



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 any known or anticipated health-related effects from polluted air. 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 numerical NAAQS or other important elements of the standard (*e.g.*, form of the standard, averaging time, etc.). 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.

*American 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.

## **B. NAAQS must be set at a level that protects everyone**

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. As 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. at 42,381 (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. EPA interprets the Clean Air Act as providing citizens the opportunity to pursue their normal activities in a healthy environment. 44 Fed. Reg. 8202, 8210 (Feb. 8, 1979). Thus, as EPA has acknowledged, it cannot deny Americans 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.<sup>1</sup> Indeed, EPA cannot deny

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<sup>1</sup> *See also* 116 Cong. Rec. 32,821, 32,901 (Sept. 21, 1970) (remarks of Senator 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.”); 116 Cong. Rec. 32,981, 33,114 (Sept. 22, 1970) (remarks of Senator 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.”); *id.* at 33,116 (remarks of Senator 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 Senator Randolph) (“we have to insure the protection of the health of the citizens of this Nation, and we have to protect against

protection against adverse health and welfare effects merely because those effects are confined to subgroups of the population or to persons especially sensitive to air pollution. *See, e.g., Nat'l Env'tl. Dev't 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. Rep. No. 95-294, 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 death and hospitalization. *See Ethyl Corp.*, 541 F.2d at 18 (“the public health may properly be found endangered ... by a lesser risk of a greater harm”).

### **C. EPA must err on the side of protecting public health when there is scientific uncertainty**

The D.C. Circuit has characterized the NAAQS as “preventative in nature.” *E.g., Ethyl Corp.*, 541 F.2d at 15; *see also* H. 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*, 283 F.3d 355, 369, 378 (D.C. Cir. 2002).

Thus, in keeping with the precautionary and preventative 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. 38,857 (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 API v. EPA*, 684 F.3d 1342, 1352 (D.C. Cir. 2012).

In the seminal case on 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 v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980). Limited data are not an excuse for failing to establish the level at which there is an absence of adverse effect. 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.

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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 Congressman Vanik) (“Human health and comfort has been placed in the priority in which it belongs -- first place.”).

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. Noting the newness of many human alterations of the environment, the court found:

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 common sense 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 Dept. 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 “is free to use conservative assumptions in interpreting the data,” “risking error on the side of overprotection rather than underprotection”). Rather, as discussed above, EPA must take a protective and precautionary approach tha

#### **D. EPA must also establish NAAQS that protect vulnerable subpopulations**

Importantly, the NAAQS must be set at levels that are not only adequate to protect the average member of the population, but also guard against adverse effects in vulnerable subpopulations, such as children, the elderly, and people with heart and lung disease. In fact, the D.C. Circuit has repeatedly found that if a certain level of a pollutant “adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard.” *American 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 Americans 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.

*American Lung Ass’n*, 134 F.3d at 390 (citations omitted); *Nat’l Envtl. Dev’t Ass’n’s Clean Air Project*, 684 F.3d at 810. Stated another way, NAAQS must “be set at a level at which there is ‘an absence of adverse effect’ on these sensitive individuals.” *Lead Indus. Ass’n*, 647 F.2d at 1153.

### **E. The only lawful consideration in setting NAAQS is the effect of the pollutant in the 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; *NRDC 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); *NRDC 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.

There is no room for doubt about this conclusion. In 2001, Justice Scalia, writing for a unanimous Supreme Court, found that the plain language of the statute makes clear that economic costs cannot be considered when establishing a standard: “Were it not for the hundreds of pages of briefing respondents have submitted on the issue, one would have thought it fairly clear that this text does not permit the EPA to consider costs in setting the standards.” *Whitman*, 531 U.S. at 465. The D.C. Circuit’s case law, which governs NAAQS, is consistent with this Supreme Court holding. For example, in 1981, the D.C. Circuit upheld the 1979 ozone standards against the argument that EPA had to consider the standards’ “attainability,” which natural and other background levels might affect. *Am. Petroleum Inst.*, 665 F.2d at 1185, 1190. The D.C. Circuit later explained, “[i]t is only health effects relating to pollutants in the air that EPA may consider.” *NRDC*, 902 F.2d at 973 (emphasis in original).

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.”<sup>2</sup> The Court found that the “text of § [74]09(b), interpreted in its statutory and historical context and with appreciation for its

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<sup>2</sup> See, e.g., Appalachian Power Co. Resp. Br. in Support of Cross-Pet’rs (“Power Co. *Whitman* Pet. Br.”) 2-5, 22-25, 30-31, *Am. Trucking*, No. 99-1426 (U.S.) (arguing that EPA must consider “broad impacts” or “indirect health, environmental and economic effects”); ATA Cross-Pet’rs Br. (“ATA *Whitman* Pet. Br.”) 26-28, *Am. Trucking*, No. 99-1426 (U.S.) (summarizing argument and characterizing D.C. Circuit case law); *id.* at 37-39 (arguing that EPA must consider “personal comfort and well-being” in setting primary standards); Ohio Br. in Support of Cross-Pet’rs (“Ohio *Whitman* Pet. Br.”) 2, 14-16, *Am. Trucking*, No. 99-1426 (U.S.) (arguing that EPA must consider “cost or other factors” and “social, economic and environmental costs”); ATA Reply Br. (“ATA *Whitman* Reply”) 6-8, *Am. Trucking*, No. 99-1426 (U.S.) (arguing that EPA must “consider competing factors including costs”); Appalachian Power Co. Reply Br. (“Power Co. *Whitman* Reply”) 20 & n.45, *Am. Trucking*, No. 99-1426 (U.S.) (arguing that EPA “must address...the cost to society (e.g., health, environmental or economic costs)” and “overall costs to society”).

importance to the [Act] as a whole,” foreclosed all these arguments about costs. *Whitman*, 531 U.S. at 471.

## II. EPA Review of the Ozone NAAQS Contains Critical Process Failures

Since 2017, EPA has made several changes to the NAAQS review process without input from CASAC, EPA career staff, or the public. These *ad hoc* changes, including the disbanding of the particulate matter expert panel, failure to form the ozone expert panel and extreme shortening of the drafting and review timeline, undermine the integrity of the review process and compromise EPA’s ability to set necessarily protective air quality standards. The members of the CASAC ozone review panel for the 2009 to 2015 review of the NAAQS for ozone (including two former chairs and ten former members of the chartered CASAC) submitted a letter to the current CASAC at the beginning of December regarding the ISA and PA for the review of the ozone NAAQS.<sup>3</sup> In these letters, they raise concerns over these process changes and the compromised nature of this ozone review and make recommendations for restoring the integrity of the process. The letter states:

“We unanimously find that myriad unwarranted changes have been made to the NAAQS review process and to the composition of the CASAC since 2017. These changes are collectively harmful to the quality, credibility, and integrity of EPA’s scientific review process and to CASAC as an advisory body.”<sup>4</sup>

We echo these concerns and emphasize the following comments:

### A. EPA’s decision not to form an expert ozone panel undermines the scientific integrity of the NAAQS review process

In July 2018, EPA issued a request for experts for the ozone review panel. In October, EPA announced that they would not form an expert ozone review panel, providing no rationale for this abrupt change. This decision goes against a successful four-decade precedent of “augmenting

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<sup>3</sup> Chris 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),” December 2, 2019.

Available at:

[https://yosemite.epa.gov/sab/sabproduct.nsf//B2AF0B23ABE6A60E852584C4007312E3/\\$File/EPA+CA+SAC+O3+Review+ISA+PA+Letter+191202+Final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf//B2AF0B23ABE6A60E852584C4007312E3/$File/EPA+CA+SAC+O3+Review+ISA+PA+Letter+191202+Final.pdf)

<sup>4</sup> Chris 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),” December 2, 2019.

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CASAC with the expertise it needs via qualified review panels that deliberate, interactively, with members of the chartered CASAC.”<sup>5</sup>

According to the former members of the ozone review panel:

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.

**B. The current CASAC is not equipped to perform a review of the ozone policy assessment**

Between 2017 and 2018, there was a complete turnover of CASAC membership, so that by 2018 no member of CASAC had served on the committee for more than a year. This turnover translates to a loss of institutional memory, and a lack of experience with this specific type of review.

Further, the current CASAC does not have the breadth or depth of expertise to perform an adequate NAAQS review. While Administrator Wheeler emphasized the representation of five panelists who work in state, local, or federal environmental agencies when he announced the CASAC members,<sup>6</sup> the committee subsequently lacks diversity and breadth in expertise. In fact, written comments from CASAC itself to Administrator Wheeler, submitted in April 2019, highlighted deficiencies of the committee, calling attention to the lack of epidemiological expertise on the panel:

“The breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals. For example, the chartered CASAC has found it difficult to achieve consensus in some areas (summarized

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<sup>5</sup> Chris 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),” December 2, 2019. Available at:

[https://yosemite.epa.gov/sab/sabproduct.nsf//B2AF0B23ABE6A60E852584C4007312E3/\\$File/EPA+CA+SAC+O3+Review+ISA+PA+Letter+191202+Final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf//B2AF0B23ABE6A60E852584C4007312E3/$File/EPA+CA+SAC+O3+Review+ISA+PA+Letter+191202+Final.pdf)

<sup>6</sup> 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,” News Release, U.S. Environmental Protection Agency, Washington, DC, October 10, 2018, <https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-actcommittee>

below), and to do so likely requires further scientific expertise from, and discussion with, epidemiologists and additional experts in human clinical studies and toxicology.”<sup>7</sup>

As the former ozone panel members emphasize:

“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.”<sup>8</sup>

Without an additional panel of experts, it’s unreasonable to expect a group of seven people to perform a thorough review of such a vast, technical topic.

In lieu of a robust panel of experts on ozone, Administrator Wheeler assembled a pool of consultants available to answer questions for members of CASAC. There are several crucial differences between this pool of consultants and the traditional expert panel. First, this pool was not selected specifically for the review of the ozone NAAQS, and therefore lacks the specific expertise, as the same consultants were involved in the particulate matter NAAQS review. No member of the consultant pool served on the ozone expert panel in the 2009-2015 review of the ozone NAAQS, suggesting that crucial expertise is missing from this pool. Secondly, the consultants only interact with CASAC in writing, and are not allowed to deliberate with the committee. This undermines the mechanisms of peer review central to a strong evaluation of science-based information. For these reasons, the consultant pool is not an adequate substitute for the expertise and input of a full panel.

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<sup>7</sup> Louis Anthony Cox et al, “CASAC Review of the EPA’s *Integrated Science Assessment for Particulate Matter (External Review Draft - October 2018)*,” Environmental Protection Agency, April 11, 2019, available at:

<https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/%24File/EPA-CASAC-19-002+.pdf>

<sup>8</sup> Chris 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)*,” December 2, 2019. Available at:

[https://yosemite.epa.gov/sab/sabproduct.nsf/B2AF0B23ABE6A60E852584C4007312E3/\\$File/EPA+CA+SAC+O3+Review+ISA+PA+Letter+191202+Final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/B2AF0B23ABE6A60E852584C4007312E3/$File/EPA+CA+SAC+O3+Review+ISA+PA+Letter+191202+Final.pdf)



### **C. The consolidated time frame for drafting and reviewing the policy assessment ignores statutory requirements and compromises the integrity of the document**

The draft policy assessment was released just over two months after the IRP was finalized – compared to over a year and a half during the previous ozone review.<sup>9</sup> This shortened drafting period appears to have placed extreme pressure on the EPA staff responsible for writing the policy assessment and led to critical omissions simply due to time constraints. One of the most concerning examples of this is the failure of the PA to consider the health effects of ozone on outdoor workers, a particularly vulnerable subgroup. EPA staff, during the December CASAC meeting, noted this omissions was the result of inadequate time.<sup>11</sup> A footnote in the draft PA, states that “outdoor workers are not a population that has been explicitly simulated in the current analyses...” despite the fact that “target analyses of outdoor workers in the 2014 REA (single study area, single year) found an appreciably greater portion of this population as compared to the full population of adults to experience exposures at or above benchmark concentration...”<sup>12</sup> Considering that nearly half of the jobs held by civilian workers require outdoor work,<sup>13</sup> failure to consider the greater ozone exposure experienced by this at-risk subpopulation severely decreases the likelihood that the ozone standard will be sufficiently protective of the health of millions of Americans.

As emphasized by the former ozone expert panel:

“The late 2020 deadline for completing the ozone review does 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. This would be true even if the committee were supported by a robust panel of experts in the multiple disciplines involved. Thus, EPA is ignoring statutory requirements for the need for a

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<sup>9</sup> U.S. Environmental Protection Agency, “Internal Review Plan for the Ozone National Ambient Air Quality Standards - External Review Draft.” September 2009. *Accessed at:*

<https://www3.epa.gov/ttn/naaqs/standards/ozone/data/externalreviewdraftO3IRP093009.pdf>

<sup>10</sup> 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](https://www.epa.gov/sites/production/files/2019-08/documents/o3-irp-aug27-2019_final.pdf)

<sup>11</sup> 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

<sup>12</sup> U.S. Environmental Protection Agency, “Policy Assessment for the Ozone National Ambient Air Quality Standards, External Review Draft,” page 3-56. November 2019. *Accessed at:*

<https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0279-0018>

<sup>13</sup> “Over 90 percent of protective service and construction and extraction jobs require work outdoors.” January 06, 2017. TED: The Economics Daily. *Accessed 12/13/19 at*

<https://www.bls.gov/opub/ted/2017/over-90-percent-of-protective-service-and-construction-and-extraction-jobs-require-work-outdoors.htm>;

thorough and accurate scientific review of the NAAQS in setting a review schedule. Statutory deadlines are not an excuse for deficiencies in the review process.”<sup>14</sup>

By prioritizing a condensed timeline over the integrity of the review itself, EPA has failed to uphold their mandate to protect human health and the environment. A second draft of the PA should be drafted, with an extended period for public comment, to remedy these critical emissions and shortcomings.

**D. The simultaneous drafting and review of the policy assessment and the integrated science assessment leads to an inappropriate “commingling” of science and policy.**

Traditionally, the ISA is drafted and finalized with opportunity for CASAC and public review before the PA is drafted. This allows for the most recent, relevant science to provide the basis for policy decisions. However, by drafting and reviewing the ISA and the PA concurrently, the necessary clarity in available science is not available for the PA. 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. Thus, the integrity of the process is harmed when policy issues are addressed before the science issues are adequately settled.”<sup>15</sup>

By attempting to draft the PA before the ISA has been finalized, EPA is ‘putting the cart before the horse’ as noted by Dr. Frey et al. and the IPMRP, which is inappropriate and severely compromises the integrity of the PA. EPA should delay further review of the PA until a second draft of the ISA has been evaluated and finalized by CASAC, augmented with the necessary expertise, and reviewed by the public with a reasonable amount of time for public comment. After the release of the final ISA, a second draft of the PA should be drafted and released, with opportunity for review by the public and CASAC. This will prevent inappropriate conflation of science and policy and ensure that the findings in the PA are based on the best available science.

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<sup>14</sup> Chris 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),” December 2, 2019. Available at:

[https://yosemite.epa.gov/sab/sabproduct.nsf//B2AF0B23ABE6A60E852584C4007312E3/\\$File/EPA+CA+SAC+O3+Review+ISA+PA+Letter+191202+Final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf//B2AF0B23ABE6A60E852584C4007312E3/$File/EPA+CA+SAC+O3+Review+ISA+PA+Letter+191202+Final.pdf)

<sup>15</sup> Chris 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),” December 2, 2019. Available at:

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### **E. The comment deadline prevents 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 (November 12, 2019 and December 2, 2019, respectively). Considering that the current draft PA covers the same scope as three assessment documents (the policy assessment, the welfare risk and exposure assessment, and the health risk and exposure assessment) did in the prior review cycle, it's unreasonable to expect a thorough review of this extensive and technical document, especially given the simultaneous review of two other major documents.

In addition, the CASAC meeting to review these three documents was held from December 3-6, 2019. The minutes from this meeting were not made publicly available before the comment deadline, preventing the public from incorporating additional contents of the CASAC review.

Additionally, EPA did not grant EDF or other organizations' requests for an extension of the comment deadline expressing these concerns.

### **III. Adverse Health Effects Below Current Standard**

The evidence presented in the draft ISA and draft PA indicates that the current ozone standard is not requisite to protect public health with an adequate margin of safety. Robust epidemiology studies indicate that adverse health responses are experienced even at levels below the current NAAQS, and that adverse health responses identified in this draft ISA (e.g., for metabolic disease endpoints) are, in fact, larger and more widespread than those detailed in the previous ISA. With respect to this point, the draft PA rightly prioritizes recent studies conducted in U.S. cities with 8-hour maximum ozone concentrations well below the current standard. These studies are compelling in demonstrating significant excess risk at exposure levels below the current standards. Such examinations are scientifically valid and policy relevant, and provide EPA with new and compelling evidence of effects at concentrations at and below the current primary ozone standards based on population studies of tens of millions of people.

The epidemiology literature synthesis presented in the draft 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.<sup>16</sup> Controlled human exposure studies showed ozone-induced decreases in lung function and inflammation in exercising adults at levels as low as 60 ppb.<sup>17</sup> 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.<sup>18</sup> Collectively, these findings are coherent in their determinations of adverse health effects below the level of the current standard.

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<sup>16</sup> Draft ISA at IS-24 to IS-25.

<sup>17</sup> Draft ISA at IS-1.

<sup>18</sup> Draft ISA at IS-26.

The findings presented in this robust analysis strengthen and reinforce conclusions from the 2013 ISA<sup>19</sup> and demonstrate that the current standard is not adequately protective of public health.

These studies have identified health risks in populations of healthy individuals; certainly underlying co-morbidities in the population confer additional risks that merit a strengthened standard. For example, at least 16 million people suffer from chronic obstructive pulmonary disease (COPD) in the US population and there were more than 7 million COPD-associated emergency department visits in 2015.<sup>20</sup> Ozone exposures are associated with increased respiratory disease severity, disease symptoms, and lung disease exacerbations in this population at levels as low as 25.1 ppb.<sup>21</sup>

Furthermore, the draft ISA indicates that the scientific literature has not established any safe level of ozone exposure. The consensus from the literature is that any threshold, if it exists at all, would occur at 8-hour maximum concentrations below 20-40 parts per billion.<sup>22</sup> For example, significant associations between short-term ozone exposure and hospital admission or emergency department visits were observed at concentrations as low as 31 ppb.<sup>23</sup>

The draft ISA also notes that part of the reason that uncertainty remains about threshold effects is that there are few observations available at concentrations levels substantially below the current standard.<sup>24</sup> This lack of information motivates 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 could better refine health effects at lower levels in the future will continue to be difficult to execute without further declines in ambient ozone concentrations.

#### **IV. Interactions Between Ozone and Climate Forcing**

The ISA properly finds a causal relationship between changes in tropospheric ozone concentrations and radiative forcing. It further finds a likely causal relationship between tropospheric ozone concentrations and climate change in the form of terrestrial temperatures, precipitation, and other “related climate variables.”<sup>25</sup> The draft ISA further finds that tropospheric ozone ranks third in contribution to detrimental climate change, behind only CO<sub>2</sub> and CH<sub>4</sub>.<sup>26</sup> This is a damaging feedback loop: increased levels of ozone increase positive radiative forcing and fuel climate change, which results in higher terrestrial temperatures, which

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<sup>19</sup> Draft ISA at IS-24.

<sup>20</sup> U.S. Centers for Disease Control and Prevention. National hospital ambulatory medical care survey. Emergency Department Summary Tables. 2015; 2015:34.

<sup>21</sup> Paulin, Laura M., Amanda J. Gassett, Neil E. Alexis, Kipruto Kirwa, Richard E. Kanner, Stephen Peters, Jerry A. Krishnan et al. "Association of long-term ambient ozone exposure with respiratory morbidity in smokers." *JAMA Internal Medicine*. Available at: <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2757312>.

<sup>22</sup> Draft ISA at IS-29.

<sup>23</sup> Draft ISA at IS-23.

<sup>24</sup> Draft ISA at 3-74.

<sup>25</sup> Draft PA at 4-44; see also ISA at IS-1, IS-80, Fig. IS-8, 9-1, and 9-16

<sup>26</sup> Draft ISA at 9-2 and 9-6; Draft PA at 4-23.

in turn leads to more ozone formation.<sup>27</sup> These effects are most pronounced at mid-latitudes worldwide and so have profound implications both for domestic health and welfare generally, and for consideration of the ozone secondary standard specifically. Epidemiologic studies have identified interactive effects between air pollution and elevated temperatures that confer heightened mortality risk.<sup>28</sup> EPA should consider the potential for synergistic effects as further motivation for strengthening the current standard.

While the mechanism linking ambient temperature and ozone patterns is established, quantitative attribution analyses of the links between recent ozone levels and climate change-triggered temperature increases are not currently available for the US. This gap does not prevent the Agency from setting NAAQS that account for the temperature-pollution link. An analysis of regulatory 2016-18 monitor data conducted in 2019 indicates that high ozone levels are indeed occurring in parts of the United States that have experienced record-setting warmth.<sup>29</sup> That analysis is consistent with the expectation that higher temperatures or drought caused by climate change will make it increasingly difficult to attain the ozone standard, and the need for strengthened control of anthropogenic precursors of ozone air pollution.

Because of this climate mechanism, U.S. emissions can affect the apparent background levels in the U.S. Because high ozone days that present the greatest health risk, and this health risk is attributable to spikes due to anthropogenic ozone formed by domestic, anthropogenic ozone precursor emissions, attainment is eminently controllable by controlling those anthropogenic emissions causing the increase.<sup>30</sup> There is nothing in the draft ISA or draft PA that calls EPA's 2015 findings on this issue into question.

## **V. The Draft PA's Discussion Around Model Uncertainty for USB is Incomplete**

The discussion around uncertainty in modeled estimates of USB is incomplete.<sup>31</sup> The draft states: "Jaffe et al., (2018) highlight that uncertainties in USB and USB component estimates come from multi-model comparisons." Understanding of model uncertainty around USB is limited to multi-model comparisons, and those are incomplete because there is often a great deal

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<sup>27</sup> Draft ISA at 9-4, U.S. Global Change Research Program. "Fourth National Climate Assessment, Volume II: Impacts, Risks, and Adaptation in the United States." Washington, D.C.: US Global Change Research Program, 2018. Chapter 13 (Air Quality) at <https://nca2018.globalchange.gov/chapter/13/>.

<sup>28</sup> Kahle, Juliette J., Lucas M. Neas, Robert B. Devlin, Martin W. Case, Michael T. Schmitt, Michael C. Madden, and David Diaz-Sanchez. "Interaction Effects of Temperature and Ozone on Lung Function and Markers of Systemic Inflammation, Coagulation, and Fibrinolysis: A Crossover Study of Healthy Young Volunteers." *Environmental Health Perspectives* 123, no. 4 (April 2015): 310–16. <https://doi.org/10.1289/ehp.1307986>; Wilson, Ander, Ana G. Rappold, Lucas M. Neas, and Brian J. Reich. "Modeling the Effect of Temperature on Ozone-Related Mortality." *The Annals of Applied Statistics* 8, no. 3 (September 2014): 1728–49. <https://doi.org/10.1214/14-AOAS754>

<sup>29</sup> American Lung Association. "State of the Air (2019)." <https://www.lung.org/assets/documents/healthy-air/state-of-the-air/sota-2019-full.pdf>.

<sup>30</sup> Caiazzo, Fabio, Akshay Ashok, Ian A. Waitz, Steve H.L. Yim, and Steven R.H. Barrett. "Air Pollution and Early Deaths in the United States. Part I: Quantifying the Impact of Major Sectors in 2005." *Atmospheric Environment* 79 (November 2013): 198–208. <https://doi.org/10.1016/j.atmosenv.2013.05.081>.

<sup>31</sup> Draft PA at 2-38.

of overlap in the model inputs (including oftentimes using the same emissions and meteorology) and parameterizations of atmospheric chemistry and dynamics. There are at least two major issues that the PA overlooks regarding model uncertainty: 1) there is evidence of decreasing influence from international contributions that could benefit from an uncertainty/sensitivity study, and 2) there is a potentially large influence of meteorological variability that could influence sources differently.

There is evidence that the background contribution from international anthropogenic emissions, to western ozone, peaked in the early to mid-2000s and has been decreasing since.<sup>32</sup> Parrish et al. (2017) used three datasets of coastal and upper atmospheric ozone measurements to estimate trends in ozone inflow to the U.S. from Asia from the 1980s to 2016. Their multiple sources of data all suggest (each with an associated level of confidence) that the contribution of ozone and precursor emissions from Asia peaked in the early to mid-2000s and Asian influence on background ozone in the US began to decrease after that peak. A second study reports that measured ozone concentration trends available from the two sites in Colorado above 2,500m (Niwot Ridge and RMNP Longs Peak) between 2000-2015 are negative, indicating that background ozone contributions to the state decreased during that time period.<sup>33</sup> A study attempting to evaluate international anthropogenic contributions to US ozone should address this and attempt to evaluate sensitivity to decreases, especially as states look to meeting standards in future time frames.

Including the cities of Denver and Salt Lake City (and Albuquerque) in the high elevation west statistics (Figures 2-19 & 2-21 & Figure 2-26 - the latter Figure with the wrong description) likely mis-represents average contributions to ozone in these areas because they have much higher US anthropogenic emissions relative to most of the rural high elevation west.

While the draft mentions the potentially large influence of meteorology on local, regional and international ozone, it does not discuss the influence of variability in annual meteorology and the relative sensitivities of ozone from different sources to this variability. The results presented in this document represent a single year of meteorology. For example, Reddy and Pfister (2016)<sup>34</sup> found a strong influence of meteorology on seasonal average ozone. It could be helpful to evaluate the relative influence of meteorological variability on different sources (ie.: local vs international) which could be important, especially in a changing climate. For example, an increase in hot stagnant days (as many models forecast with climate change) might indicate an increased average contribution of U.S. anthropogenic emissions to ozone.

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<sup>32</sup> Parrish, D.D., Petropavlovskikh, I. and Oltmans, S.J., 2017. Reversal of Long-Term Trend in Baseline Ozone Concentrations at the North American West Coast. *Geophysical Research Letters*, 44(20), pp.10-675.

<sup>33</sup> Bien, T. and Helmig, D., 2018. Changes in summertime ozone in Colorado during 2000–2015. *Elem Sci Anth*, 6(1).

<sup>34</sup> Reddy, P.J. and Pfister, G.G., 2016. Meteorological factors contributing to the interannual variability of midsummer surface ozone in Colorado, Utah, and other western US states. *Journal of Geophysical Research: Atmospheres*, 121(5), pp.2434-2456.

## VI. Conclusion

Thank you for the opportunity to provide comments on EPA's External Review Draft of the Policy Assessment for the Ozone National Ambient Air Quality Standards. If you have any questions about our submission, please reach out to Rachel Fullmer at [rfullmer@edf.org](mailto:rfullmer@edf.org).

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