UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

***Policy Assessment for Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft,* 84 Fed. Reg. 47,944 (Sept. 11, 2019).**	**Docket ID No. EPA-HQ-OAR-2015-0072** *Submitted via Regulations.gov* *November 12, 2019*

Clean Air Task Force, Environmental Defense Fund, and Natural Resources Defense Council respectfully submit the following comments on the Environmental Protection Agency's ("EPA") "Policy Assessment for Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft." 84 Fed. Reg. 47,944 (Sept. 11, 2019). Our organizations have millions of members 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.

Our comments discuss the following:

I. The EPA's legal obligations in implementing the NAAQS program;
II. EPA's critical process failures during the current review of the particulate matter NAAQS;
III. The clear scientific basis supporting more protective standards for the primary particulate matter NAAQS

I. EPA's Legal Obligations Under the NAAQS Program

A. EPA's role in setting and revising the 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).

The NAAQS drive the Clean Air Act's requirements for controlling emissions of conventional air pollutants. Once EPA establishes a 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 to keep it there. *Id.* § 7410.

The Clean Air Act provides a clear process for establishing the NAAQS. The first step in establishing a NAAQS 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 reflecting "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 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.[1] Indeed, EPA cannot deny 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 Envtl. 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).

[1] *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 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 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.

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 that errs on the side of caution in interpreting uncertainty.

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."[2] 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.

II. EPA's Review of the $PM_{2.5}$ NAAQS Contains Critical Process Failures

A. EPA erred in disbanding the particulate matter review panel and must reinstate the panel

On October 10, 2018, EPA disbanded the review panel for particulate matter. The 20-member panel was comprised of leading experts in various disciplines critical to a science-based review of the PM NAAQS including experts in "air quality, exposure assessment, dosimetry, toxicology, epidemiology, medicine, risk assessment methodology, uncertainty analysis, and related fields."[3] The use of review panels was common practice by EPA/CASAC, with decades of precedent for CASAC relying on the diverse and critical expertise of such panels to inform their NAAQS reviews. When seeking to form the PM review panel in 2015, EPA noted expert nominees were needed in the fields of "air quality and climate responses, atmospheric science and chemistry, dosimetry, toxicology, controlled clinical exposure, epidemiology, biostatistics, human exposure modeling, risk assessment/modeling, characterization of PM concentrations and light extinction, and visibility impairment and related welfare effects."[4] The current, 7-member CASAC lacks an air pollution epidemiologist and does not include experts in related fields. It is, therefore, not well equipped solely to conduct a scientific, thorough review of the copious documents and extensive body of science that should underpin the NAAQS review for PM. The decision to disband the panel will fail to ensure the review fully accounts for the latest public health and scientific information.

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[2] *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").

[3] Comments of the Independent Particulate Matter Review Panel, October 22, 2019, *available at*: https://yosemite.epa.gov/sab/sabproduct.nsf//81DF85B5460CC14F8525849B0043144B/%24File/Independent+Particulate+Matter+Review+Panel+Letter+on+Draft+PA.pdf

[4] EPA, "Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel," Federal Register, 80(23):6086-6089 (February 4, 2015). https://www.govinfo.gov/content/pkg/FR-2015-02-04/pdf/2015-02265.pdf

Written comments from CASAC to EPA on April 11, 2019 also reflect the need for additional expertise for the PM review and include a recommendation from CASAC itself that the panel be reappointed:

> Additional expertise is needed for the Clean Air Scientific Advisory Committee (CASAC) to provide a thorough review of the particulate matter (PM) National Ambient Air Quality Standards (NAAQS) documents. 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 below), and to do so likely requires further scientific expertise from, and discussion with, epidemiologists and additional experts in human clinical studies and toxicology. Some of the proposed changes in causality determinations in the Draft ISA, for example changing the causality designation of long-term exposure to ultrafine particles (UFP) on nervous system outcomes from "inadequate" to "likely," are driven primarily by animal toxicology studies. Therefore, additional expertise is needed in comparative toxicology, dosimetry, and extrapolation of findings in animals to humans.
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> Over the past 30 years, the CASAC's advice to the EPA on NAAQS reviews has been assisted by expert review panels that supplement and expand the scientific expertise brought to bear. Such a review panel was appointed by the EPA for the current PM review. However, the panel was disbanded by the EPA prior to the release of the Draft ISA.
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> The CASAC recommends that the EPA reappoint the previous CASAC PM panel or appoint a panel with similar expertise, as well as adding expertise in biological mechanisms of causation, causal inference, multi-stressor interactions, and potentially others such as: epidemiology, human clinical studies; comparative toxicology, dosimetry, and extrapolation of findings in animals to humans; characterization of sampling errors and biases from continuous ambient PM measurements and satellite remote sensing aerosol optical depth (AOD) analysis; errors and biases in dispersion modeling and photochemical grid modeling; errors-in-variables methods and effects of exposure (and covariate) estimation errors on epidemiologic study results; epidemiology of low-dose causal concentration response functions; and effects of PM on visibility impairment, climate, and materials. The panel should be appointed in time to review the Second Draft ISA.[5]

EPA announced in August 2019 it would take nominations to establish a pool of scientific consultants that CASAC could draw from to provide additional expertise in the areas of:

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[5] 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

> Air quality, atmospheric science and chemistry (including ambient measurements and satellite remote sensing aerosol optical depth analysis); exposure assessment (including dispersion modeling, photochemical grid modeling, and errors-in-variables methods and effects of exposure/covariate estimation errors on epidemiologic study results); dosimetry; toxicology; comparative toxicology (including extrapolation of findings in animals to humans); controlled clinical exposure; epidemiology (including low-dose causal concentration-response functions); biostatistics; human exposure modeling; causal inference; biological mechanisms of causation; risk assessment/modeling; multi-stressor interactions; ecology and effects on welfare and the environment; and effects on visibility impairment, climate, and materials.[6]

Compared to the traditional process EPA has followed, the pool is limited in its ability to interact and deliberate with CASAC and all of its chartered members. The pool, comprised of just 12 experts to advise on both the PM and Ozone reviews (compared to 28 on the particulate matter panel alone), was established in September and does not include any members of the original PM review panel. The pool is not adequate to complete the review and the PM review panel should be reinstated.

B. EPA's overall approach to the 2020 NAAQS review processes, as laid out in EPA's May 9th memorandum, is flawed and EPA should return to the traditional approach to reviewing the NAAQS

EPA's approach to the Draft PA is consistent with the approach contemplated by the Agency's deeply flawed memorandum issued by former Administrator Pruitt on May 9, 2018 (the "Pruitt NAAQS Memo").[7] The Memo lays out inherently flawed review processes and encourage EPA to return to the agency's traditional, and legally required, approach to reviewing and updating the NAAQS.

Among other deficiencies, the Memo suggests that EPA will seek advice from CASAC on cost and other economic considerations that both the Clean Air Act and Supreme Court precedent make clear are not relevant to the standard setting process. Indeed, the agency itself recognizes that these questions will elicit information that EPA is foreclosed from considering at this point in its review.[8] As described in detail above, EPA's review of the NAAQS is to rest solely on criteria documents that "accurately reflect the latest scientific knowledge . . . 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." 42 U.S.C. § 7408(a)(2). The Act unambiguously bars EPA from considering factors that fall outside the scope of these scientific criteria

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[6] Federal Register Notice, *Request for Nominations of Consultants To Support the Clean Air Scientific Advisory Committee (CASAC) for the Particulate Matter and Ozone Reviews,* August 7, 2019 https://www.federalregister.gov/documents/2019/08/07/2019-16913/request-for-nominations-of-consultants-to-support-the-clean-air-scientific-advisory-committee-casac

[7] Memorandum from E. Scott Pruitt, EPA Adm'r, to Assistant Adm'rs, Back-to-Basics Process for Reviewing National Ambient Air Quality Standards (May 9, 2018) ("Pruitt NAAQS Memo"), https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf.

[8] 83 Fed. Reg. 29,784 (June 26, 2018).

documents at the standard-setting phase. See *Am. Trucking*, 531 U.S. at 470. The Pruitt NAAQS Memo is a bald attempt to circumvent this clear statutory mandate.

As discussed above, the Memo also attempts to confuse science and policy considerations by combining core review steps throughout the NAAQS review process. The Memo directs EPA to "consider combining its integrated science, risk and exposure, and policy assessment into a single review."[9] As John Bachmann, the Former Associate Director for Science/Policy and New Programs in EPA's Office of Air Quality Planning and Standards, pointed out in recommendations presented to EPA at the May 31, 2018 Science Advisory Board Meeting these shifts contain both logistical and technical flaws:

> These documents are intended to be logically sequential, each building on the one before. Producing them concurrently risks conflict with principle four, the separation of science and policy. It also would require an unreasonable effort by EPA staff produce these three documents simultaneously, and somehow create initial drafts independently of each other, coordinate them quickly, and be of such quality that they would require only a [single] CASAC review for each. The CASAC panelists and interested members of the public would be required to review all three at the same time.

Bachmann also noted that that concurrent preparation of the Policy Assessment and Integrated Science Assessment could jeopardize CASAC's review and public review processes for each of these documents, which are meant to build upon each other and could each require re-drafting if an error is discovered in one.

Accordingly, we urge EPA to return to the decades of precedent followed by both Republican and Democratic administrations in ensuring NAAQS reviews are done by panels that include a full array of expertise and perspectives needed to conduct high quality reviews of the complex issues related to the NAAQS.

C. EPA should issue a second Draft PA and ISA for particulate matter

EPA has not yet issued a second draft version of the ISA and does not appear to be planning to do so. In the April 2019 CASAC review of the draft ISA, the committee "recommend[ed] development of a Second Draft ISA for CASAC review" due to "the need for substantial revisions of the Draft ISA to provide clearer definitions, and technical details and methods in order to enable meaningful independent scientific review."[10]

In response to the CASAC review, Administrator Wheeler wrote that while "the difficulty [of completing the PM NAAQS review by the end of 2020] is not lost on [him]," he has "asked that

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[9] Pruitt NAAQS Memo at 3.

[10] 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/$File/EPA-CASAC-19-002%20.PDF.

staff maintain their focus on meeting [the] statutory deadlines…"[11] and create a final PM ISA by the end of 2019, implying that a second draft ISA will not be developed.

These complex and technical documents often require substantial revisions and 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. Additionally, the sequencing of the documents EPA has released is concerning. The first draft of the PA should not be released until the ISA has been reviewed by CASAC and finalized. Releasing the ISA and PA drafts simultaneously contravenes decades of EPA and CASAC practice and is deficient for obvious reasons: until the ISA is reviewed, there is no way to reliably determine what the air quality criteria — information which "accurately reflect[s] 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" — are. 42 U.S.C 7408(a)(2). A determination of what is relevant from a policy standpoint cannot meaningfully take place without first completing this review to determine the scope of relevant air quality criteria in the ISA. EPA's process unacceptably puts the cart before the horse. Finally, EPA has also dispensed with completing a separate Risk and Exposure Assessment (REA) for PM and has instead included it as part of the PA, which is counter to past practice to ensuring the PA is separate from and informed by the REA and ISA.

III. The Existing $PM_{2.5}$ Standard Is Not Sufficiently Protective of Public Health and Must be Strengthened

The evidence presented in the PA indicates that the current $PM_{2.5}$ 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. With respect to this point, the draft PA rightly prioritizes recent studies conducted in U.S. cities with annual average $PM_{2.5}$ levels well below current standards. These studies are compelling in demonstrating significant excess risk at exposure levels below the current standards.[12] 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 $PM_{2.5}$ standards based on population studies of tens of millions of people.

Specifically, the draft ISA includes robust evidence of mortality risks at levels as low as 8 $\mu g/m^3$, and increased precision in the risk estimates of exposures at levels below the current standard. Additional studies of the $PM_{2.5}$-mortality relationship conducted outside of the U.S. and Canada

[11] Andrew Wheeler, Letter to Louis Anthony Cox, Chair, Clean Air Scientific Advisory Committee, Environmental Protection Agency, July 25, 2019, *available at:* https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf.

[12] Di, Qian, Yan Wang, Antonella Zanobetti, Yun Wang, Petros Koutrakis, Christine Choirat, Francesca Dominici, and Joel D Schwartz. "Air Pollution and Mortality in the Medicare Population." *New England Journal of Medicine* 376, no. 26 (2017): 2513–22; Di, Qian, Lingzhen Dai, Yun Wang, Antonella Zanobetti, Christine Choirat, Joel D Schwartz, and Francesca Dominici. "Association of Short-Term Exposure to Air Pollution with Mortality in Older Adults." *JAMA* 318, No. 24 (2017): 2446–56.

support this finding.[13] As is made clear by these studies, an annual exposure level of 12 μg/m^3 is not adequately protective of public health.

Indeed, EPA has, as recently as 2012, acknowledged that no safe threshold for $PM_{2.5}$ has been scientifically established.[14] Emerging evidence indicates that relatively low levels of exposure to air pollution may actually confer greater incremental risk[15] than even the current EPA dose-response approach and the draft ISA for $PM_{2.5}$ exposure assumes, per mass exposure.[16] Expert opinion summarized by EPA in a 2010 Technical Support Document further bolsters the evidence base identifying no safe exposure threshold.[17] Based on currently available evidence, the exposure-response relationship is approximately linear and there is no threshold within this range, nor is there evidence of a specific threshold below this range.

This evidence base directly contradicts unfounded claims made by Dr. Lange[18] about supposed deficiencies of the scientific evidence. The literature that Dr. Lange cites in major point #5 of her comments is outdated and does not reflect the best available scientific evidence that is described in the draft ISA, which identified "consistent evidence of positive associations between long-term $PM_{2.5}$ exposures and mortality."[19] In further refutation of Dr. Lange's claims, the draft ISA further notes that "concentration-response relationships remain linear over the distribution of ambient $PM_{2.5}$ concentrations with no evidence of a threshold" and overall reduced uncertainty in establishing this relationship. Dr. Lange claims that, in the PA, "consideration needs to be made for the problems with epidemiology studies"; indeed, this consideration has already been made in

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[13] Pinault, Lauren, Michael Tjepkema, Daniel L Crouse, Scott Weichenthal, Aaron van Donkelaar, Randall V Martin, Michael Brauer, Hong Chen, and Richard T Burnett. "Risk Estimates of Mortality Attributed to Low Concentrations of Ambient Fine Particulate Matter in the Canadian Community Health Survey Cohort." *Environmental Health* 15, No. 1 (2016): 18;
Weichenthal, S, Lavigne, E, Evans, G, Pollitt, K and Burnett, RT (2016a). "Ambient $PM_{2.5}$ and risk of emergency room visits for myocardial infarction: Impact of regional $PM_{2.5}$ oxidative potential: A case-crossover study." Environmental Health 15:46:
Weichenthal, S, Lavigne, E, Evans, GJ, Godri Pollitt, KJ and Burnett, RT (2016b). "$PM_{2.5}$ and emergency room visits for respiratory illness: effect modification by oxidative potential." American Journal of Respiratory and Critical Care Medicine 194(5): 577-586.

[14] McCarthy G. Letter to Fred Upton, Chairman of the House of Representatives Committee on Energy and Commerce, Feb 3, 2012. Available at: https://www.nrdc.org/sites/default/files/epa-letter-upton-pm-benefits-20120203.pdf.

[15] Burnett, R. T., Pope III, C. A., Ezzati, M., Olives, C., Lim, S. S., Mehta, S., ... & Anderson, H. R. (2014). An integrated risk function for estimating the global burden of disease attributable to ambient fine particulate matter exposure. *Environmental Health Perspectives*, *122*(4), 397.

[16] U.S. EPA. Integrated Science Assessment (ISA) For Particulate Matter (External Review Draft). U.S. Environmental Protection Agency, Washington DC, EPA/EPA/600/R-18/179, 2018.

[17] U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards. "Summary of Expert Opinions on the Existence of a Threshold in the Concentration-response Function for $PM_{2.5}$-related Mortality," 2010. https://www3.epa.gov/ttnecas1/regdata/Benefits/thresholdstsd.pdf.

[18] Clean Air Science Advisory Committee, Preliminary Comments from CASAC Members on the PM Policy Assessment (October 21, 2019). *available a*t: https://yosemite.epa.gov/sab/sabproduct.nsf//01A6E0DE6D9865AC8525849A003EFD8D/$File/Preliminary+CASAC+PM+PA+Comments-102119.pdf.

[19] U.S. EPA. Integrated Science Assessment (ISA) For Particulate Matter (External Review Draft). U.S. Environmental Protection Agency, Washington DC, EPA/EPA/600/R-18/179, 2018 (Page 3-19).

the draft ISA, which notes that studies "consistently report positive associations with mortality across different geographic locations, populations, and analytic approaches." Regardless of remaining uncertainties within the epidemiology literature, which have been reduced since the 2009 PM ISA, robust evidence clearly demonstrates that the current standards are not adequately protective of public health.

U.S. multi-city epidemiologic studies, supported by Canadian multi-city epidemiologic studies providing additional evidence for a causal relationship, collectively constitute strong scientific evidence that the current $PM_{2.5}$ standards do not adequately protect human health. The expanded evidence summarized in the draft ISA includes both long-term studies[20] and short-term studies,[21] as well as meta-analyses[22] detailing new evidence of mortality risks at levels below the current standards.

The PA and risk assessment support the science represented in the draft ISA that, at the levels of the current fine particle standards, the risk of premature mortality is unacceptably high. The evidence-based approach offers the most robust approach demonstrating unacceptably high health risks at the current $PM_{2.5}$ standards. While it is true that uncertainties remain in the epidemiology literature about specific $PM_{2.5}$ health-relevant endpoints, the PA notes that these uncertainties have been reduced since the 2009 ISA and do not call into question the strong weight of scientific evidence in support of lowering the levels of the annual and 24-hour standards. As demonstrated in the risk assessment, lowering the level of the annual standard will proportionally reduce mortality attributed to $PM_{2.5}$.

According to the latest available analysis, more than 20.9 million Americans live in fine particle nonattainment areas, relative to the 2012 standard.[23] The scientific evidence detailed in the draft ISA demonstrates ongoing harm to people's health in these areas, but also indicates harm to those living in attainment areas. The fine particle standard should be lowered in order to more adequately protect Americans from these harms.

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[20] Crouse DL, Peters PA, van Donkelaar A, Goldberg MS, Villeneuve PJ, Brion O, et al. (2012). Risk of nonaccidental and cardiovascular mortality in relation to long-term exposure to low concentrations of fine particulate matter: a Canadian national-level cohort study. Environ Health Perspectives 120708–714.; 10.1289/ehp.110404.

[21] Zanobetti, A., & Schwartz, J. (2006). Air pollution and emergency admissions in Boston, MA. Journal of Epidemiology & Community Health, 60(10), 890-895.

[22] Adar, Sara D., et al. "Ambient coarse particulate matter and human health: a systematic review and meta-analysis." Current Environmental Health Reports 1.3 (2014): 258-274;
Li, Man-Hui, et al. "Short-term exposure to ambient fine particulate matter increases hospitalizations and mortality in COPD: a systematic review and meta-analysis." *Chest* 149.2 (2016): 447-458:
Fan, Jingchun, et al. "The impact of PM2. 5 on asthma emergency department visits: a systematic review and meta-analysis." *Environmental Science and Pollution Research* 23.1 (2016): 843-850;
Zheng, Xue-yan, et al. "Association between air pollutants and asthma emergency room visits and hospital admissions in time series studies: a systematic review and meta-analysis." *PloS one* 10.9 (2015): e0138146.

[23] EPA, US. "PM-2.5 (2012) Designated Area/State Information." (last accessed November 10, 2019). https://www3.epa.gov/airquality/greenbook/kbtc.html.

Based on 2016-18 data, monitors with design values of 25 or 30 experienced an average of 20 or 25 days over the standard level as a result of the 98th percentile form (29 sites with 14 - 37 days over the standard level). Only three sites had a design value of 35, just meeting the current daily standard; these sites experienced 24 days over the standard level for 2016-18. As observed in the data, the 98th percentile form of the standard allows for a week each year to exceed the level of the daily standard; based on the sites meeting design values of 25/30/35 for 2016-18, peak days exceeded the 98th percentile by ~9 $\mu g/m^3$. Effectively, these extreme days that represent the worst 2% of days contribute ~0.8 $\mu g/m^3$ to the annual average, which is ~9% of the total annual average mass for these locations. Therefore, strategies that reduce these extreme daily levels would have the greatest impact on reducing annual average levels; a reduction in the daily standard would incentivize strategies to reduce the most polluted days.

While Dr. Cox has attempted to undermine the robust and still-growing epidemiology evidence base for the $PM_{2.5}$-mortality relationship, other CASAC members have noted rightly that the "causal relationship between $PM_{2.5}$ exposure and mortality is robust, diverse, and convincing."[24]

Based on this evidence, we urge EPA to revise the primary annual $PM_{2.5}$ standard to between 8-10 $\mu g/m^3$ and the 24-hour standard to 25-30 $\mu g/m^3$ in order to protect public health with an adequate margin of safety, though the lower ends of these ranges will provide greater public health protections.

IV. Conclusion

Thank you for the opportunity to provide comments on EPA's External Review Draft of the Policy Assessment for Review of the NAAQS for Particulate Matter. If you have any questions about our submission, please reach out to Rachel Fullmer at rfullmer@edf.org.

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[24] CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018), 11 April 2019 *available at*: https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf.