loss is acceptable. Moreover, the CASAC's rejection of 17 ppm-hrs as the top of the range was not based solely on the assumption of a 6% biomass loss at that level. CASAC also relied on evidence of adverse effects at 10 and 7 ppm-hrs.[230]

One 2014 CASAC member provides more context in his individual comments where he states:

> We favor using a measure of central tendency of the data, specifically the median across species (the green line in Fig. 5-2). This analysis provides the median of best available estimates within each species, and the median across species with all species treated equally. Table 6-1 presents the RBL results for individual species for different levels of W126. This table demonstrates that a range of 7 ppm-hrs to 15 ppm-hrs will protect against RBL of 2% for at least 5 of the 12 species. We do not consider a value of 17 ppm-hrs from Table 6-1 because even though only 5 of 12 tree species are estimated to have relative biomass loss of 2 percent or less at this level, the median species has relative biomass loss of 6.0 percent, which is unacceptably high. With compounding over the harvest cycle or life span of these species, this will result in considerably greater cumulative RBL as discussed above. For the more sensitive tree seedlings, a value closer to the lower end of the range (7 ppm-hrs) would be more appropriate. The level of 7 ppm-hrs is the only level analyzed for which the relative biomass loss for the median tree species is less than or equal to 2 percent.[231]

The issue of percent RBL compounding is not only related to how loss would occur year after year, it also pushes the total standing biomass backward in terms of a tree's capacity to sequester carbon. The first point is simply that a loss of 2% per year becomes 6% after 3 years with all other things held equal. Over the lifetime of trees that live 50-100 years, the loss would be very detrimental. Even if a tree's growth or biomass accumulation is faster than 2% a year in

[230] Even if EPA rationally excludes the cottonwood data and could rationally move the top of CASAC's range from 15 ppm-hrs to 17 ppm-hrs, our point in this sentence still stands.
[231] CASAC Letter 2014a at 14.

the presence of ozone, the impact of the loss would still factor in annually, as it would not grow as much as it would in the absence of ozone. The second point is that just like a loss in invested savings, a loss of biomass in one year makes it difficult to catch up in future years. This is particularly germane to the ability of an individual tree and a forest as a whole to sequester carbon moving forward.

Further, these RBL data, based on the E-R dataset, do not stand on their own and have been supported by other studies, as EPA recognizes in the 2020 ISA: "A meta-analysis by Wittig et al. (2009) found that average ozone exposure of 40 ppb significantly decreased annual total biomass by 7% across 263 studies."[232]

Of note, CASAC advised that levels above 15 ppm-hrs should not be options for the secondary standard. By way of example, CASAC noted that at 17 ppm-hrs, the median tree species has an "unacceptably high" loss of tree biomass (6%).[233] Further, they state that a level of "7 ppm-hrs is protective of ecosystem services" as it is the only level in which the median loss for the tree species examined is less than or equal to 2%.[234]

EPA must not misconstrue the reasoning and position of CASAC when making a final decision on the secondary standard. Instead the Agency must consider the science squarely and set a W126 secondary standard to 7 ppm-hrs to protect tree growth and health and thereby public welfare.

ii. EPA fails to offer a reasonable explanation for why the three-year average, 17 ppm-hrs benchmark is appropriate, notwithstanding CASAC's advice to the contrary.

During the 2015 review, CASAC advised EPA that it did not recommend the use of the three-year averaging period, finding that use of such an averaging period "is not supported by the available data."[235] CASAC instead advised using a single year benchmark, on the grounds that it is more biologically relevant, provides more protection to annual crops, protects perennials from the cumulative effects of ozone exposure, and protects against single unusually damaging years.[236]

EPA nonetheless finalized reliance on a three-year average benchmark and attempted to justify its decision by arguing that the benchmark provided a focus on welfare effects of "potentially greater" significance than effects "associated with a single year" of exposure. 80 Fed. Reg. at 65,404. In *Murray Energy*, the D.C. Circuit rejected this position as "inconsistent" with EPA's recognition that ozone effects in plants are cumulative and that a single season of

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[232] 2020 ISA, *supra* at 8-30.
[233] CASAC Letter 2014a at iii.
[234] *Id*.
[235] *Id.* at 13.
[236] *Id*.

high ozone exposure can have a "negative impact on species regeneration in subsequent years." 936 F.3d at 617. The court concluded that EPA had identified "no contrary evidence" to demonstrate why "single-year effects matter less than a three-year average" and remanded the issue to EPA to "explain its conclusion that the unadjusted average is an appropriate benchmark." *Id.* at 617-18.

Here, EPA yet again proposes reliance on a three-year average benchmark and fails to offer a reasonable explanation for why it is an appropriate benchmark to protect against harms to the public welfare.

EPA cites variability in ambient ozone concentrations from year to year, but fails to explain why that justifies a 3-year average over a single year standard. First, as the previous CASAC noted, the variability in a single-year W126 standard is reduced by the fact that it is the sum of 3 months of data, so it is not nearly as sensitive to extreme events as an hourly or 8-hour averaging period. EPA has asserted in the past review that the PA found greater significance for effects associated with multiple-year exposures, but that PA observation was referring to potential carryover effects from one year to the next. It does not show that a single year metric would provide inadequate protection, or that a 3-year average would provide better protection. In fact, the PA finds that use of 3-year averages may lead to underestimation of RBL. EPA further asserted in the past review that CASAC's concern about protecting against adverse effects associated with a single year's exposure "can be addressed through use of a three-year average metric, chosen with consideration of the relevant factors." 75 Fed. Reg. at 75,347. But EPA still does not explain how such an approach can address CASAC's concern, nor does EPA commit to adopting such an approach. EPA also asserts that the Administrator recognizes greater confidence in judgments related to public welfare impacts based on a three-year average metric, but fails to explain why this is so, and fails to cite scientific evidence in support. Finally, EPA disregards CASAC's advice that if a 3-year average is used, it should be set at a lower level than a single-year standard to protect against single unusually damaging years that will be obscured in the average. EPA does not and cannot claim that its selected 17 ppm-hrs, 3-year average, protects against single-year W126 values at or above the 19 ppm-hrs single-year level that EPA again says corresponds with the 6% RBL that must be prevented. EPA further offers no explanation for failing to follow CASAC's advice on this score.

EPA arbitrarily undermines the E-R functions it also touts, claiming there are few directly observing the relevant levels of ozone, raising questions about how the underlying experiments were translated to functions, noting that some of the functions rely on few experiments, and noting general variability and the existence of other factors besides cumulative ozone exposure that affect RBL. *See* 85 Fed. Reg. at 49,901, 49,910. Yet the E-R functions remain a solid foundation of quantitative data that EPA used to justify its last revision of the secondary standard. They are based on chamber experiments that controlled for other variables, which then identifies ozone's direct effects. EPA's treatment of the E-R functions also accounts for the variation by using multiple E-R functions for species when available and looking at median RBL

based on the E-R functions for 11 different species. But there are also larger-scale exposure studies including FACE that reinforce their findings in ozone biomass impact assessment. Expert CASAC made clear that E-R functions can be used with certainty, stating:

> Care should be taken not to overstate uncertainties. For example, there is quite a lot of certainty in estimates of biomass loss for forest tree seedling species and crop species for which E-R functions have been developed. Because several dominant crop species have E-R functions, there is a quite a lot of certainty about impacts of ozone on crop yield across most annual cropland in the U.S.[237]

Without rational explanation, EPA claims 3-year averaging meshes better with the E-R functions than does relying on annual W126 levels. 85 Fed. Reg. at 49,910. This is especially confounding as the E-R functions are based on shorter timeframes and prorated to 92 days when used to calculate the RBL. The argument that W126 annual values would be highly variable is also inconsistent with the fact that W126 is a 3-month cumulative metric, which would be much less variable than an 8-hour average.

EPA arbitrarily says it can't really predict the difference between biomass loss over 3-year periods with the same 3-year average W126 index but different patterns of annual levels (e.g., 17-17-17 vs. 10-17-24) by (1) pointing to an example it supplies in Appendix 4A of the PA for aspen, and (2) writing off differences between different exposure results as the residue of imprecision or inexactitude. 85 Fed. Reg. at 49,901. While using it to try to explain-away this important decision, EPA describes this analysis as "not intensive or elaborate and intended for illustration of a concept."[238] EPA presents its limitations as well, including that it does not account for carryover, which may be significant after a high exposure year, and that this example is only for aspen, but other species may not respond similarly. More concerning is that the analysis focused on how the biomass loss at variable annual levels compare to biomass estimated at the 17 ppm-hr level rather than to biomass levels under ambient, unpolluted conditions (based on the King et al. 2005 dataset ambient ozone averaged 37 ppb). Aspen will see biomass loss even at 10 ppm-hr; however, when EPA compares loss under a 10 vs 17 ppm-hrs year in its example it looks like at 4.9% gain. Clearly EPA's presentation of the data doesn't capture the full impact. If the estimated biomass loss were compared to ambient biomass data the biomass loss ranged between 5.3-16.3% in a single year and averages across the six years range from 9.9-11.7% for all the scenario patterns.

EPA points out that after year 1 the differences between total aboveground biomass was always less than 2% in their example. This is flawed reasoning for supporting EPA position that it can't predict biomass loss differences between a 1 year interval vs a 3 year interval because, as shown in Table 3, the impact on tree biomass is always greater than 5.3% with most years greater than 9% compared to ambient, which is more representative of the true impact; year one

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[237] CASAC Letter 2014a at 15.
[238] *See* 2020 Policy Assessment, *supra* n. 64, at 4A-21.

should not be excluded and in two of EPA's scenarios show 5% biomass loss in year 1; the percent difference in total tree biomass for the two scenarios shown below (10-24-17 vs 24-17-10) range from +4.9 to –5.0 in year 1 a differential of 9.9% and reach a differential of 2% in year 3 and year 6; expert CASAC used 2% RBL *in one year* as the most protective level and if EPA is not providing an analysis of the differences in annual growth impacts to which RBL is applied EPA is not addressing the issue directly; and finally, EPA must account for the cumulative impact over three years relative to 1, which it failed to do here.

Table 3. EPA Table 4A-7 (columns 1-6 and 9-10) and the percentages of the scenarios 17-17-17, 10-24-17, and 24-17-10 compare to ambient

From EPA Table 4A-7									Added		
			Biomass (g/m2) under different W126 levels			% difference in total tree biomass compare to 17			% difference in total tree biomass compare to ambient		
Year	Ambient Biomass*	%growth	W126 17	10,24,17	24,17,10	10,24,17	24,17,10		W126 17	W126 10,24,17	W126 24,17,10
Y0-1997	9.1		9.1	9.1	9.1						
1998	280.2	2979.1	254	266.1	240.9	4.9%	-5.0%		-10.5%	-5.3%	-16.3%
1999	849.5	203.2	767	752.9	754.4	-1.9%	-1.7%		-10.7%	-12.8%	-12.6%
2000	1335.5	57.2	1206	1191.2	1215.1	-1.2%	0.8%		-10.8%	-12.1%	-9.9%
2001	1581.1	18.4	1427	1424.1	1425.1	-0.2%	-0.1%		-10.8%	-11.0%	-10.9%
2002	2099.4	32.8	1895	1867.2	1892.6	-1.4%	-0.1%		-10.8%	-12.4%	-10.9%
Y6-2003	2695.2	28.4	2432	2404.6	2457.4	-1.1%	1.0%		-10.8%	-12.1%	-9.7%
* this removes the foliage from previous year											

Further, EPA's reliance on purported inexactitude, imprecision, or uncertainty as a rationale for privileging 3-year averaging is arbitrary for the reasons given above. Thus, for all the foregoing reasons, EPA's rejection of the expert CASAC's advice for adoption of a single-year W126 metric is arbitrary and violates EPA's duty to adequately justify a departure from CASAC's recommendation.

5. EPA Arbitrarily and Unlawfully Proposes to Use the Primary Standard's Form for the Secondary Standard.

EPA proposes to retain the primary standard's form for the secondary standard despite CASAC's conclusion that the single-year W126 index is the appropriate scientifically relevant

form and averaging time to ensure protection of the public welfare.[239] EPA fails to provide rational explanation as to why it is departing from CASAC's expert determination.

During the 2015 review of the secondary ozone standard, CASAC recommended that EPA use the single-year W126 index as the form and averaging time for the standard.[240] CASAC explicitly stated that the "form of the current standards is inadequate" to protect vegetation and ecosystem services from adverse effects.[241]

EPA rejected this advice and instead retained the existing form and averaging time: the three-year average of the fourth-highest daily maximum eight-hour ozone concentration. EPA argued that it was not necessary to adopt the W126 index because the ozone exposure levels associated with the existing form and averaging time and a three-year average of the W126 index were "highly correlated."[242] In *Murray Energy*, the D.C. Circuit explained that it could not assess the relevance of this claim, and thus the reasonableness of EPA's decision not to adopt the W126 index as the form and averaging time, because "EPA never explained why it was reasonable to focus on a three-year average of the W126 in the first place." 936 F.3d at 618.

Here, EPA again arbitrarily disregards the science and proposes to use the primary standard's form and averaging time for the secondary standard. Further, with its flawed discussion of the correlation between the DV and W126 metrics, EPA fails to offer a reasonable explanation for its decision not to adopt a single-year W126 standard.

i. EPA disregards the merits of W126.

The scientific foundation supporting the use of a cumulative standard to protect vegetation began in the 1997 review. At that time, EPA had a significant amount of science recognizing that the form of the standard used to protect human health was not appropriate for protecting vegetation. In the 2008 review, again in the reconsideration in 2010, in the 2015 review, and in the current review, EPA clearly supports the main assertions that ozone's impact on vegetation is cumulative and that higher ozone concentrations are more important in causing measurable impacts to plants than lower concentrations.[243] This is the foundation for the W126 metric, which uses a sigmoidal weighting function to weight higher concentrations more than lower levels and sums the seasonal ozone exposure. EPA has continued to focus on this type of metric as the "most biologically relevant metrics for consideration of O_3 exposures eliciting vegetation-related effects. Such a metric has an 'explanatory power' that is improved 'over using indices based on mean and peak exposure values.'"[244] As shown in the record for the current

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[239] *See* CASAC Letter 2014a at 12.
[240] *See id.*at iii.
[241] *Id.* at 11.
[242] EPA quoted in *Murray Energy*, 936 F.3d at 618.
[243] *See* 2020 ISA, *supra* n. 147, at IS.3.2.
[244] 79 Fed. Reg. at 75,316 (citing U.S. EPA, 2013a, ISA for Ozone, section 2.6.6.1, p. 2-44).

rulemaking, CASAC and EPA's staff have repeatedly and unequivocally recommended adoption of this metric for the secondary ozone standard.

Considering this long-standing support of the W126 metric, vetted in two reviews (and one re-consideration) over a nearly 25-year period, it is clear that the implementation of this metric is too long delayed. EPA must adopt this metric as the standard instead of the health-based metric that is used for the primary health standard.

ii. The DV 8-hour standard is not appropriate to address vegetation harms.

EPA cannot lawfully or rationally set a national welfare standard based on a metric designed to protect public health. It is arbitrary and unlawful for EPA to propose a welfare standard in the 8-hour form in direct contradiction with its own conclusion that public welfare protection is – as a matter of science – appropriately judged through the use of the cumulative seasonal W126-based metric. EPA's decision also disregards CASAC's advice that is founded on a plethora of scientific information and context built in this review and past reviews. This is the very definition of an arbitrary and capricious decision.

Moreover, EPA fails to offer a full scientific basis for rejecting CASAC's advice on this issue, as the law requires.[245] The agency makes no claim that reliance on the 8-hour form will do a better job of protecting welfare than the W126 form, and indeed the record provides no support for such a claim. Nor is there any claim by the agency that some statutorily relevant purpose is served by foregoing the W126 metric – which the agency agrees is more biologically relevant and appropriate. Implementation concerns are not legally or rationally relevant at the standard-setting stage.

EPA arbitrarily argues that the W126 form is inferior to the current form because W126 "would not explicitly limit the occurrence of hourly concentrations at or above specific magnitudes" (relevant, EPA says, to visible leaf damage, 85 Fed. Reg. at 49,913, an effect EPA arbitrarily and unlawfully does not specify an air quality threshold for), whereas the 8-hour standard "can provide control of both peak concentrations and concentration-weighted cumulative exposures," as EPA says the evidence shows. 85 Fed. Reg. at 49,913. EPA's argument is irrational. It is internally inconsistent: it criticizes W126 because it "would not explicitly limit" hourly levels but praises the current form that also doesn't explicitly limit cumulative exposures. *Id.* EPA also ignores that a cumulative standard would be implemented alongside the primary standard, which focuses on 8-hour exposures, and fails to consider the possibility of having both a cumulative standard and a standard that focuses on shorter exposures, like the primary PM NAAQS.

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[245] *Murray Energy*, 936 F.3d at 614; *Mississippi*, 744 F.3d at 1358 ("to the extent that CASAC has exercised scientific judgment, EPA must respond in kind.").

EPA's attempt to justify use of the primary standard form and averaging period by claiming that compliance with the primary standard will provide incidental protection against excessive cumulative exposure is also arbitrary because it relies on happenstance. The expert CASAC made clear that:

> The form of the current standard is inadequate to provide [the requisite welfare] protection. From correlation analysis based on the Higher Order Direct Decoupled Method (HDDM), the EPA suggests that a W126 level of 15 ppm-hrs may in many cases be similar to the current standard. However, as noted in the CASAC's review of the Second Draft WREA (EPA-CASAC-14-003), the CASAC finds that a W126 level of 15 ppm-hrs may not be similar to the current standard, since the actual approaches that would be used to achieve such a level are likely to be different than those assumed in the HREA air quality scenarios for just meeting the current standard. Specifically, and quoting from our review of the Second Draft WREA:
>
> > "The currently reported finding of only small differences in risk between just meeting the current standard and a W126-based level of 15 ppm-hrs must not be interpreted to mean that just meeting the current standard will be as protective as meeting a W126-based standard at 15 ppm-hrs. There are two key factors that must be considered when making this comparison. First, air quality was simulated in the Second Draft WREA based on the magnitude of across-the-board reductions in NOx emissions required to bring the highest monitor down to the target level. Meeting a target level at the highest monitor requires substantial reductions below the targeted level through the rest of the region. This artificial simulation does not represent an actual control strategy and may conflate differences in control strategies required to meet different standards and different targets. As a result, there may be a number of monitors that meet the current standard but would not meet an alternative W126 standard. Second, and equally important, the current form of the standard is much less biologically relevant for protecting vegetation than is a seasonal, peak weighted index such as the W126, which was designed to measure the cumulative effects of ozone exposure."[246]

The expert CASAC reiterated that the unsuitability of the primary standard form and suitability of the W126 form is a scientific judgment.[247]

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[246] CASAC Letter 2014a at 11-12.
[247] *Id.* at 12-15.

EPA itself has previously agreed that the lack of a relationship between 8-hour and cumulative levels "indicates that in some locations, [ozone] air quality patterns can lead to elevated cumulative, seasonal [ozone] exposures without the occurrence of elevated daily maximum 8-hour average [ozone] concentrations." 79 Fed. Reg. at 75,344/2. And even this CASAC notes that the primary standard does not protect against ozone exposures measured in ways that differ from the current form, explaining that "decreasing peak ozone concentrations will not consistently decrease the mean ozone concentrations."[248] Though the specifics of the scenario the current CASAC discusses differ from the distinction between the primary standard form and the W126 metric, the basic point stands: the primary standard focuses on controlling one type of ozone exposure, and cannot be rationally relied on to control other types.

Moreover, even on its own terms, EPA's comparison between the level of protection fails. EPA's own data over 19 years show numerous areas that met the 0.070 ppm 8-hour health standard but violated thresholds measured under the W126 metric that correspond with adverse welfare effects. As explained above, the proper, scientifically based threshold is 7 ppm-hrs, measured over a single year. There are over 3,000 instances where a monitor met the primary standard but exceeded the 7 ppm-hrs single-year threshold. That same result holds even under EPA's unsupported preferred 3-year average. Further, as the table below shows,[249] there are numerous instances of monitors meeting the existing primary standard but violating even the under-protective thresholds EPA prefers, whether expressed as single-year or 3-year averages.

[248] 2020 CASAC Review of Policy Assessment, *supra* n. 33, at 4.

[249] The following four tables are derived from air quality data EPA provided on W126 values and 8-hour design values at https://www.epa.gov/air-quality-analysis/ozone-naaqs-review-analyses-and-data-sets, which EPA incorporated into the docket at EPA-HQ-OAR-2018-0279-0073 and EPA-HQ-OAR-2018-0279-0310. For the all-sites data, we followed EPA's data-completeness approach given at PA app.4D, at 4D-3 to -4. (The Class I-proximate area data appears already to have been cleared of insufficiently complete data.) Nevertheless, there appear to be discrepancies between the results EPA describes at PA 4-66 tbl.4-1 and the results we derived for all sites: we found more instances of sites with 8-hour design values complying with the 70 ppb primary standard, but exceeding the 17 ppm-hrs (3-year average) benchmark EPA arbitrarily set.

	# Observations							
	**3-yr W126 average				***1-yr W126 average			
***Design Value (ppb)**	≥ 19 (ppm-hrs)	> 17 (ppm-hrs)	> 7 (ppm-hrs)	Total	≥ 19 (ppm-hrs)	> 17 (ppm-hrs)	> 7 (ppm-hrs)	Total
≤ 70	2	21	3020	8197	50	117	3009	8970
65-70	2	21	2744	4529	48	113	2546	4864
68-70	2	21	1809	2358	41	93	1571	2523

*ranges inclusive of boundaries

** Annual 4th Max Percent Complete ≥ 75; Annual W126 Percent Complete ≥ 75; 3-Year Average 4th Max Percent Complete ≥ 90; 3-Year Average W126 Percent Complete ≥ 90. Rows where 3-year average W126 values were not given were excluded from totals.

*** Annual 4th Max Percent Complete ≥ 75; Annual W126 Percent Complete ≥ 75. Rows where annual W126 index value was not given were excluded from totals.

As the table below indicates, similar results hold even for just the monitors in or near Class I areas.

	# Observations							
	3-yr W126 average				1-yr W126 average			
***Design Value (ppb)**	≥ 19 (ppm-hrs)	> 17 (ppm-hrs)	> 7 (ppm-hrs)	Total	≥ 19 (ppm-hrs)	> 17 (ppm-hrs)	> 7 (ppm-hrs)	Total
≤ 70	2	7	193	498	41	62	586	1494
65-70	2	7	160	219	41	62	477	657
68-70	2	7	102	115	36	54	295	345

*ranges inclusive of boundaries

EPA is well aware of this mismatch. Even in the prior review, in the 13-year period studied by EPA, there were more than 1,300 occurrences where monitors reached or exceeded CASAC's 7 ppm-hours benchmark for protecting tree growth (even after averaging over three years), while meeting the health standard.[250] And if EPA had looked at single-year cumulative levels as CASAC recommended (rather than averaging them out over 3 years), it would have found that numerous national parks and wilderness areas far exceeded even a 17 ppm-hours

[250] "Wells max4 w126 comparison memo" at 14 tbl.9 (EPA-HQ-OAR-2008-0699-4325).

threshold while meeting the health standard.[251]. These include national parks and Class I wilderness areas like Grand Canyon (maximum annual level of 21.7 ppm-hours), Petrified Forest (18.6 ppm-hours), Saguaro (20.2 ppm-hours), Mesa Verde (22 ppm-hours), Canyonlands (23.6 ppm-hours), Zion (19.8 ppm-hours), Carlsbad Caverns (26.7 ppm-hours), Wind Cave (20.6 ppm-hours), Chiricahua (19.8 ppm-hours), Superstition (19.6 ppm-hours), Maroon Bells-Snowmass (23 ppm-hours), Weminuche (20.8 ppm-hours), and Bridger (18.8 ppm-hours). 79 Fed. Reg. at 75,331-32, tbl.7.[252] Indeed, EPA's data show that areas in compliance with the 0.070 ppm 8-hour health standard experienced cumulative exposures that EPA agrees correspond to adverse effects on welfare. Worse, this has occurred in some of the nation's most iconic national parks, including Grand Canyon, Canyonlands, Mesa Verde, and Zion, as well as Maroon Bells-Snowmass and Weminuche wilderness areas. Monitors in each of these locations have recorded cumulative 3-year average levels higher than 17 ppm-hours during periods when a 0.070 ppm 8-hour level was met.[253]

Thus, EPA is mistaken when it claims that "virtually all" areas in compliance with a design value of 70 ppb do not exceed the target level of 17 ppm-hrs on the W126 index. *E.g.*, 85 Fed. Reg. at 49,911/3. EPA is also wrong to conclude, as the agency appears to do, that these elevated cumulative exposures that occur despite compliance with the health standard are insignificant or de minimis. EPA's own data shows that, since 2000, EPA's monitors have recorded 25 observations with 3-year average W126 in excess of 17 ppm-hrs despite compliance with a 70 ppb 8-hour standard, and 52 observations with annual W126 values exceeding 19 ppm-hours despite such compliance. Moreover, in its effort to dismiss this evidence that cumulative levels corresponding to adverse welfare effects in fact will occur despite compliance with the primary standard, EPA irrationally compares these recorded instances to the total number of ozone measurements. EPA fails to explain why this is the appropriate comparator. To evaluate the protection of welfare values provided by the health standard, EPA should rationally compare these problematic observations only to the subset of observations where ozone levels are close to the health standard, but compliant with it. When EPA's data are considered in proper context, they show a large and significant number of exceedances of harmful W126 thresholds in areas that meet the primary standard. That comparison, for both all sites and Class I area proximate sites, is presented in the tables below.

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[251] *See* Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (Aug. 2014) at 5-28 to -29 tbl.5-2; *see also* Class I Areas dvle75 w126ge15 July 2015 for Final Rulemaking; Dataset on which Table 3 in the Preamble to the 2015 Final Rule is based (Sept. 2015) (EPA-HQ-OAR-2008-0699-4249).

[252] *See* Class 1 area data at EPA-HQ-OAR-2008-0699-4249

[253] *See* Class I Area data at EPA-HQ-OAR-2008-0699-4249.

All Sites	# Observations												
	**3-yr W126 average							***1-yr W126 average					
*Design Value (ppb)	≥ 19 (ppm-hrs)	%	> 17 (ppm-hrs)	%	> 7 (ppm-hrs)	%	Total	≥ 19 (ppm-hrs)	%	> 17 (ppm-hrs)	%	> 7 (ppm-hrs)	%	Total
≤ 70	2	0.02%	21	0.26%	3020	36.84%	8197	50	0.56%	117	1.30%	3009	33.55%	8970
65-70	2	0.04%	21	0.46%	2744	60.60%	4528	48	0.99%	113	2.32%	2546	52.34%	4864
68-70	2	0.08%	21	0.89%	1809	76.72%	2358	41	1.63%	93	3.69%	1571	62.27%	2523

*ranges inclusive of boundaries

** Annual 4th Max Percent Complete ≥ 75; Annual W126 Percent Complete ≥ 75; 3-Year Average 4th Max Percent Complete ≥ 90; 3-Year Average W126 Percent Complete ≥ 90. Rows where 3-year average W126 values were not given were excluded from totals.

*** Annual 4th Max Percent Complete ≥ 75; Annual W126 Percent Complete ≥ 75. Rows where annual W126 index value was not given were excluded from totals.

Class I areas	# Observations												
	3-yr W126 average							1-yr W126 average					
*Design Value (ppb)	≥ 19 (ppm-hrs)	%	> 17 (ppm-hrs)	%	> 7 (ppm-hrs)	%	Total	≥ 19 (ppm-hrs)	%	> 17 (ppm-hrs)	%	> 7 (ppm-hrs)	%	Total
≤ 70	2	0.40%	7	1.41%	193	38.76%	498	41	2.74%	62	4.15%	586	39.22%	1494
65-70	2	0.30%	7	1.07%	160	24.35%	219	41	6.24%	62	9.44%	477	72.60%	657
68-70	2	0.58%	7	2.03%	102	29.57%	115	36	10.43%	54	15.65%	295	85.51%	345

*ranges inclusive of boundaries

As well as comparing monitors' compliance with the primary standard form with arbitrarily weak W126 thresholds over a 19-year period, EPA also examines the relationship between the primary standard and W126 values, finding it to be positive and nonlinear, at least based on the 2016-2018 period. 85 Fed. Reg. at 49,893/1. This comparison provides only limited information, as it is based on just three years' worth of data. Moreover, to the extent the relationship changes over time, EPA's assumption that it will continue to hold is baseless and thus arbitrary. Accordingly, EPA must make a rational examination of whether the relationship will continue to hold. Such an examination may be informed by studying how the relationship has changed over time. Regrettably, EPA's arbitrarily short comment period limits our ability to carry out the analysis.

Similarly, EPA characterizes the relationship between the long-term change in the DV metric and the W126 metric as positive and linear, measured over the 2000-2002 to 2016-2018 period. 85 Fed. Reg. at 49893/2. But, again, the relevant question is whether that relationship will continue to hold moving forward, and EPA's comparison ignores important considerations. For example, the relationship may be different over a somewhat narrower range of years. If it is different in recent years from what it was in earlier years, or overall, that may have implications for what the relationship is likely to be moving into the future. Particularly relevant date ranges are tied to implementation of standards using the DV metric. The DV metric only started being the focus of implementation in 2004, at the earliest, when designations for the 1997 NAAQS were made. Thus, a relevant question becomes what the relationship looks like from 2004-2006 to 2016-2018. Further, in most areas, implementation of the 1997 NAAQS has been superseded by implementation of newer, more stringent NAAQS. Implementation of the 2015 NAAQS is in its infancy still. Thus, what is the relationship from 2012-2014 (when the 2008 NAAQS started being implemented) to 2016-2018? Again, however, EPA's arbitrarily short comment period limits our ability to carry out the analysis.

Additional support for the lack of a necessary relationship between the two metrics comes from the regional differences in the relationship that EPA acknowledges in the policy assessment. EPA has failed to rationally address the importance of these differences and what they mean about the nature of the relationship moving forward.

EPA itself has shared these concerns about the mismatch between the primary standard and the actually protective W126 form. In 2014, it noted that there was no consistent relationship between 8-hour and W126 levels. 79 Fed. Reg. at 75,344 ("These known differences between urban and rural sites suggest that there is the potential for an inconsistent relationship between 8-hour daily peak O_3 concentrations and cumulative, seasonal exposures in those areas.").

Finally, we note once more that this is not the first time EPA has tried to force the secondary standard to fit into the primary standard. EPA's effort here is arbitrary for the same fundamental reason it was arbitrary before: the forms are not the same, and emissions control that affects one form does not necessarily affect the other. Because of the core repetition, we also

incorporate here by reference our comments on this point from the 2015 review. EPA-HQ-OAR-2008-0699-2720 at 194-99.

VI. THE ADMINISTRATOR'S PUTATIVE ENVIRONMENTAL JUSTICE ANALYSIS IS ARBITRARY

EPA directly mentions "environmental justice" exactly once in the Proposal – to assert that it "believes that this action does not have disproportionately high and adverse human health or environmental effects on minority, low-income populations and/or indigenous peoples." 85 Fed. Reg. at 49,914. The Agency claims that since it has considered "at-risk groups," this fulfils its obligations under E.O. 12,898. The two terms are not necessarily synonymous, and at minimum, EPA has done nothing to indicate or explain that they are. Further, as discussed above, the Agency has entirely failed to analyze the susceptibility of communities of color and lower socioeconomic status to different levels of ozone pollution, and has done nothing to remediate the environmental justice issues that permeated the 2015 review.[254]

Executive Order 12,898 calls for agencies to "identify[] and address[], as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low income populations in the United States and its territories and possessions, the District of Columbia, the Commonwealth of Puerto Rico, and the Commonwealth of the Mariana Islands." EPA must assess whether its Proposal to "retain, without revision," the outdated ozone NAAQS harms human health or the environment, and whether those impacts will be disproportionately borne by communities of color and low-income communities.[255] EPA's own record in both the 2020 and 2015 reviews makes clear that the human health harms of maintaining the outdated standard are disproportionately distributed and, as already described above, EPA is already flouting the Clean Air Act's separate statutory mandate under the NAAQS Program to consider effects on these same populations.[256]

The analysis the Executive Order calls for is different from the analysis the Act calls for. Indeed, the 4th Circuit recently rejected an attempt to conflate the two. In *Friends of*

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[254] Comments of American Lung Association, et al., on EPA's Proposed Revisions to the National Ambient Air Quality Standards for Ozone, March 17, 2015, 79 Fed. Reg. 75,234, ID No. EPA-HQ-OAR-2008-0699-2720, at 240-57 (describing irrationalities of EPA's proposed environmental justice analysis). We incorporate here by reference the cited comments.

[255] Bell, Michelle L., Antonella Zanobetti, and Francesca Dominici. "Who Is More Affected by Ozone Pollution? A Systematic Review and Meta-Analysis." *American Journal of Epidemiology* 180, no. 1 (July 1, 2014): 15–28, *available at* https://doi.org/10.1093/aje/kwu115.

[256] The Proposal itself notes that "[a]mong populations of different races or ethnicities, black non-Hispanic children aged five to 14 have the highest prevalence, at 16.1%. Asthma prevalence is also increased among populations in poverty. For example, 11.7% of people living in households below the poverty level have asthma compared to 7.3%, on average, of those living above it (CDC, 2019, Tables 3–1 and 4–1; PA, Table 3–1). Population groups with relatively greater asthma prevalence might be expected to have a relatively greater potential for O3-related health impacts." 85 Fed. Reg. at 49,850.

Buckingham v. State Air Pollution Control Board, the Court explained, "'The purpose of an environmental justice analysis is to determine whether a project will have a disproportionately adverse effect on minority and low income populations.'" 947 F.3d 68, 87 (4th Cir. 2020) (quoting *Mid States Coal. for Progress v. Surface Transp. Bd.*, 345 F.3d 520, 541 (8th Cir. 2003)). Based on that understanding, the Court held that it was irrational for the government's environmental justice analysis to "merely fall[] back on NAAQS and state air quality standards not tailored to this specific EJ community." *Id.* at 90. The Court explained

> The Board's reliance on air quality standards led it to dismiss [environmental justice] concerns. Even if all pollutants within the county remain below state and national air quality standards, the Board failed to grapple with the likelihood that those living closest to the Compressor Station—an overwhelmingly minority population according to the Friends of Buckingham Survey—will be affected more than those living in other parts of the same county. The Board rejected the idea of disproportionate impact on the basis that air quality standards were met. But environmental justice is not merely a box to be checked, and the Board's failure to consider the disproportionate impact on those closest to the Compressor Station resulted in a flawed analysis.

Id. at 91-92.

EPA here is repeating the same irrationality. Its reliance on its overall analysis ignores precisely the disproportionate impacts that the Executive Order compels it to analyze and that EPA purports to have analyzed. EPA's approach reduces environmental justice analysis to "merely a box to be checked." That approach is not consistent with the Executive Order, is independently not rational, and is not in keeping with core principles of justice and equity.

Notwithstanding the Agency's attempt to characterize its Proposal as merely maintaining the status quo, the studies contained in EPA's own record both now and from 2015 are sufficient to trigger EPA's responsibility under E.O. 12,898 to assess whether health harms from maintaining the current ozone standard are disproportionately borne by vulnerable communities and, if so, how EPA should address this disparity. The fact that the status quo is inequitable is not a rational reason either to forego meaningful analysis of the inequities of the status quo or to avoid redressing those inequities. As the record notes, communities of color and lower socioeconomic communities—which can and often do overlap—are frequently disproportionately exposed to higher levels of ozone air pollution, to more types of elevated air pollution and to more chronic air pollution. And, perhaps not surprisingly, communities of color and lower socioeconomic communities suffer a disproportionately higher asthma burden in the United States—particularly Blacks, Puerto Ricans, and Native Americans. Further, and as discussed extensively in our 2015 comments, in many parts of the country, as air quality progressively worsens in an area, representation of Blacks and other communities of color in the population increases while representation of whites in the population decreases. It is critical to

consider the cumulative impacts of multiple stressors on these communities when assessing health impacts, including a population's exposure to multiple pollutants, exposure to higher levels of multiple pollutants, and chronic exposure to lower levels of multiple pollutants.

Further, in the midst of a pandemic that disproportionately harms communities of color and low-income communities, the mandates of E.O. 12,898 have never been more urgent. The Administrator signed this rule six months into a global pandemic, and yet the Proposal nowhere discusses the disproportionate impact that COVID-19 has on communities of color and low-income communities and how that informs setting the ozone standard. Doubly burdening these communities during a respiratory pandemic is unconscionable, and the Administrator's silence in the face of these disproportionate impacts further underscores the inadequacy of the Proposal's environmental justice review.

EPA's failure protect sensitive subpopulations is a violation of its legal requirement under E.O. 12,898 review and under the mandates of the Clean Air Act. It further is irrational. Contrary to EPA's assertion, Section II of its August 14, 2020 Federal Register notice does not document that this proposed action does not have disproportionately high and adverse human health or environmental effects on communities of color, low-income populations, or indigenous peoples, as specified in the Executive Order. *See* 85 Fed. Reg. at 49,914. If the 2020 Ozone NAAQS is to adequately address environmental justice issues, as it must, EPA must undertake a serious environmental justice review of the cumulative impacts these communities face, and set a standard using a precautionary approach to protect the health of these vulnerable populations.

VII. THERE IS NO LAWFUL OR RATIONAL BASIS FOR WEAKENING THE OZONE NAAQS

As explained elsewhere in these comments, EPA has arbitrarily failed to explain how its review remotely justifies maintaining the outdated 2015 standard rather than strengthening it. *A fortiori*, the science available to the agency in no way justifies a weaker standard, notwithstanding EPA's attempt to redefine the relevant exposure level in the Schelegle study relied on by the Administrator in 2015.[257] To the extent EPA appears to consider relevant factors, its purported concerns about "uncertainty" in setting the standard seems only to drive it toward setting a less protective standard. That is precisely the opposite of the orientation of the Act and is thus unlawful and irrational. E.g., *Lead Indus. Ass'n*, 647 F.2d at 1155 ("orientation" of the Act is toward protection and precaution)

[257] See, e.g., 85 Fed. Reg. 49,840, n. 29: "For the 70 ppb target exposure, Schelegle et al. (2009) reported, based on O3 measurements during the six 50-minute exercise periods, that the mean O3 concentration during the exercise portion of the study protocol was 72 ppb. Based on the measurements for the six exercise periods, the time weighted average concentration across the full 6.6- hour exposure was 73 ppb (Schelegle et al., 2009)." The 2015 review described this study as having a concentration of 72 ppb, and in the 2020 review, the Agency instead adorts the "weighted average concentration" of 73 ppb.

We also reiterate that EPA may not consider background ozone levels and their purported impact on the standards' attainability at all in setting the standard. The Proposal asserts the D.C. Circuit:

> rejected the argument that the EPA was required to take background O_3 concentrations into account when setting the NAAQS, holding that the text of CAA section 109(b) precluded this interpretation because it would mean that if background O_3 levels in any part of the country exceeded the level of O3 that is requisite to protect public health, the EPA would be obliged to set the standard at the higher nonprotective level []. Thus, the court concluded that the EPA did not act unlawfully or arbitrarily or capriciously in setting the 2015 NAAQS without regard for background O_3 [].

85 Fed. Reg. 49,836 (citing *Murray Energy Corp. v. EPA*, 936 F.3d 597 (D.C. Cir. 2019)) (internal citations omitted).

EPA falsely characterizes the Court's holding. Rather than holding merely that EPA was not required to consider background ozone's purported effect on attainability, the court made exceedingly clear that background levels may not be considered in setting the standard. It held that the Act makes only public health and welfare relevant considerations in standard setting, and thus that "'the agency is not free to trespass beyond the bounds of its statutory authority by taking other factors into account.'" *Murray Energy*, 936 F.3d at 623 (quoting *Lead Indus.*, 647 F.2d at 1150). It further held that, based on the structure of the Act, "Congress decided that EPA should account for background ozone during enforcement, not when setting standards." *Id.* It also held that its own binding precedent forecloses the polluters' argument: "Simply put, 'the question of attainability is not relevant to the setting of ambient air quality standards under the Clean Air Act.'" *Id.* at 623-24 (quoting *API*, 665 F.2d at 1190). And, capping it off with a clear, concise, to the point statement, the Court summarized its holding: "the Clean Air Act prohibits EPA from adjusting for background ozone in setting the NAAQS." *Id.* at 624. To the extent EPA's [258]is an attempt to re-introduce discussion of background levels into the consideration of the standards, this is a violation of the plain language of section 109, the Act's structure, and the D.C. Circuit's controlling precedent.[259] The D.C. Circuit has repeatedly chastised EPA for repeatedly violating its binding decisions in the same ways. *E.g.*, *NRDC v. EPA*, 643 F.3d 311, 322-23 (D.C. Cir. 2011); *Sierra Club v. EPA*, 479 F.3d 875, 884 (D.C. Cir. 2007). EPA must resist the temptation to go down that path yet again.

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[259] *See, e.g.*, 85 Fed. Reg. 49,838, "In such locations, the modeling suggests the potential for episodic and relatively infrequent events with substantial background contributions where daily maximum 8- hour O3 concentrations approach or exceed the level of the current NAAQS (i.e., 70 ppb). This contrasts with most monitor locations in the U.S. for which international contributions are predicted to be the lowest during the season with the most frequent occurrence of daily maximum 8-hour O3 concentrations above 70 ppb."

VIII. CONCLUSION & SUMMARY OF RECOMMENDATIONS

For all of the reasons explained above, EPA must re-do its inadequate scientific review process, revise its Proposal for the primary ozone NAAQS to no higher than 60 ppb, propose a primary standard that targets long-term ozone exposure, revise its Proposal for the secondary NAAQS to no higher than 7 ppm-hours (measured as a single-year W126 metric), and then reopen the comment period. Only these actions would reflect the Clean Air Act's directives and binding case law, which make clear that EPA's responsibility is to protect public health with an adequate margin of safety and protect public welfare against any known or anticipated adverse effect, based on the best available science.

Sincerely,

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