

October 22, 2019

The Honorable Andrew R. Wheeler  
Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

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

Subject: Advice from the Independent Particulate Matter Review Panel (formerly EPA CASAC Particulate Matter Review Panel) on EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019)

Dear Administrator Wheeler:

We were members of the U.S. Environmental Protection Agency (EPA) Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel that was dismissed without notice by press release on October 10, 2018. After being disbanded, we formed the nongovernmental Independent Particulate Matter Review Panel (IPMRP, or "the Panel"). The Panel submitted comments to the CASAC on the draft PM Integrated Science Assessment (ISA) on December 10, 2018 and March 27, 2019. The IPMRP met on October 10-11, 2019, and October 18, 2019, to peer review EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019), hereafter referred to as the draft PA.

The roster of IPMRP members is given as **Attachment A**. Compared to the chartered CASAC, this IPMRP has more experts, covers more scientific disciplines, and has multiple experts who provide diversity of perspectives in many key disciplines, such as epidemiology, toxicology, and human clinical studies, among others. The IPMRP includes 20 members of the disbanded CASAC PM Review Panel, including seven members who have served on the chartered CASAC, three members who have chaired CASAC review panels, and one former CASAC chair. IPMRP members were subject to a good faith ethics review by the former director of the EPA Science Advisory Board Staff Office. The IPRMP meeting was conducted according to the same procedures as a CASAC meeting. Panelists were reimbursed by the Union of Concerned Scientists for travel to attend the October 10-11, 2019 meeting but did not accept honoraria or other compensation. The content of the meetings, this letter, and attachments were determined exclusively by the Panel, and reflect exclusively the Panel's deliberations.

The IPMRP's consensus responses to the agency's charge questions, and supplemental charge questions developed by us, are given in **Attachment B**. Individual review comments from members of the Panel are given in **Attachment C**. The history, membership criteria, and administrative procedures of the Panel are in **Attachment D**. Panel member biographies are in **Attachment E**. Major comments and recommendations are highlighted below and detailed in the consensus responses to charge questions, with additional details in individual comments.

### Summary

Based on scientific evidence, as detailed in Attachment B, the Panel finds that the current suite of primary fine particle (PM<sub>2.5</sub>) annual and 24-hour standards are not protective of public health. Both of these standards should be revised to new levels, while retaining their current indicators, averaging times, and forms. The annual standard should be revised to a range of 10 µg/m<sup>3</sup> to 8 µg/m<sup>3</sup>. The 24-hour standard should be revised to a range of 30 µg/m<sup>3</sup> to 25 µg/m<sup>3</sup>. These scientific findings are based on consistent epidemiological evidence from multiple multi-city

studies, augmented with evidence from single-city studies, at policy-relevant ambient concentrations in areas with design values at and below the levels of the current standards, and are supported by research from experimental models in animals and humans and by accountability studies.

The weight of evidence framework for causality determination that is applied by EPA is an appropriate and well-vetted tool for drawing causal conclusions. The epidemiologic evidence, supported by evidence from controlled human studies and toxicological studies, supports the 'causal' and 'likely to be causal' determinations for combinations of exposure duration, indicator, and health outcome that are the focus of the draft PA for the evidence- and risk-based approaches. The epidemiologic evidence provides strong scientific support for recommendations regarding current and alternative standard levels. Arguments offered in the draft PA for retaining the current primary PM<sub>2.5</sub> standards, which among other things, would require disregard of the epidemiological evidence, are not scientifically justified and are specious.

There is no new information that calls into question the current indicator, form, and averaging time for the coarse PM primary standard. The level of the coarse PM standard should be revised downward, consistent with the recommended downward revision of the 24-hour primary PM<sub>2.5</sub> standard, to at least maintain, if not increase, the current level of public health protection to coarse particles. A second draft of the PA should provide supporting analyses for this and other possible revised coarse PM standards.

The current annual secondary standard has no effect given that its level is higher than that of the current primary standard. Based on available evidence regarding visibility effects, and to be requisite to protect public welfare, the annual secondary standard should be revised to a level at least equal to that of the revised primary annual PM<sub>2.5</sub> standard. The current 24-hour secondary standard is also not adequate to protect against visibility effects. A second draft of the PA should analyze options for alternative secondary standards. The Panel offers detailed recommendations regarding alternative indicators, averaging times, forms, and levels that should be considered.

The Panel finds that background PM<sub>2.5</sub> levels are substantially below the levels of current and recommended alternative standards. Specific recommendations for areas of new research are provided.

A second draft of the ISA should be reviewed by CASAC and the public, and the ISA should be finalized, prior to release of a second external review draft of the PA. Although a smaller "pool" of consultants was recently appointed to support the CASAC, the pool is not focused on PM, did not review the draft PM ISA, interacts with the CASAC only in writing, and is not allowed to deliberate with the CASAC; therefore, the pool does not adequately or appropriately substitute for the disbanded CASAC PM Review Panel. The CASAC PM Review Panel should be reappointed to provide CASAC with the expertise it needs.

### **Unacceptable Process Changes Should be Documented and Corrected**

The Panel finds that the EPA staff in the Office of Air Quality Planning and Standards have undertaken a good faith effort to produce a first draft of the PA. This draft was produced under extenuating, unprecedented, and inappropriate constraints. The Panel commends the staff for this effort.

Chapter 1 should document all deviations to the CASAC and the National Ambient Air Quality Standards (NAAQS) review process for PM relative to the process outlined in the final 2016 PM Integrated Review Plan. Chapter 1 should cite and discuss the implications of the August 23,

2019 decision of the Court of Appeals for the District of Columbia Circuit in *Murray Energy v. EPA*.

Since 2017, the Panel finds that the EPA has made unwarranted changes to the CASAC and the NAAQS review process. At the least, these inappropriate changes should be mentioned in Chapter 1 in explaining the revised process used in this review, which differs so radically from that utilized in all prior reviews. Detailed recommendations to reverse the unwarranted changes are in the consensus responses.

## **Air Quality**

Depending on the location, either the annual or the daily standard may be controlling. New fine-spatial-scale modeling approaches (referred to in the draft PA as “hybrid” approaches) represent important and impressive scientific progress in the ability to quantify spatial variability in ambient concentrations. The performance of these approaches is sufficient to support their use in epidemiological studies and in risk assessment. In addition, the Panel recommends the development of Federal Reference Methods (FRMs) for measurement of Ultrafine Particles (UFP) and Black Carbon (BC), for which there is emerging evidence of health effects.

### **Primary Fine Particulate Matter Standards**

The evidence-based approach in the draft PA to reaching conclusions regarding the current and alternative primary PM<sub>2.5</sub> standards is a thoughtful and comprehensive synthesis of the epidemiological, controlled human exposure, and animal toxicological studies presented in the ISA, which strengthens the evidence since the last review. Given uncertainties, the risk assessment provides useful qualitative insights regarding risk and risk reduction. The Panel gives more weight to the evidence-based approach with the risk-based approach providing supporting information.

Limiting the evidence-based approach to assessment of associations and outcomes deemed as ‘causal’ or ‘likely causal’ is reasonable. The Panel recommends more extensive discussion and consideration of environmental justice with regard to disparities in health risk born by minority communities.

### Need for Both Annual and 24-hour Primary PM<sub>2.5</sub> Standards

The Panel concurs with the draft PA that there is compelling scientific evidence that the annual primary PM<sub>2.5</sub> standard is the ‘controlling’ standard in much of the U.S. and, if set at an appropriate level, can provide public health protection from both long- and short-term effects. However, the Panel finds, more strongly than is expressed in the draft PA, that the 24-hour standard is an important component of the suite of PM<sub>2.5</sub> standards. Specifically, the 24-hour standard, if set at an appropriate level, can provide needed public health protection not afforded by current or revised annual standards in locations for which the current or revised 24-hour standard is controlling.

### Current Fine Particulate Matter Primary Standards are Not Adequate to Protect Public Health

The weight of evidence framework for causality determination that is applied by EPA is an appropriate and well-vetted tool for drawing causal conclusions. The epidemiologic evidence, supported by evidence from controlled human studies and toxicological studies, supports the ‘causal’ and ‘likely to be causal’ determinations for combinations of exposure duration, indicator, and health outcome that are the focus of the draft PA for the evidence- and risk-based approaches. The epidemiologic evidence provides strong scientific support for recommendations regarding current and alternative standard levels. The existing strong and consistent epidemiological evidence was developed using accepted scientific methods, is peer-reviewed, and is coherent with peer-reviewed controlled human studies and toxicological

studies, which were also developed using accepted scientific methods. It would be irresponsible to dismiss any or all of the policy-relevant epidemiologic studies, as some on CASAC have suggested, merely because they have not been analyzed using emerging un-vetted advanced statistical methods that are still in their infancy for application to air pollution studies. The IPMRP notes that the epidemiologic evidence is extensive, particularly in terms of the large geographic domain and population sample size, and provides an overall consistent scientific basis for finding that the current primary PM<sub>2.5</sub> standards are not protective of public health. The epidemiologic evidence is scientifically valid and more than sufficient for informing recommendations regarding levels.

US multicity epidemiological studies, supported by consistent results from Canadian multicity epidemiologic studies, consistent results from accountability studies, and coherent results from animal toxicological and controlled human exposure studies, provide clear and compelling scientific evidence that the current PM<sub>2.5</sub> standards are not adequate to protect human health. The epidemiological evidence is based on different locations, study designs, and statistical approaches, which enhances its robustness. Of particular importance are the studies which continued to find health effects even when the air quality distribution was truncated to remove all days where annual PM<sub>2.5</sub> concentrations exceeded 12 µg/m<sup>3</sup> (the level of the current annual standard), and the pseudo-design value analyses which found health effects in areas likely to have design values of 12 µg/m<sup>3</sup> or less.

#### Retaining the Current Primary Standards is Not Scientifically Justifiable

Arguments offered in the draft PA for retaining the current standards are not scientifically justified and are specious. The revised PA should acknowledge the implausibility of these arguments or drop them altogether.

#### Revise the Annual Primary PM<sub>2.5</sub> Standard to a Level Between 10 µg/m<sup>3</sup> and 8 µg/m<sup>3</sup>

The Panel concurs with the draft PA that the current indicators, averaging times, and forms for the annual and 24-hour standards are suitable based on available scientific evidence, as detailed in Attachment B, and should be retained.

As detailed in Attachment B, based on the scientific evidence, the Panel finds that levels above 10 µg/m<sup>3</sup> for the annual standard are not protective of public health. An annual standard in the range of 10 µg/m<sup>3</sup> to 8 µg/m<sup>3</sup> would protect public health for the general public and for at-risk groups. However, even at the lower end of the range, risk is not reduced to zero. The margin of safety increases as the level of the standard is lowered within this range. The choice of margin of safety within this range is a policy judgment reserved for the Administrator. Based on the available scientific evidence, there is not a population threshold for annual concentration, within or below the recommended levels, at which the risk would drop to zero.

#### Revise the 24-hour Primary PM<sub>2.5</sub> Standard to a Level Between 30 µg/m<sup>3</sup> and 25 µg/m<sup>3</sup>

The Panel does not agree with the recommendation in the draft PA to leave the level of the 24-hour standard at 35 µg/m<sup>3</sup> if the annual standard is strengthened. Based on the scientific evidence, this would not provide an adequate level of public health protection in locations for which the 24-hour standard, and not the annual standard, would be controlling. Based on the scientific evidence and acknowledging that there is a continuum of adverse effects that decrease as the level of the standard decreases, the Panel recommends that the 24-hour standard be set between 30 µg/m<sup>3</sup> and 25 µg/m<sup>3</sup>. Lower levels within this range would provide an additional margin of safety. The choice of margin of safety within this range is a policy judgment reserved for the Administrator. Based on the available scientific evidence, there is not a population threshold for 24-hour exposure, within or below the recommended levels, at which the risk would drop to zero.

### **Primary Coarse Particulate Matter Standard: Maintain or Strengthen Level of Protection**

Although new evidence is available since the last review for a broader range of health outcomes associated with short- and long-term exposures to thoracic coarse particulate matter (PM<sub>10-2.5</sub>), this evidence is subject to considerable uncertainty. PM<sub>10-2.5</sub> can penetrate to the airways past the vocal cords, which should be acknowledged and discussed in the draft PA. While the Panel concurs that PM<sub>10</sub> is an appropriate choice at this time for the indicator for PM<sub>10-2.5</sub>, the Panel strongly recommends movement away from PM<sub>10</sub> and toward PM<sub>10-2.5</sub> as the indicator in the next review cycle. The Panel concurs with the draft PA that it is scientifically reasonable to retain at least *the level of protection* afforded by the current PM<sub>10</sub> standard. A second draft of the Policy Assessment should assess revision of the coarse particle standard downward coupled with a downward revision of the 24-hour fine particle standard, to at least maintain the current level of protection against exposure to coarse particles, as well as other recommendations from CASAC in the last review cycle for a range of alternative standards that would offer more protection.

### **Current Welfare Standards are Not Adequate; 2<sup>nd</sup> Draft PA Should Analyze Alternatives**

The Panel concurs with the draft PA that it is appropriate to focus quantitative assessments of welfare effects on visibility effects. Important scientific information regarding visibility effects has been omitted, perhaps inadvertently, from the draft ISA and should be included. Based on the scientific evidence, the Panel finds that the current welfare standards are not requisite to protect the public welfare from known and anticipated adverse effects from reduced visibility. The level of the secondary annual standard, which is higher than the level of the primary annual standard, is not requisite to protect against welfare effects and should be revised to at least match the level of the revised annual primary PM<sub>2.5</sub> standard. The draft PA fails to give due consideration to scientifically-justifiable alternatives for the indicator, averaging time, form, and level of possible alternative visibility-based welfare standards, particularly for the 24-hour standard. The combinations of indicator, averaging time, level and form recommended by CASAC in the past two NAAQS reviews are all considerably more protective than the current NAAQS. A second draft of the PA should systematically address these issues while taking into account the implications of revisions to the 24-hour PM<sub>2.5</sub> standard recommended by the Panel, which would have co-benefits with respect to visibility effects. The Panel concurs that the evidentiary basis for climate and materials effects are not sufficient to support quantitative assessment.

### **Areas for Future Research**

The Panel has identified numerous recommended areas for research to reduce uncertainties in support of the next NAAQS review for particulate matter. These recommendations focus on areas including air quality measurement, air quality modeling, health studies, analysis methods, and others. Examples of key recommendations include, but are not limited to, development and deployment of FRMs for UFP and BC, quantification of daily and sub-daily exposures and associations with adverse health effects for various PM sizes and compositions, development and application of improved approaches for accounting for confounding and effect modification in multipollutant models, and characterization of exposures and adverse effects for new health endpoints.

### **Status of the Integrated Science Assessment**

Scientific issues in the draft ISA should have been resolved prior to development and review of the PA. A second external review draft of the ISA should be made available to CASAC and the public, reviewed, and finalized, prior to release of a second draft of the Policy Assessment. The second draft of the Policy Assessment should be reviewed by CASAC and the public only after the ISA has been finalized. A summary of previous IPMRP comments on the draft ISA is given

at the end of the responses to charge questions. The Panel is concerned about the footnote to Table 3-1 in the draft PA indicates that final causality determinations for some endpoints are pending consideration of advice from CASAC. CASAC has already admitted, explicitly, that it is not qualified to offer these judgments, because it lacks the breadth, depth, and diversity of expertise for review of the PM NAAQS. Therefore, the CASAC PM Review Panel should be reappointed to augment CASAC during this review cycle before CASAC is asked to offer advice that it is not qualified to give.

Sincerely,

/signed/

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Chartered CASAC: Member 2008-2012, Chair 2012-2015  
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CASAC Sulfur Oxides Review Panel: Member 2008-2009, 2015-2018  
CASAC Oxides of Nitrogen Review Panel: Member 2008-2009, Chair 2013-2015,  
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CASAC Lead Review Panel: Chair 2011-2013  
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CASAC PM Review Panels: Member 2001-2006, 2008-2012, 2015-2018  
CASAC Ozone Review Panel: 2005-2008, 2010  
CASAC Lead Review Panels: Member 2006-2008, 2008-2013  
CASAC SO<sub>x</sub>/NO<sub>x</sub> Secondary Review Panels: Member 2008-2011, 2015-present  
CASAC Ambient Air Monitoring and Methods Subcommittee: Member 2004-2010

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CASAC PM Review Panel: Member 2015-2018

CASAC Ozone Review Panel: Member 2005-2008, 2010, 2011

CASAC Sulfur Oxides Review Panel: Member 2007-2010, 2014-2018

CASAC Oxides of Nitrogen Review Panel: Member 2007-2010, 2013-2017, Chair 2016-2017

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CASAC Ozone Review Panel: Member 2009-2014

CASAC Sulfur Oxides Review Panel: Member 2013-2018

CASAC Oxides of Nitrogen Review Panel: Member 2008-2010, 2013-2017

CASAC PM Review Panel: Member 2008-2011, Member 2015-2018

cc: Louis Anthony (Tony) Cox, Jr., Ph.D., Chair  
EPA Clean Air Scientific Advisory Committee

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

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## NOTICE

This report has been written as part of the activities of the Independent Particulate Matter Review Panel (IPMRP). The IPMRP is not affiliated with the U.S. Federal Government. This report has not been reviewed for approval by the U.S. Environmental Protection Agency (EPA) and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies within the Executive Branch of the federal government.

IPMRP members were subject to a good faith ethics review by the former director of the EPA Science Advisory Board Staff Office. The IPRMP meeting was conducted according to the same

The October 10-11, 2019 and October 18, 2019 meetings of the IPMRP were sponsored by the Union of Concerned Scientists, a 501(c)3 nonprofit organization. UCS does not take policy positions on NAAQS criteria and standards, other than to advocate that independent science advice be followed.<sup>1</sup> UCS is funded by individual members and private foundations and accepts no money from corporations or government entities.<sup>2</sup> Panelists were compensated for travel to attend the October 10-11, 2019 meeting but did not accept honoraria or other compensation for either meeting. The viewpoints and opinions of members of the IPMRP, and of the consensus of the IPMRP, are their own and do not represent any position of UCS. The content of the meetings, this letter, and attachments were determined exclusively by the Panel, and reflect exclusively the Panel's deliberations.

Any mention of trade names or commercial products does not constitute a recommendation for use.

The IPMRP reports are posted at [ucsusa.org/pmpanel](https://ucsusa.org/pmpanel).

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<sup>1</sup> Goldman, G.T. 2015. Union of Concerned Scientists. Comment on EPA-HQ-OAR-2008-0699-2472: Proposed Rule: National Ambient Air Quality Standards for Ozone. <https://www.regulations.gov/document?D=EPA-HQ-OAR-2008-0699-2472>

<sup>2</sup> Union of Concerned Scientists. 2018. Internal Revenue Service Form 990. <https://www.ucsusa.org/sites/default/files/attach/2019/03/ucs-fy18-990.pdf>

## Independent Particulate Matter Review Panel

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Mr. Chris Zarba, filling the role of a Designated Officer.

\* Denotes a former member of the chartered U.S. EPA Clean Air Scientific Advisory Committee

\*\* Denotes a former chair of the chartered U.S. EPA Clean Air Scientific Advisory Committee

## Attachment B

### Consensus Responses to Charge Questions on the EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019)

***EPA-1. Chapter 1 – Introduction: To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for the review?***

The Independent Particulate Matter Review Panel (IPMRP, or “the Panel”) finds that the staff in the U.S. Environmental Protection Agency’s (EPA’s) Office of Air Quality Planning and Standards have undertaken a good faith effort to produce a draft of the Policy Assessment (PA) under extenuating, unprecedented, and inappropriate constraints, as detailed below. The Panel commends the staff for this effort.

Chapter 1 clearly and concisely describes the purpose (Section 1.1), legislative requirements (Section 1.2), and history of National Ambient Air Quality Standard (NAAQS) reviews (Section 1.3). Its coverage of the current NAAQS review (Section 1.4) is inadequate and incomplete because it fails to document recent process changes. As detailed below, the Chapter omits mention of recent policy changes, including decisions and changes that affect the functioning of the review process and the timeline of the review. These are important parts of the peer review and public input process for the draft PA and the documents that feed into it. Section 1.4 also does not outline the process described in the final Integrated Review Plan (IRP) for Particulate Matter<sup>3</sup> or indicate how the current process is deviating from the PM IRP. Of particular concern, the draft PA is being reviewed before the Integrated Science Assessment (ISA) has been finalized, thus creating a blending of scientific and policy considerations. This sequence of events is not logical or appropriate.

Chapter 1 should clearly explain the difference between the sequences of draft documents indicated in the IRP versus the actual sequence of draft documents in this review. For example, contrary to the IRP, there is not a separate Risk and Exposure Assessment (REA) document in this review. To be consistent with the final IRP for this review, the text should state that EPA intended to make available to the U.S. EPA Clean Air Scientific Advisory Committee (CASAC) and the public two drafts of the REA. Furthermore, the IRP included a plan for two drafts of the ISA and two drafts of the PA. Although the scope of two drafts each of the ISA, REA, and PA were approved by CASAC in its 2016 review of the draft IRP,<sup>4</sup> the final IRP differed from the draft IRP<sup>5</sup> with regard to sequencing, as discussed further below. Thus, CASAC did not approve the sequence given in the final IRP.

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<sup>3</sup> EPA, “Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter,” EPA-452/R-16-005, U.S. Environmental Protection Agency, Research Triangle Park, NC, December 2016. <https://www3.epa.gov/ttn/naaqs/standards/pm/data/201612-final-integrated-review-plan.pdf>

<sup>4</sup> Diez Roux, A., “CASAC Review of the EPA’s Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016),” EPA-CASAC-16-003, Letter to Gina McCarthy, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, August 31, 2016. [https://yosemite.epa.gov/sab/sabproduct.nsf/9920C7E70022CCF98525802000702022/\\$File/EPA-CASAC+2016-003+unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/9920C7E70022CCF98525802000702022/$File/EPA-CASAC+2016-003+unsigned.pdf)

<sup>5</sup> EPA, Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter, EPA-452/D-16-001, U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. <https://www3.epa.gov/ttn/naaqs/standards/pm/data/201604-draft-integrated-review-plan-casac-review.pdf>

The first draft of the PA should not be released until the ISA has been finalized. CASAC, the IPMRP, and the public have recommended that there be a second draft of the ISA, which has been denied by the Administrator. Given that the ISA will go from first draft to final, but as of now has not been finalized, it is unclear what changes are pending for the final ISA and whether or how they will affect the content of the final PA. This is an unacceptable process deficiency that commingles policy considerations prior to finalization of the science assessment. This ‘puts the cart before the horse.’

Chapter 1 also fails to document the *ad hoc* changes to the NAAQS review process and to the CASAC that have been made since the final IRP was published in 2016. Compared to the final IRP, the following steps have been omitted in the current review: (a) no REA planning document(s); (b) no second external review draft of the ISA; (c) no external review drafts of the REAs; (c) no provision for a second draft of the PA; (d) no final REA as a separate document; and (e) no final ISA until after CASAC has completed its review of the draft PA. Although the IRP is cited on page 1-1, line 7, the deviations of the current review from the IRP are completely omitted. Both the omissions of the descriptions of these deviations, and the deviations themselves, are inappropriate and should be corrected. The chapter should enumerate all of the changes to the NAAQS review process, the CASAC, and the PM NAAQS review since 2016.

The final IRP scheduled that this review would end in 2022. Although the May 9, 2018 memo by then Administrator Pruitt<sup>6</sup> set a new end date of 2020, this is not consistent with the final IRP and there was no reference to the final IRP. While the five-year review schedule is a matter of law, it is also a matter of law that these must be science-based reviews. There are many factors in the review schedule that are in the control of EPA and not in the control of CASAC. The science review should not be sacrificed for the sake of expediency to play catch-up with the schedule. Deadlines do not excuse substantive deficiencies.

The following sections set forth detailed discussion reflecting the Panel’s profound concern with the process issues, and the Panel’s concern about science issues not being settled before the PA is drafted. The Panel makes consensus recommendations to reverse the numerous *ad hoc* changes to the CASAC and the NAAQS review process, that the draft PA be revised; that the second draft of the PA be reviewed by CASAC and the public after the ISA is finalized; that Chapter 1 document all deviations from the process outlined in the IRP; and that Chapter 1 cite and discuss the implications of the August 23, 2019 decision of the United States Court of Appeals for the District of Columbia Circuit in *Murray Energy v. EPA*.<sup>7</sup> Below are the Panel’s specific recommendations.

## Process Issues

Since 2017, numerous changes have been made to the scientific review process for the NAAQS, including changes that affect the membership and composition of the

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<sup>6</sup> Pruitt, S.E., “Back to Basics Process for Reviewing National Ambient Air Quality Standards,” Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 9, 2018. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>

<sup>7</sup> *Murray Energy Corp. v. Environmental Protection Agency, Respondent, and American Lung Association et al., Interveners*, No. 15-1385, United States Court of Appeals for the District of Columbia Circuit, Decided August 23, 2019. <https://cases.justia.com/federal/appellate-courts/cadc/15-1385/15-1385-2019-08-23.pdf?ts=1566572432>



CASAC.<sup>4,8,9,10,11,12</sup> These changes have been made without advance notice to, or input from, the CASAC, EPA staff, or the public. The changes include: (a) imposing non-scientific criteria for appointing CASAC members related to geographic diversity and affiliation with governments; (b) replacing the entire membership of the chartered CASAC in a period of one year; (c) banning nongovernmental recipients of EPA scientific research grants while allowing persons affiliated with regulated industries to be members of CASAC; (d) ignoring statutory requirements for the need for a thorough and accurate scientific review of the NAAQS in setting a review schedule; (e) reducing the number of drafts of a document for CASAC review irrespective of whether substantial revision of scientific content is needed; (f) commingling science and policy issues; (g) depriving CASAC of the needed breadth, depth, and diversity of scientific expertise for the PM NAAQS review by disbanding the CASAC PM Review Panel; (h) depriving CASAC of the needed breadth, depth, and diversity of scientific expertise for the ozone NAAQS review by refusing to form a CASAC Ozone Review Panel; and (i) creation of an ad hoc “pool” of consultants that fails to address the deficiencies created by disbanding the CASAC PM Review Panel and not forming a CASAC Ozone Review Panel. Each one of these changes harms the quality, credibility, and integrity of the NAAQS review for both PM and ozone.

The IPMRP recommends that EPA appoint members to CASAC and its review panels based on the need for breath, depth, and diversity of scientific expertise, not geographic diversity and government affiliation, other than to meet the minimum requirement for the latter as required by the Clean Air Act. EPA should allow leading nongovernmental researchers who hold EPA scientific research grants to serve on CASAC and its augmented panels, consistent with existing Federal peer review guidance. EPA should appoint CASAC members to staggered overlapping terms to promote institutional memory and continuity. EPA should allow adequate time for scientific review by CASAC, including opportunities for public input. EPA should not combine assessment documents in a review unless this is consistent with a final Integrated Review Plan that has been agreed to by CASAC. EPA should develop NAAQS review schedules that allow for the likelihood that complex scientific and policy documents, such as an Integrated Science Assessment, a Risk and Exposure Assessment, and a Policy Assessment, may need substantial revision and re-review. EPA should better manage the timing of key milestones in the NAAQS review process so as not to selectively take time away from CASAC as a means to compensate for delays created by EPA elsewhere in the review. EPA should not be producing a Policy Assessment in advance of first finally determining what the science being assessed is – i.e. prior to finalizing the ISA. To do otherwise puts the cart before the horse. EPA should not introduce policy considerations until the scientific issues have been adequately settled. EPA

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<sup>8</sup> Pruitt, E.S., “Strengthening and Improving Membership on EPA Federal Advisory Committees,” Memorandum, U.S. Environmental Protection Agency, October 31, 2017. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>

<sup>9</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-act-committee>

<sup>10</sup> EPA, “Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts,” News Release, U.S. Environmental Protection Agency, Washington, DC, September 13, 2019. <https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts>

<sup>11</sup> GAO, EPA Advisory Committees: Improvements Needed for the Member Appointment Process, GAO-19-280, General Accountability Office, Washington, DC. <https://www.gao.gov/assets/710/700171.pdf>

<sup>12</sup> EPA, “Request for Nominations of Consultants To Support the Clean Air Scientific Advisory Committee (CASAC) for the Particulate Matter and Ozone Reviews,” *Federal Register*, 84(152):38625 (August 7, 2019). <https://www.govinfo.gov/content/pkg/FR-2019-08-07/pdf/2019-16913.pdf>

should continue to follow the successful practice, proven for four decades, of augmenting CASAC with the expertise it needs via review panels that deliberate interactively with members of the chartered CASAC. EPA should not make *ad hoc* changes to the NAAQS review process in the middle of a review. The changes since 2017 lead to a situation in which standards will not reflect air quality criteria — an “accurat[e] reflect[ion] [of] 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 present of [the] pollutant in the ambient air” (CAA section 108 (a)(2)) — since the CASAC and the process under which it is operating is incapable of properly assessing what that science is. If EPA wishes to make changes to the NAAQS review process, EPA should do so in a systematic manner similar to that employed in 2006, when EPA staff, CASAC, and others had an opportunity to provide input.<sup>13</sup>

Per its own statement in its letter of April 11, 2019, the current CASAC (or any CASAC, with only seven members, that is not augmented with a panel of experts) does not have adequate breadth, depth, and diversity of scientific expertise and experience needed to conduct thorough reviews based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to the Particulate Matter NAAQS.<sup>14</sup> Thus, CASAC should be properly augmented, consistent with its charter with the U.S. Congress,<sup>15</sup> by reinstatement of the disbanded CASAC Particulate Matter Review Panel for the PM NAAQS Review.<sup>16</sup> Likewise, CASAC should be augmented with a properly constituted CASAC Ozone Review Panel.<sup>17</sup> Please see individual comments of Dr. H. Christopher Frey for more details on these points.

### **Scientific Issues Need to be Settled Before Formulating the Policy Assessment**

The lack of a second draft of the ISA is highly problematic, particularly because the draft Policy Assessment is based on scientific evidence from the ISA. In prior NAAQS reviews, it has been typical practice that CASAC reviews a second and sometimes third draft (as in the cases of the most recent lead and ozone reviews) of the ISA. It has been typical practice that CASAC has had the opportunity to review a draft Policy Assessment *after* it has completed reviews of draft ISAs. This sequence was by design. A key principle of the 2006 revisions to the NAAQS review

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<sup>13</sup> Peacock, M., “Process for Reviewing National Ambient Air Quality Standards,” Memorandum to George Gray and Bill Wehrum, U.S. Environmental Protection Agency, Washington, DC, December 7, 2006

<sup>14</sup> Cox, L.A. (2019), “CASAC Review of the EPA’s Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018),” EPA-CASAC-19-002, Letter to A. Wheeler, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, April 11, 2019. [https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf)

<sup>15</sup> United States Environmental Protection Agency Charter, Clean Air Scientific Advisory Committee, Filed with Congress, June 5, 2019, [https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/\\$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf)

<sup>16</sup> Yeow, A., Formation of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel, Memorandum to C. Zarba, Science Advisory Board Staff Office, U.S. Environmental Protection Agency, Washington, DC, November 17, 2015, [https://yosemite.epa.gov/sab/sabproduct.nsf/0/EB862B233FBD0CDE85257DDA004FCB8C/\\$File/Determination%20memo-CASAC%20PM.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/EB862B233FBD0CDE85257DDA004FCB8C/$File/Determination%20memo-CASAC%20PM.pdf)

<sup>17</sup> EPA, “Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel,” *Federal Register*, 83(145): 35635- 35636 (July 27, 2018). <https://www.govinfo.gov/content/pkg/FR-2018-07-27/pdf/2018-16116.pdf>

process, which were modified in part in 2007 and 2009,<sup>18,19,20</sup> is that the scientific foundation of the review must be established before addressing policy issues. Failure to do 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. The IPMRP recommends that the ISA be finalized before a second version of the PA is provided and reviewed.

## **Chapter 1 Should Enumerate All of the Deviations from the Final Integrated Review Plan**

As detailed above, key steps have been omitted in the current review with respect to all key documents that provide the foundation for formulation of scientific advice. These omissions are inappropriate and have introduced deficiencies that undermine the scientific record regarding air pollutant criteria and upon which CASAC and the public may develop their advice to EPA. Chapter 1 should enumerate these changes and their impacts. See also detailed comments regarding process issues in the individual comments of Dr. H. Christopher Frey.

The schedule in the final IRP specified two drafts of each of the ISA, REA, and PA. However, the final IRP indicated that the drafts of the REA and PA would be concurrent. This differs from the schedule in the external review draft of the IRP that was reviewed by CASAC earlier in 2016. In the external review draft of the IRP, EPA had proposed to sequence the release of first drafts of the ISA, REAs, and PA such that CASAC would review them sequentially on a staggered schedule. Thus, under the initial proposed schedule, CASAC would have been able to provide its advice on the first draft of the REAs before receiving the first draft of the PA. The schedule in the draft IRP allowed for two drafts each of the ISA, REA, and PA.

The final IRP sequencing of the first drafts of the REA documents, such that they are released after receiving CASAC review of both the first draft of the ISA and of REA planning documents is appropriate. Since the REA builds upon information in the ISA, it is logical and appropriate that EPA consider CASAC's advice on the ISA before releasing a draft of the REA. Because the Policy Assessment is intended to integrate information from the ISA and the REA, it is generally not appropriate for a first draft of the PA to be released at the same time as the first draft of the REA. Simultaneous release of the first drafts of the REA and PA was done, for example, in the last review of the ozone NAAQS. As colleagues have pointed out (see November 26, 2018 letter to CASAC from former members of the 2009 to 2014 CASAC Ozone Review Panel),<sup>21</sup> the first

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<sup>18</sup> Peacock, M., "Process for Reviewing National Ambient Air Quality Standards," Memorandum to George Gray and Bill Wehrum, U.S. Environmental Protection Agency, Washington, DC, December 7, 2006

<sup>19</sup> Peacock, M., "Modifications to Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, April 17, 2007

<sup>20</sup> Jackson, L., "Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 21, 2009.

<https://www3.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf>

<sup>21</sup> Frey, H.C., J.M. Samet, A.V. Diez Roux, G. Allen, E.L. Avol, J. Brain, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, S.R. Kleeberger, F.J. Miller, H.S. Neufeld, A.G. Russell, H.H. Suh, J.S. Ultman, P.B. Woodbury, and R. Wyzga, "CASAC Advice on the EPA's Integrated Review Plan for the Ozone National Ambient Air Quality Standards (External Review Draft)," 24 page letter with 42 pages of attachments, submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA-HQ-OAR-2018-0279, November 26, 2018.

[https://yosemite.epa.gov/sab/sabproduct.nsf/0AC9E8672B0CA54985258351005BE54F/\\$File/Ozone+Letter+181126+Submitted-rev2.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0AC9E8672B0CA54985258351005BE54F/$File/Ozone+Letter+181126+Submitted-rev2.pdf)

draft of the PA in that review was very preliminary and required substantial revision. Transparency of the review process, and clear distinction of science and policy issues, is enhanced by obtaining CASAC's advice on the REA before submitting a first draft of the PA for CASAC review. However, in this review, there is no separate REA. The content of the REA has been incorporated into the draft PA. This is not appropriate since there are important scientific issues pertaining to the REA that should be reviewed and vetted prior to use in the PA.

The IPMRP recommends that Chapter 1 clearly explain the difference between the sequences of draft documents indicated in the IRP versus the actual sequence of draft documents in this review. Rather than multiple drafts of the ISA, REA, and PA, staggered so that science issues are vetted and settled before proceeding to policy issues, this review cycle has devolved into one draft of the ISA and one draft of the PA, with the drafts of the ISA and PA overlapping such that policy issues are inappropriately being addressed before the science issues are finalized.

## **Other Issues**

Given the importance of so-called wildfires as a source of ambient particulate matter, Chapter 1 could include more discussion of the rule regarding "Treatment of Data Influenced by Exceptional Events," (Federal Register, 81(191):68216-68282, October 3, 2016), particularly with respect to the role of events that are at least partly anthropogenic in origin and the case-by-case nature of the exception events rule. As noted elsewhere in this Panel's responses to charge questions, not all wildfires are purely natural in their ignition or extent. Whether and, if so, how wildfires might be appropriately considered is pertinent to the quantification of adverse health and welfare effects of such events, which in recent years are growing in frequency and magnitude, especially in some parts of the country. This topic might be appropriate for inclusion in Chapter 2 rather than Chapter 1.

***EPA-2. Chapter 2 – PM Air Quality: To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for the review?***

***SCQ-2.1 What are the Panel's views regarding whether the draft PA accurately reflects and communicates the air quality related information most relevant to its subsequent evidence-based assessment of the health and welfare effects studies, including uncertainties, as well as the development of the risk assessment for current and alternative standards? In particular, do the following sections accurately reflect and communicate current scientific understanding, including uncertainties, for: (a) relationships between annual and daily distributions of PM; (b) the review of hybrid modelling approaches used to estimate exposure in some studies and the risk assessment; and (c) information on background levels of various PM indicators?***

### **Relationships Between Annual and Daily Distributions of PM<sub>2.5</sub>**

Figure 2-11, page 2-26 shows several locations in the northwest U.S. and California that are below the annual primary PM<sub>2.5</sub> standard level of 12 µg/m<sup>3</sup> but above the 24-hour primary PM<sub>2.5</sub> standard level of 35 µg/m<sup>3</sup>. An extreme example of this is the Fairbanks (North Pole) valley site with a 2016-2018 24-hour-to-annual PM<sub>2.5</sub> design value ratio of 5.1 compared to the 2.9 ratio of 24-hour to annual primary PM<sub>2.5</sub> levels. The PA notes that, in the Northwestern US, daily and sub-daily (e.g., 2-hr average) concentrations (and the relationship between annual and daily concentrations) are heavily influenced by wildfire emissions in the summer/fall and stagnation in

the winter. Not reflected adequately here are the impacts of controllable emissions, including seasonal or episodic emissions on ambient concentrations. The text implies that these high concentrations are beyond our control. The episodic but substantial contribution of residential wood combustion for home heating is one of these anthropogenic sources. Currently, the inaccurate impression that is created regarding 24-hour and sub-daily concentrations is used to discount and exclude ambient measurements in the Northwest and California from the risk assessment and the consideration of whether the annual standard can adequately control for health effects associated with short-term exposures as discussed in Chapter 3.

The PA does not acknowledge that anthropogenic activities impact climate, which contributes to drought, and increased frequency and magnitude of fire, in the western U.S. (Abatzoglou and Williams, 2016; Barbero et al., 2015; Dennison et al., 2014; Littell et al., 2009; Miller and Safford, 2012; O'Dell et al., 2019). Based on 1.5 million government-recorded wildfires from 1992 to 2012, Balch et al. (2017) estimated that 84% of wildfires were human-caused, accounting for 44% of the total area burned. This study excluded prescribed burns for forest management that would add to the total of manmade fires.

The current 24-hour primary PM<sub>2.5</sub> standard, being based on a midnight-to-midnight 24-hour calendar day average, artificially divides a single overnight air quality event for smoke emitted from residential wood combustion into two separate days. As more monitoring sites transition to continuous PM<sub>2.5</sub> measurements that meet Federal Equivalent Method (FEM) performance requirements, the monitoring network will have the capability to support other averaging times for epidemiologic research and possible alternative forms of standards. For example, some exposure scenarios are less than 24-hours in duration, such as overnight peaks in ambient concentrations from residential wood smoke in some locations.

### **Hybrid Modeling Approaches**

In the context of this review of health-based standards, the air quality section on hybrid modeling approaches to PM<sub>2.5</sub> is important, since this is the area where substantial improvements in characterizing ambient PM<sub>2.5</sub> concentrations (exposures) over large areas have been made since the last PM NAAQS review. These methods clearly lead to improved ambient concentration estimates in locations without samplers. Impressively, some of the more sophisticated methods have n-fold cross validation coefficient of determination (R<sup>2</sup>) better than 80% and root-mean-square error (RMSE) of 2-3 µg/m<sup>3</sup> for daily PM<sub>2.5</sub> predictions. Approaches that account for high spatial resolution land-use features are better at capturing concentration gradients close to sources than are downscaling approaches based on 12 km by 12 km gridded air quality modeling predictions. The consistency of the regional concentration estimates across methods is remarkably good (Table 2-3).

The PA should explain why some methods work better than others. Larger spatial gradients, especially in the western U.S., are not well characterized by the 12-km downscaler models. The neural network (machine learning) 1-km model does better: Figure 2-28 (page 2-47) clearly shows the difference in resolution between the downscaler 12-km and neural network 1-km models. The Bayesian downscaler does not incorporate information about locations of primary PM<sub>2.5</sub> sources (i.e., surrogates such as land use variables), whereas several other methods, including the neural network, do. All these methods are designed to predict broad spatial PM<sub>2.5</sub> features, but the neural network and other methods including land use variables do a better job of capturing spatial gradients near sources. Ideally, the concentrations predicted across the US from the *best* performing methods should be used to conduct risk assessment for the entire country, rather than conducting the risk assessment for only a modest number of sites. The Bayesian downscaler is the worst of these methods (especially for the Northwest and

California), and yet it was the one selected for further analysis. The selection of the Bayesian downscaler likely leads to an underestimation of exposure and risk in the Northwest and California, assuming that populations are spatially collocated with sources. Although the Bayesian downscaler appears to have worse performance compared to the other methods, it is capable of providing reasonable estimates of spatially averaged concentrations even though it is not capable of capturing higher resolution variations. Thus, although it may not be the best choice for use in risk assessment, it is capable of supporting risk assessment at the urban scale as is done for 47 urban areas of the country in the risk assessment. See also the Panel's response to Supplemental Charge Question 3.4(c) for comments about the important features of exposure models for risk assessment versus epidemiologic inference.

Importantly, the text (e.g., p 2-41) is wrong as to the reason that there is less agreement between among these methods in the West. The reason is not because concentrations are low in the West; rather, it is because spatial concentration gradients are substantially greater in the West than in the East, where  $PM_{2.5}$  is more influenced by large secondary particle formation and more therefore regionally homogeneous. Models that are based on higher spatial resolution, and that account for localized spatial features, such as the machine learning-based method, are better at representing such gradients.

### **Background $PM_{2.5}$**

Background  $PM_{2.5}$  is low (10-20%) relative to the current annual NAAQS. However, the estimates of background  $PM_{2.5}$  concentrations provided in the draft PA are too high, because  $PM_{2.5}$  concentrations attributed as background are influenced, in part, by anthropogenic activity.

Wildfire, secondary organic aerosol (SOA), and dust are the major contributors to background  $PM_{2.5}$  concentration. However, some wildfire events are influenced by human activity. Hotter, drier western summers (driven in part by climate change) have resulted in increased major wildfire events in the western US and Canada over the last few years (see climate and wildfire references cited earlier on page B-7). Figure 2-2 of the draft PA shows estimated 2014 National Emission Inventory (NEI)  $PM_{2.5}$  emissions that include 32% from fires (mostly wild) and 18% from dust; these are surprisingly high. Page 2-50 (last line) says wildfire smoke is 10% to 20% of primary  $PM_{2.5}$  emissions; this difference compared to Figure 2-2 needs to be explained.

Background was estimated by assuming all biogenic SOA is natural, which provides an unacknowledged upper bound. Even though it is made from biogenic hydrocarbons, biogenic SOA is not necessarily purely natural, which should be acknowledged and discussed. There is substantial evidence that anthropogenic emissions impact the formation of SOA from biogenic VOCs. This was raised in comments from Dr. Turpin on the first draft of the ISA. A leading oxidation pathway of many biogenic VOCs is with ozone, which is clearly enhanced by anthropogenic emissions. Another important example is isoprene. Oxidation of isoprene leads to several gas phase products. A major SOA precursor is isoprene epoxydiol (IEPOX), which forms SOA when it reacts with wet acidic sulfate (anthropogenic). Thus, IEPOX SOA is formed as a result of reactions with anthropogenic emissions and, therefore, is controllable. Field studies measuring tracers of IEPOX SOA suggest that it is a major source of aerosol (roughly one-third of organic  $PM_{2.5}$ ) in the southeastern US in both rural and urban locations (Budisulistiorini et al., and in the draft ISA). As another example, model predictions by Carlton et al., suggest that more than 50% of biogenic SOA in the eastern U.S. could be controlled by reducing anthropogenic  $NO_x$  emissions. The draft PA should include a brief discussion regarding the challenges in attributing the share of natural origin of ambient particles and implications for determination of background ambient  $PM_{2.5}$  concentrations.

The thoracic size fraction of "dust" (coarse PM, the size range between 2.5 and 10  $\mu\text{m}$ ) is regulated as a component of  $\text{PM}_{10}$ . These are primary emissions from non-combustion sources, mostly from agricultural, construction, and road sources. These sources can also contribute smaller particles in the  $\text{PM}_{2.5}$  size range. A drier climate in parts of the U.S. could contribute to an increase in PM from these sources (Reich et al., 2018, Tong et al., 2017), so it may not be appropriate to consider all coarse PM as natural background. This is not discussed in the first draft of the PA.

## **Additional Comments on Chapter 2**

### **Issues with Federal Reference Method and Federal Equivalent Method $\text{PM}_{2.5}$ Monitor Comparisons.**

Monitoring agencies continue to struggle with getting their continuous FEM  $\text{PM}_{2.5}$  monitor performance within acceptable levels for them to be used to demonstrate compliance with the  $\text{PM}_{2.5}$  NAAQS. Of the ~900 FEMs in use, data from 40% of them cannot be used as "official" FEM measurements due to performance issues. This problem is caused by how filter-based Federal Reference Method (FRM) instruments are run as a benchmark for testing FEM performance compared to how FRMs are run in routine state and local monitoring networks. For FEM testing, FRM filters are removed and chilled immediately at the end of the 24-hour sampling period. For routine monitoring, FRM filters remain in the sampler at or somewhat above ambient temperatures for up to 6 days. FRM filters can lose up to 10% of their non-water mass over 24-96 hours if not removed from the sampler and chilled immediately. Therefore, in field comparisons of co-located FEM and FRM monitors, FEM measurements typically appear to be biased high compared to the FRM, when in reality this is an artifact of field sample handling for the FRM and not an actual limitation of the FEM. However, as a result of such comparisons, the FEM is often found (erroneously) to be deficient with respect to performance requirements for NAAQS compliance purposes. While changes could be made to either the way FEMs are tested or how FRMs are run in the field, neither of these approaches are currently practical in a regulatory context. There are approaches that could be implemented to make nearly all the existing FEM data of acceptable quality for comparison to the NAAQS based on data collected from co-located FRM and FEM  $\text{PM}_{2.5}$  monitors over the last several years, since nearly all FEMs produce 24-hour average  $\text{PM}_{2.5}$  concentrations that are well-correlated with FRM samples.

### **Federal Reference Methods Needed for Ultrafine Particles and Black Carbon**

The Panel recommends the development of FRMs for measurement of ultrafine particles (UFP) and black carbon (BC). UFP is classified as "likely to be causal" for long-term nervous system effects, and there is a growing body of literature on the health effects of BC. UFP is measured at some of the near-road network sites, and BC is measured at most of them, as well as at National Air Toxics Trends Stations (NATTS) sites. Both are good indicators of traffic-related air pollution and have substantial gradients away from the road. There is also a need for comprehensive measurements of UFP and BC that go beyond near-roadway monitoring. Chapter 2 mentions the history of development of the FRM for coarse particles. Likewise, an FRM for UFP should be developed, for similar reasons. Thus, Chapter 2 should note that there is not an UFP FRM. Such a statement is important because a future research need is to obtain more ambient monitoring data over space and time for UFP to support epidemiology based on UFP; the same goes for BC. Given that EPA has in the past established FRMs in anticipation of possible new indicators, it is appropriate to provide a rationale for establishing FRMs for UFP and BC. The rationale for development of an FRM for  $\text{PM}_{10-2.5}$  is on page 2-18, at the top of the page. This is a good example of the similar rationale for development of new FRMs for UFP and BC.

UFP needs to be more clearly defined as particle number concentration with a low-end 50% response size of less than 10 nm; the low-end response particle size is an important parameter for UFP measurements.

### **Leverage Near-Road Monitoring Network**

A useful summary of the increase in PM<sub>2.5</sub> at near-road sites is given, showing an average increment over urban background of less than 1 µg/m<sup>3</sup> with short-term (morning rush-hour) peaks of 3 µg/m<sup>3</sup> to 4 µg/m<sup>3</sup>. Briefly noted in Section 2.2.5 are other particle measurements at some of the near-road network sites, including BC and UFP concentration measurements. Although BC is being measured at many near-road sites, it is not required to be reported to EPA's Air Quality System (AQS) under current regulations, and some agencies still do not report it. Over the last several years, a network of approximately 75 near-road monitoring sites has been deployed to determine compliance with the hourly NO<sub>2</sub> NAAQS. There is a large body of literature showing cardiovascular health effects from traffic-related air pollution (TRAP), presumably driven by particles and not NO<sub>2</sub> or CO (see for example Jhun et al., 2019, and George Allen's individual comments). The existing near-road site infrastructure could be leveraged by adding additional particle measurements at a subset of sites with the largest traffic influence to inform future PM NAAQS reviews. In addition to robust UFP and BC measurements, EPA should consider augmenting some of the existing monitoring sites to measure lung-deposited surface area (using charge-based continuous methods), PM-coarse, on-line (hourly) total aerosol carbon (and OC by difference with BC), and on-line (hourly) elemental measurements using XRF (brake wear can produce particles containing iron, copper, and other aerosol fumes). Similar measurements could be added to the nearest NCore site in the same urban area. This paired network design would provide information on the elevated exposures (gradients) to these pollutants in the near-road environment.

### **Emissions and Air Quality Trends**

The summary of emission categories averaged nationally was of limited usefulness. It would be more useful to provide attributions of emissions to source categories for regions of the country that illustrate the variability among the sites included in the risk assessment. Figure 2-2 (page 2-5), emissions by source sector, is misleading; geographically stratified emissions would be preferred. There are differences in the quantified percentages given for emissions by source type between the draft ISA and draft PA; see Dr. Judith Chow's individual comments for more detail. These differences should be reconciled.

The national downward trend in PM<sub>2.5</sub> ambient concentration over the last two decades, especially in the eastern US, has stopped and appears to have recently reversed (Figure 2-9, page 2-24). The draft PA should acknowledge and discuss this. For example, the recent change in the trend may be related to the end of substantial Electricity Generating Unit (EGU) SO<sub>2</sub> emission reductions, which could be assessed in the second draft by evaluating evidence from speciation data. The draft PA notes recent increases in wildfire events, which could also be a factor in the recent change in the trend.

The discussion of UFP trends was weak and did not make use of available near-road UFP data in AQS. As noted above, establishing an FRM for UFP is a first step in expanding information needed for evaluating UFP trends and concentrations.



**EPA-3. Chapter 3 – Review of the Primary PM<sub>2.5</sub> Standards: What are the CASAC views on the approaches described in Chapter 3 to considering the PM<sub>2.5</sub> health effects evidence and the risk assessment in order to inform preliminary conclusions on the primary PM<sub>2.5</sub> standards? What are the CASAC views regarding the rationales supporting the preliminary conclusions on the current and potential alternative primary PM<sub>2.5</sub> standards?**

**SCQ-3.1 Does the Panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM<sub>2.5</sub> review? Are there additional policy-relevant questions that should be addressed?**

The questions posed in Chapter 3 appropriately reflect important policy-relevant issues for the PM<sub>2.5</sub> review.

**SCQ-3.2 What are the Panel's views on the relative weight that the draft Policy Assessment gives to the evidence-based (i.e. draft PA, section 3.2) and risk-based (i.e. draft PA, section 3.3) approaches in reaching conclusions and recommendations regarding current and alternative PM<sub>2.5</sub> standards?**

Together the evidence-based and the risk-based approaches show that the current PM<sub>2.5</sub> standard is not requisite to protect public health, with the evidence-based approach appropriately given more relative weight. Together these approaches, with more weight given to the evidence-based approach, provide a scientific evidentiary basis for recommending alternative levels for the annual and daily PM<sub>2.5</sub> standards. The Panel found that the PA evidence-based approach is a thoughtful and comprehensive synthesis of the observational (epidemiological) and experimental science (controlled human exposure and animal toxicological studies) presented in the ISA. The risk-based approach provides context for the scientific findings for current and alternative PM<sub>2.5</sub> standard levels in a large sample of the US population. The risk-based approach is limited in scope and would benefit from a clearer presentation of methods. The risk assessment is subject to uncertainty and is viewed as providing qualitative insight regarding magnitudes of, and relative differences in, risk. Nevertheless, the risk-based approach informs the scientific evaluation that risk would be reduced by alternative PM<sub>2.5</sub> standards. The Panel gives more weight to the evidence-based approach that documents the ambient levels at which adverse effects are observed, although no evidence was found for a discernable population threshold. Together, the complementary evidence-based and risk-based analyses, with more weight given to the evidence-based approach, provide strong support for drawing conclusions regarding current and alternative PM<sub>2.5</sub> standards.

**SCQ 3.3 What are the Panel's views on the evidence-based approach, including:**

- a) The emphasis on health outcomes for which the draft ISA causality determinations are "causal" or "likely causal"?**
- b) The identification of potential at-risk populations?**
- c) Reliance on key multicity epidemiology studies conducted in the US and Canada for assessing the PM<sub>2.5</sub> levels associated with health effects?**
- d) Characterizing air quality in these key studies using two approaches: the overall mean and 25<sup>th</sup>/75<sup>th</sup> percentiles of the distribution and the "pseudo design value" reflecting a monitor with the highest levels in an area?**
- e) The preference for continuing the use of an annual PM<sub>2.5</sub> standard as the principle means of providing public health protection against the bulk of the distribution of short- and long-term PM<sub>2.5</sub> exposures?**
- f) The draft PA conclusions on the extent to which the current scientific information strengthens or alters conclusions reached in the last review on the health effects of PM<sub>2.5</sub>?**
- g) Whether the discussions of these and other issues in Chapter 3 accurately reflect and clearly communicate the currently available health effects evidence, including important uncertainties, as characterized in the ISA?**

- a) *The emphasis on health outcomes for which the draft ISA causality determinations are "causal" or "likely causal"?*

Limiting the evidence-based approach to assessment of associations and outcomes deemed as 'causal' or 'likely to be causal' is reasonable. However, specific attention should be given in future assessments to emerging evidence involving associations which, while less well-established, may provide more sensitive indicators of PM<sub>2.5</sub>-mediated risks. These include, for example, associations between various PM size fractions and corresponding neurological and metabolic effects.

- b) *The identification of potential at-risk populations?*

The Panel felt that the more expansive identification of 'at-risk' populations employed in the draft PA is a positive change from the previous PA of the last review cycle. At-risk populations, as defined in the draft ISA and draft PA, include traditional definitions involving biological susceptibility, as well as those exposed to elevated PM due to social disparities. EPA staff deserves credit for thinking of risk in terms of sensitivity and vulnerability and for refining the approach to identification and assessment of at-risk populations in recent review cycles for other criteria pollutants and applying these concepts in the current PM review.

The Panel recommends more explicit discussion of environmental justice, including more depth regarding disparities in PM<sub>2.5</sub> risk borne disproportionately within African American and Hispanic communities. For example, the Di et al. (2017a) chronic mortality study presents a result of concern in this vein: the three times higher relative risk (hazard ratio) for African Americans compared to the general population.

- c) *Reliance on key multicity epidemiology studies conducted in the US and Canada for assessing the PM<sub>2.5</sub> levels associated with health effects?*

The Panel supports the decision to focus the evidence-based assessment on multicity epidemiologic studies. As stated in the draft PA, such studies examine potential associations over large geographic areas with diverse atmospheric conditions and population demographics. The Panel also supports and concurs with the choice in the draft PA to devote specific attention to recent studies conducted in cities with PM<sub>2.5</sub> levels well below current standards; these studies are compelling in showing excess risk at levels below the current standards. The Panel noted the strong concordance of findings among these observational studies, conducted throughout North America, in locations with varying exposure scenarios, using a range of exposure estimation and concentration-response modeling methods, which collectively provide strong evidence-based support for assessment of the adequacy of the current PM standards. Findings from toxicological, controlled human exposure, and accountability studies are coherent with these observational findings. Truncated distribution analysis, such those conducted by Di et al. (2017a&b), provides additional confidence of effects at levels below current standards.

The Panel notes that the draft PA focuses on U.S. and Canadian studies exclusively, and does not take into account that studies outside of North America (e.g., in Europe) could also be informative. The evidentiary basis from the U.S. and Canadian studies is sufficient to support findings regarding the adequacy (or lack thereof) of the current standards and alternative standards.

- d) *Characterizing air quality in these key studies using two approaches: the overall mean and 25<sup>th</sup>/75<sup>th</sup> percentiles of the distribution and the “pseudo design value” reflecting a monitor with the highest levels in an area?*

The Panel supports the approach described in the draft PA of focusing on the mean level of PM<sub>2.5</sub> in short- and long-term epidemiologic studies, especially for mean values at or below the level of the annual and 24-hour current standards. However, the Panel notes that there are scientifically valid and meaningful inferences to be made for other statistics of the PM<sub>2.5</sub> concentration distribution in epidemiological studies. While assessment of adverse effects at mean concentrations continues to be a suitable practice for quantifying threats to public health, the Panel notes that, as detailed in the attached individual comments by Dr. Douglas W. Dockery, statistical power is a function of exposure variance, not the mean. In this vein, the Panel finds that the evidence from epidemiologic studies over a continuum of observed concentrations, such as from the 25<sup>th</sup> to 75<sup>th</sup> percentiles, is also informative, and that evidence of adverse effects at levels below the mean observed concentrations provides information of value in assessing both the adequacy of the current standard and potential alternative levels.

The Panel finds that the pseudo design values (PDVs) are useful in providing a systematic basis for comparing individual studies (both single city and multicity) with the current and alternative standards. The PDVs essentially convert exposure metrics used in the observational studies (i.e., mean annual ambient concentrations) into values that are interpretable from a regulatory standpoint. Despite this, several Panel members felt that the PDVs were presented in a confusing manner in the draft PA, limiting their interpretability. Perhaps some of the detailed explanation in Appendix B of the draft PA could be included in the body of Chapter 3. Suggestions raised by Panel members for improving the PDV discussion include: adding a PDV column in Figure 3-3, which presents results from the multicity epidemiologic studies; remove the material within the PA describing the PDVs as reflecting health response; and provide comparisons between PDVs and conventional DVs.

EPA should also provide 98<sup>th</sup> percentile of PDVs for short-term (24-hour) studies to aid in the use of such studies to assess effects for the 24-hour standard at current and alternative levels. However, as noted in the draft PA, the PDVs are up to 10% higher than an actual design value, which should be taken into account when using the studies to support inferences related to actual design values.

- e) *The preference for continuing the use of an annual PM<sub>2.5</sub> standard as the principal means of providing public health protection against the bulk of the distribution of short- and long-term PM<sub>2.5</sub> exposures?*

While there was considerable debate among the Panel members concerning sub-populations not adequately protected by the annual standard (e.g., populations in the northwestern and northeastern US who may be exposed to episodic ambient PM<sub>2.5</sub> peak concentrations from residential wood combustion), there was consensus that the annual standard is appropriate as the principal means of protecting public health from PM exposures. The Panel concurs with prioritizing the annual standard based on the rationale outlined in the PM ISA from the prior NAAQS PM review cycle and noted that risks associated with long-term PM exposures are typically an order-of-magnitude larger than those associated with short-term exposures. However, the Panel notes that the annual standard is not the ‘controlling’ standard in all parts of the U.S., meaning, addressing the annual standard will not necessarily be protective of health effects in all parts of the country due to short-term exposures. In some parts of the U.S., the annual levels can be lower than the standard even though there are levels at or over the the 24-hour standard. Thus, for some parts of the U.S., the 24-hour standard is controlling, or would be controlling under revised standards. Therefore, both the annual and 24-hour standards are needed to provide public health protection for situations in which one or the other would be controlling.

- f) *The draft PA conclusions on the extent to which the current scientific information strengthens or alters conclusions reached in the last review on the health effects of PM<sub>2.5</sub>?*

Scientific findings since the last PM NAAQS review based on epidemiological and controlled exposure studies, relating to both short- and long-term exposure to PM<sub>2.5</sub> and corresponding acute and chronic effects, provide a robust foundation for assessing the adequacy of the current PM<sub>2.5</sub> standards. U.S. multicity epidemiologic studies, supported by Canadian multicity epidemiologic studies, coherent results from animal toxicology and controlled human exposure studies, and accountability studies that provide additional causal evidence, provide clear and compelling scientific evidence that the current PM<sub>2.5</sub> standards are not adequate to protect human health. The Panel agrees with and supports the assessment in the draft PA highlighting the U.S. and Canadian epidemiologic studies, specifically, those conducted in locations where study period PM<sub>2.5</sub> concentrations (and their PDVs) were clearly below the current annual and 24-hour standards. Most notable are an American study (Di et al., 2017a) and three Canadian studies (see Weichenthal et al., 2016b, 2016c and Pinault et al., 2016) that provide evidence of adverse health effects from long-term exposures and health; and two studies that examined risk from short-term exposures (Di et al., 2017b; Shi et al., 2016).

For example, the Di et al. (2017a) and Shi et al. (2016) studies are characterized by very large sample sizes, and Shi et al. (2016) has mean concentrations near 8 µg/m<sup>3</sup>. Even when data were truncated in Shi et al. (2016) such that air quality only under 12 µg/m<sup>3</sup> was considered, the effects were consistent. The Shi et al. (2016) study includes hybrid model-predicted concentrations that average just above 8 µg/m<sup>3</sup> and are well below 7 µg/m<sup>3</sup> at the 25<sup>th</sup> percentile of the distribution. The hybrid modeling approach is a substantial

advancement in exposure estimation that enables epidemiologic studies of large cohorts not served by the ambient monitoring network. Although the hybrid model air quality predictions are subject to some uncertainty, the performance of the hybrid models is quite good based on results described in Chapter 2 and serves as a valid basis for epidemiologic inference. The Canadian studies are informative in that they include notably low levels of exposure at which effects are observed, which provides consistency with the U.S.-based studies. These are groundbreaking studies that provide new results since the last review that are highly compelling.

Some discussion of PM<sub>2.5</sub> components other than based simply on particle diameter (i.e. ultrafine particles) is desirable. Such components typically include elemental carbon, organic carbon, nitrate, sulfate, mineral matter, and trace species, as well as black carbon. Although virtually all PM components have been shown to have some adverse health impacts, there is scientific evidence of some differences in toxicity among major components for both respiratory and cardiovascular endpoints. Although currently available scientific evidence is not sufficient to support development of standards related to differences among PM<sub>2.5</sub> components and variability in PM<sub>2.5</sub> composition, the limited available information about components is noteworthy and could help inform risk managers about the need to consider all major PM<sub>2.5</sub> components in achieving compliance.

- g) *Whether the discussions of these and other issues in Chapter 3 accurately reflect and clearly communicate the currently available health effects evidence, including important uncertainties, as characterized in the ISA?*

As noted above, the Panel finds that key uncertainties still exist concerning the adequacy of the existing standard, especially the daily standard, in protecting specific sub-populations, including those living in the areas affected by high PM<sub>2.5</sub> concentration episodes from residential wood combustion. The Panel recommends that additional analyses be conducted to assess the degree to which the current 24-hour standard is correlated with, or captures, sub-daily exposures occurring over a few hours.

Acute health effects associated with sub-daily exposures to PM<sub>2.5</sub> and UFP continue to be a key uncertainty in assessing PM health risk. While controlled human exposure and panel-based studies typically assess sub-daily exposures, endpoints used in these investigations are commonly sub-clinical, yielding important mechanistic rather than clinical insights. The Panel also agreed that uncertainties and limitations exist in using multi-pollutant models as a primary means of assessing confounding and robustness of PM health epidemiologic results, as is typically the case in the key studies noted above. However, such uncertainties and limitations were taken into account by the Panel in making expert scientific judgments that inferences from the studies were valid and robust, and in making scientific judgments based on these studies regarding the adequacy of existing and alternative standards. The scientific evidence supports robust inferences because of the consistency of epidemiological findings, and the coherence among multiple lines of scientific evidence from epidemiology, controlled human studies, and toxicology, and biological plausibility.

The draft PA should reframe the inference of policy-relevance of controlled human studies. While it is true that the controlled human studies in Table 3-2 for which effects were observed tend to have very short averaging time periods (e.g., sub-daily over a few hours), if the measured levels are averaged over 24 hours they are comparable to or below the level of the current 24-hour primary PM<sub>2.5</sub> standard. Thus, these studies represent 24-hour

concentrations that are policy relevant. Of course, there are challenges with interpretation of subclinical endpoints with respect to implications for clinical adverse effects. However, these studies provide indication of the potential importance of sub-daily exposures, including peak exposures. Therefore, the Panel recommends that the policy relevance of these studies receive more emphasis.

**SCQ 3.4 What are the Panel's views on the quantitative risk assessment for PM<sub>2.5</sub> including:**

- a) The choice of health outcomes and studies selected for developing concentration-response functions for long and short-term effects?**
- b) The selection criteria for the 47 urban areas and PM<sub>2.5</sub> air quality scenarios analyzed?**
- c) The hybrid modeling approach used for quantifying exposure surrogates across an area and adjusting air quality for alternative standard levels, as supplemented by interpolation/extrapolation?**
- d) The characterization of variability and uncertainty in the risk assessment?**
- e) The robustness and validity of the risk estimates?**

Overall the risk assessment has been thoughtfully and reasonably conducted given the compressed timeframe. However, as a procedural matter, and as noted earlier, it is a process deficiency and contrary to the final IRP that there was not a first draft of an REA to enable review of scientific issues in risk assessment prior to the use of risk assessment to support the PA. The risk assessment illustrates that there is more impact in terms of reduction in premature mortality from lowering the level of the annual standard, rather than the level of the 24-hour standard. However, there are nonetheless substantial risk reductions obtained by lowering the 24-hour standard, especially in locations for which the 24-hour, and not the annual, standard would be controlling. A second draft of the PA should include risk assessment analyses for combinations of alternative levels of the annual and 24-hour standards commensurate with the levels recommended by this Panel that are not already included: i.e., in the range of 10 µg/m<sup>3</sup> to 8 µg/m<sup>3</sup> for the annual standard combined with a range of 30 µg/m<sup>3</sup> to 25 µg/m<sup>3</sup> for the 24-hour standard. See also the Panel's discussion of SCQ-3.6.

The risk assessment indicates that there will be a large number of estimated premature deaths attributed to PM<sub>2.5</sub> for persons of age 30 or older for the 47 selected urban study areas based on simulation of air quality that just meets the current standard. The risk assessment accounts for approximately one-third of the U.S. population that is age 30 or older. Therefore, the risk estimates are based on a large population but underestimate the national total. Based on Table 3-5, the median estimated all-cause mortality from long-term exposure to PM<sub>2.5</sub>, based on 2015 air quality adjusted to just meet the existing standards, ranges from 13,500 based on Thurston et al. (2016) to 52,100 based on Pope et al. (2015). The estimated all-cause mortality from short-term exposure to PM<sub>2.5</sub> ranges from 1,200 based on Ito (2013) to 3,870 based on Zanobetti et al. (2014). The variability in these estimates account for two different air quality simulation approaches as well as different concentration-response functions from more than one study; most of the variability is due to the underlying study. While the specific estimates are uncertain, and should be interpreted qualitatively with regard to their magnitude, the draft PA risk assessment buttresses the conclusions based on the scientific evidence that at the levels of the current fine particle standards, the risk of premature mortality is unacceptably high.

The Panel has quite a few comments regarding the risk assessment, including: (a) the lack of clear rationale for the choice of health effect endpoints; (b) exclusion of some study areas that are of concern; (c) limitations of the Bayesian downscaler hybrid modeling approach and its

application; (d) the opportunity to improve the characterization of variability and uncertainty; and (e) robustness and validity of the risk assessment. Each of these are discussed in more detail below.

### **a) Rationale for Health Endpoints**

The IPMRP agrees with the draft PA's focus on *health outcomes* that were judged in the ISA to be causal or likely causal. However, the risk assessment only focuses on three health outcomes (total mortality, ischemic heart disease mortality, and lung cancer mortality) and the rationale for this choice is not clearly articulated. Omitted are cardiovascular effects (long-term) other than IHD mortality, such as cerebrovascular (stroke); any short-term cardiovascular effects other than IHD mortality; respiratory effects at either long- or short-term time scales; cancer mortality other than lung cancer; and nervous system effects. Note that, by comparison, the Global Burden of Disease analyses have developed risk assessment estimates for mortality from All Causes, Ischemic Heart Disease (IHD), Cerebrovascular Events (Stroke), Lower Respiratory Infections (LRI), Chronic Obstructive Pulmonary Disease (COPD) and Lung Cancer. While the three selected endpoints are appropriate given their clear public health importance, the draft PA's characterization of risk is limited due to the focus on only a subset of endpoints. Nonetheless, the studies selected as the basis for quantification of exposure-response relationships in the risk assessment are large and well-designed; there is clear articulation of the criteria for selecting these studies and these are appropriate. Table C-1 is a succinct distillation of each of the selected studies with key information relevant to the risk assessment.

### **b) Selection of Study Areas**

The individual *selection criteria* for the 47 urban areas are reasonable. They include PM<sub>2.5</sub> concentrations, availability of monitoring data, and geographic diversity. However, the manner in which these criteria are evaluated is not specifically and clearly explained. For example, the criterion related to "PM<sub>2.5</sub> air quality concentrations" is related to the need for adjustments of observed air quality to levels corresponding to current and alternative standards. The text does not clearly describe how the three criteria are assessed and or balanced in the process of decision-making regarding selection of study areas. Although the selected urban areas are reasonable, they do not adequately represent the range of geographic diversity that is needed, especially with respect to the 24-hour standard. For example, Figure 3-10 indicates that large parts of the central, northern, and western US were not included in the areas assessed. Fifty-six areas met the initial 10/30 (annual/24 hour) standard criteria for inclusion, but 9 (20%) were later excluded because of influence of wildfires (7 areas), high local conditions (Eugene, OR), and "uncertain" projections (Phoenix, AZ). The Panel is concerned that areas for which there are exposures to smoke from residential wood combustion are not represented. As noted earlier, the Panel is concerned that the draft PA is too easily dismissive of the fact that there have been a growing number of human-induced wildfires during the past two decades which have had evident adverse health and environmental effects. Based on 1.5 million government-recorded wildfires from 1992 to 2012, Balch et al. (2017) estimated that 84% of wildfires were human-caused, accounting for 44% of the total area burned. Nonetheless, the draft PA's approach is likely broad enough to provide a sufficient basis for making inferences regarding the potential for risk reduction from lowering standards given that nearly one-third of the U.S. population over the age of 30 is included and areas with large populations are included. The IPMRP suggests that EPA explore the feasibility of using the entire U.S. as an alternative to selecting only a subset represented by the 47 urban study areas, and expand the geographic scope of the risk assessment commensurate with data availability.

### c) Modeling Approach

The *hybrid modeling approach* relies on the Community Scale Air Quality (CMAQ) model predictions and a Bayesian downscaler method. The reductions in emissions needed to scale air quality to levels of current and alternative standards were specified based on adjustments in emissions from either primary PM<sub>2.5</sub> or secondary PM<sub>2.5</sub> precursors (specifically, SO<sub>2</sub> and NO<sub>x</sub>). Using two methods to estimate emissions allows better understanding of the sensitivity of the downscaling approach to the emissions estimates. Limitations include: (i) restricting the analysis to only one year, 2015, without adequate characterization of inter-annual variability; (ii) modeling at the 12-km grid level, which is relatively coarse with respect to spatial gradients found in some study areas; and (iii) the assumption of proportionate reductions scaled by fixed percentages.

While these decisions are justified and reasonable given the limited timeframe that EPA staff had to complete this risk assessment, a more complete analysis would evaluate the sensitivity to these assumptions. For example, the model could be run with data for multiple years to assess the robustness of the risk estimate to inter-annual variability. The risk modeling could be performed at a finer grid scale for at least a few representative choices among the study areas. Alternative assumptions regarding scaling and their impacts on spatial and temporal variability in predicted air quality and associated risk could be tested. Such analyses should be included in a second draft of the PA.

Nonetheless, the hybrid modeling approach is a practical and acceptable way of estimating effects that would occur over a range of current and alternative standards. The hybrid approach is a more realistic improvement over the rollback approaches employed in the previous NAAQS review cycle.

In a second draft of the PA the Panel would like to see more information to better understand the spatial scales, species specifics, and proportionate emissions reductions that ended up being used to meet the various PM concentration thresholds in the different urban areas. This information could be included in Appendix C, either as a tabular summary or for a few illustrative typical examples for cities in different regions of the U.S. These would show the spatial scales and absolute reductions (or increases) required of specific primary and secondary emissions species associated with the different PM thresholds evaluated.

The description and explanation of the 2015 downscaler is fairly cursory (Section C.1.4.5). While it is possible that this is justified given EPA's previous work (cited as U.S. EPA, 2018c), more details are warranted so that the PA can be a stand-alone self-explanatory document.

The risk assessment results are potentially very sensitive to the choice of the downscaler vs. one of the other "hybrid" models described in Chapter 2. For risk assessment, it is important that the model predict the same mean and capture the full variation of the distribution represented by the underlying concentration distribution in the area under consideration. While ground truth can only be approximated due to inherently limited monitoring data, it would be helpful to see a more direct assessment of the performance of the model for risk assessment purposes.

The linear interpolation approach to assessing additional standards represents a reasonable compromise to reduce EPA staff workload given the compressed timeframe for producing the Policy Assessment. However, the scientific quality of the work is compromised when not enough time is allowed. The IPMRP suggests modeling at least one more level in order to understand better whether the linear assumption is reasonable. (For further details on the above points, see Dr. Sheppard's individual comments.)



#### **d) Variability and Uncertainty**

The *characterization of variability and uncertainty* is generally appropriate, given the analyses that have been conducted, and is reasonably summarized in Section 3.3.2.4 with more detail provided in Appendix Section C.3. The draft PA appropriately references and utilizes the WHO multi-tiered approach to assessing uncertainty. By endpoint, the risk estimate results indicate that the most important factor influencing the estimated range of variability is the choice of underlying study from which the concentration-response function is selected. The draft PA has appropriately articulated this important source of variation by showing results based on multiple epidemiologic studies. Overall the IPMRP recommends a stronger discussion of the key features of the approach that affect variability and uncertainty of estimates produced, particularly for the sources discussed in the qualitative assessment section. As noted earlier, deadlines do not excuse substantive deficiencies. With more time to conduct the risk assessment it would be possible for the EPA to quantify at least some aspects of these qualitative sources and incorporate them into a second draft of the PA.

There has been incomplete consideration of uncertainties in the exposure estimates. The IPMRP recommends that EPA better articulate the analyses that could be conducted to reduce some of these sources of uncertainty in the revised PA, even if the schedule does not allow them to be conducted. This will be a valuable reference for future risk assessments. In particular, in the limitations section of Appendix C (Section C.1.4.7), some important limitations of the air quality projections are listed. These are important to consider because they could be a key source of uncertainty of the risk estimates. The IPMRP recommends adding:

- a. Reconsideration of reliance only on modeled 2015 concentrations, and not for multiple years, for which model performance was assessed at the national level (it appears), rather than with a focus on the 47 urban study areas.
- b. Additional assessment of whether the downscaler captures the full PM distribution within Core-Based Statistical Areas (CBSAs) (separately addressing spatial variation for long-term studies and temporal for short-term studies).
- c. Additional articulation of the performance of the hybrid models (most particularly the Bayesian downscaler). Model performance is not hampered by low concentrations but rather by strong spatial concentration gradients. Hybrid methods that include land use factors related to primary sources are better able to address spatial gradients. Regional secondary formation in the East means that spatial gradients are much smaller and the models perform better. For this reason, it makes sense that the neural network model would perform better than the Bayesian downscaler in the West. Thus, the uncertainty is larger for the Bayesian downscaler specifically in locations with large concentration gradients. In the West, more weight should be placed on the other hybrid models.

#### **e) Robustness and Validity**

The risk estimates appear to be *robust and valid* although they represent only a subset of at-risk individuals and health endpoints. The ability to assess the robustness and validity of the risk assessment is, however, hampered by the lack of needed clarity in the description of the approach and its application.

While Appendix C provides documentation of multiple aspects of the estimates, the text describing this process on page 3-83 is fairly brief. Although it points to Appendix C, it does not present the key findings or conclusions in a comprehensible way. The goals of this analysis need to be more clearly stated, and the text on the rationale for the different risk modeling approaches should be articulated up front. While the general approaches of upper bound

estimates and the use of sensitivity analysis are justified, as is the use of qualitative uncertainty assessment, several aspects are unclear. The process for selection of concentration-response functions should be explained more specifically. More specific explanation is needed regarding how sensitivity analysis was or will be conducted. The plausibility of the ranges of estimates values should be more completely described in the body of the PA.

The summary of associated premature mortality estimates under alternative standards and exposure reduction scenarios has results in the range that would be expected, although the process for obtaining them is hard to follow and the key features of the appendix tables cited are not well described. The lack of clarity in the descriptions of the approach hampers the ability to assess the robustness and validity of the risk assessment.

As noted, the primary factor that explains variability in the risk estimates for a specific air quality standard is the underlying concentration-response function from a published study. The IPMRP is concerned about whether the estimates are also sensitive to the use of the ambient concentration model, specifically the Bayesian downscaler versus one of the other national models presented in Chapter 2.

Nonetheless, considering all of the information about, and features of, the risk assessment approach, the robustness of the results is enhanced by key sources of variability and uncertainty that are taken into account. The risk estimates have been calculated across 47 urban areas that represent approximately one third of the U.S. population over age 30. They have been estimated using multiple underlying health studies, multiple endpoints classified as causal or likely causal in the ISA, and under different air quality standards and scenarios for downscaling estimates. Thus, the risk assessment is deemed to be adequate for its intended purpose, albeit there is opportunity for substantial improvement based on the recommendations offered here.

**SCQ-3.5 *What are the Panel's views on the draft PA preliminary conclusion that, taken together, the available scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary PM<sub>2.5</sub> standards?***

The draft PA reaches the preliminary conclusion that, taken together, the available scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary PM<sub>2.5</sub> standards. The Panel concurs with the scientific rationale but recommends a stronger finding based on the scientific evidence: the current primary standards are unequivocally not adequately protective. The entire weight of scientific evidence supports more stringent standards. The Panel concludes that arguments offered in the draft PA for retaining the current standards are not scientifically justified. Both major points are elaborated below.

**Calling into question the adequacy of the current standards**

Overall, the IPMRP concurs with the draft PA's preliminary conclusion that the weight of scientific evidence from various study types and analyses calls into question the adequacy of the current standards to protect public health. This conclusion is based on scientific evidence from epidemiological, controlled human exposure, and animal toxicological studies. The evidence from both long-term and short-term studies supports this conclusion. There is also consistent support from policy-relevant accountability studies that allow more direct causal inferences. Overall, the results provide coherence from multiple scientific disciplines and biological plausibility. In this review there is new and compelling evidence that health effects are

occurring in areas that already meet the levels of the current primary PM<sub>2.5</sub> standards and that are at levels well below those of the current primary PM<sub>2.5</sub> standards. Similar to the prior review (e.g., see EPA-CASAC-10-015, Samet, 2010b), there is no evidence of an ambient concentration threshold for health effects. The concentration-response relationships are approximately linear. The epidemiologic evidence shows increased risks at the levels of the current standards and that there are at-risk groups that are disproportionately affected. The risk assessment is illustrative of a large magnitude of estimated premature mortality at the levels of the current standard. Thus, the scientific evidence in this review provides clear and compelling support of the conclusion, unanimously supported by this expert scientific Panel, that the current primary PM<sub>2.5</sub> standards do not protect public health. The risk-based approach provides additional support. The new scientific evidence in this review strengthens conclusions compared to previous reviews.

The weight-of-evidence framework for causality determination applied by EPA is appropriate and has been well-vetted over more than a decade by many previous CASAC reviews. The weight-of-evidence causal determination framework applied by EPA is an appropriate tool for drawing causal conclusions.

The existing strong and consistent epidemiological evidence was developed using accepted scientific methods, is peer-reviewed, and is coherent with peer-reviewed controlled human studies and toxicological studies that were also developed using accepted scientific methods. This combined body of evidence provides strong support for developing causal determinations. The existing epidemiological studies contain important insights, and, when taken together, provide a weight of evidence that is substantially stronger than any single study can provide alone. The IPMRP notes that the epidemiologic evidence is vast, particularly in terms of the geographic domain and number of subjects included, and provides an overall consistent scientific basis, supported by coherence with controlled human and toxicological studies, for finding that the current primary PM<sub>2.5</sub> standards are not protective of public health. The epidemiologic evidence is scientifically valid for informing recommendations regarding levels of alternative primary PM<sub>2.5</sub> standards.

There are recently emerging causal inference methods for the analysis of individual studies that members of the current CASAC have argued should be imposed as a condition of a study being considered in EPA's weight-of-evidence review. While it may be possible for EPA to integrate applications of emerging causal inference tools in future reviews, these emerging tools still require considerable development before they can be implemented in air pollution epidemiology studies (Carone et al., 2019). The existing epidemiologic evidence meaningfully contributes to the causal conclusions reached in the draft ISA and used in the draft PA. It would be irresponsible to dismiss any or all of these epidemiologic studies, which the Panel finds to be valid, merely because they have not been analyzed using emerging un-vetted advanced statistical methods that are still in their infancy for application to air pollution studies. The Clean Air Act requires EPA to act to protect public health in the presence of uncertainty. For this reason EPA's review and the Panel's advice rely upon the entire body of the scientific evidence.

The collective weight of the scientific evidence from the epidemiologic studies along with supporting experimental evidence from controlled human exposure studies and animal toxicology is unambiguous in showing serious human health effects of PM<sub>2.5</sub> at levels below the current primary standards. The overall strength of evidence from the longstanding body of evidence presented and reviewed in the 2009 ISA (EPA/600/AR-08/139F, U.S. EPA, 2009) has been further bolstered with new studies with a range of study designs. The strong evidence on mortality and morbidity endpoints, coupled with emerging evidence for less extensively studied health endpoints, such as nervous system effects, is scientifically credible. The expert scientific judgment of the IPMRP is that the evidence is credible even based on the epidemiologic studies

alone; other studies, including animal toxicology and human controlled exposure studies support and strengthen this evidence. In particular, the animal study evidence supports biologic plausibility for PM effects on the cardiovascular, respiratory, and nervous systems, as well as for cancer effects. The epidemiologic evidence includes multiple new epidemiologic studies in the U.S. and Canada not included in the 2009 review. These studies consider huge populations and report effects below the current standard, either by restriction of the cohort to individuals living in areas with lower exposures (Di et al., 2017a&b; Shi et al., 2016), or because the average cohort exposures are well below the annual standard (Weichenthal et al., 2016a&b; Pinault et al., 2016). The populations quantified in such recent studies are more than an order-of-magnitude larger than studies available in previous reviews, which has been made possible by scientific developments in the quantification of spatial variability in exposure concentrations using new modeling tools. The ambient air quality hybrid modeling tools are found to perform well and provide a solid foundation for including populations that are not well-served by the existing ambient monitoring network. Furthermore, these studies do not show any evidence of a threshold, including under a variety of statistical approaches and for analyses restricted to concentrations below the levels of the current primary PM<sub>2.5</sub> standards. Indeed, it is possible that the annual concentration-response relationship is steeper at lower exposures. For these reasons the conclusion that the existing standards are inadequate is warranted.

The draft PA considers potential at-risk populations and notes that older adults, populations at increased risk due to existing health conditions (e.g., existing cardiovascular and/or respiratory conditions), and populations with increased exposures (e.g., disadvantaged populations) are all sizable and represent a substantial portion of the U.S. population. These populations are at increased risk due to geographic location, proximity to sources, or population characteristics (specifically age and/or prior disease status) that increase their susceptibility. The conclusion that the existing standards do not provide an adequate margin of safety for these at-risk populations is warranted. There are environmental justice concerns associated with disparity in the distribution of risks which show that at least some minority groups are disproportionately affected. Given that spatial averaging, as described on page 3-102 of the draft PA, can result in disproportionate impacts in minority populations and populations with lower SES, it is appropriate to retain the approach of not using spatial averaging in the form of the standard.

In evaluating population exposures, the draft PA appropriately considers both epidemiologic and controlled human exposure studies. With respect to controlled human exposure studies, the IPMRP puts more weight than the draft PA on the significance of these exposures for informing the appropriateness of the current standard. While exposures are at levels higher than the 24-hour standard, the durations of exposures in these studies are short (typically 2 hours or less) meaning that when these two-hour exposures are averaged over 24 hours, their average levels can be below the 24-hour standard. Several of the controlled human studies indicate significant subclinical effects at high peak levels that are below the level of the current 24-hour standard when averaged over 24 hours.

In considering the epidemiologic studies, the draft PA looks at both the concentration means and lower (10<sup>th</sup> & 25<sup>th</sup>) percentiles in key studies, as well as pseudo-design values, to more directly address whether exposures in these studies would have occurred in areas which would attain the annual standard. The IPMRP concurs with the draft PA's conclusion that the epidemiological evidence for air quality scenarios that meet or are below the level of the current annual PM<sub>2.5</sub> primary standard is compelling, and that this evidence for effects at concentrations below the standard has been strengthened in the most recent review.

While the IPMRP concludes that the scientific evidence alone is sufficient to call into question the existing standards, the Panel finds that the risk assessment also supports this conclusion. As noted earlier (see response to SCG-3.4), the risk assessment indicates that there will be a

large number of estimated premature deaths attributed to PM<sub>2.5</sub> for persons of age 30 or older for the 47 selected urban areas based on simulation of air quality that just meets the current standard. The risk assessment accounts for approximately one-third of the U.S. population that is age 30 or older. Therefore, the risk estimates are based on a large population but underestimate the national total. Based on Table 3-5, the median estimated all-cause mortality from long-term exposure to PM<sub>2.5</sub>, based on 2015 air quality adjusted to just meet the existing standards, ranges from 13,500 based on Thurston et al. (2016) to 52,100 based on Pope et al. (2015). The median estimated all-cause mortality from short-term exposure to PM<sub>2.5</sub> ranges from 1,200 based on Ito et al. (2013) to 3,870 based on Zanobetti et al. (2014). Two different air quality simulation approaches are compared and contribute a smaller portion of variability to the risk estimates than the inter-study variability in concentration-response relationships. While the specific estimates are uncertain, and should be interpreted qualitatively with regard to their magnitude, the draft PA risk assessment buttresses the conclusions based on the scientific evidence that at the levels of the current fine particle standards, the risk of premature mortality is unacceptably high.

While the IPMRP strongly supports the conclusion in the draft PA that the current standards are inadequate, uncertainties remain, as discussed and taken into account in our consensus statements for both the evidence-based and risk-based approaches (SCG-3.3 and SCG-3.4, respectively). The IPMRP concludes that these uncertainties do not in any way overcome the strong weight of scientific evidence in support of lowering the levels of the annual and 24-hour standards.

### **Arguments for keeping the current standard are not justified**

The draft PA suggests a potential alternative argument for retaining the current standard, along with arguments that could be used to support alternative, more stringent standards. The Panel finds that the draft PA's alternative argument in favor of retaining the current standard is a scientifically unjustifiable interpretation of the evidence that over-emphasizes and inappropriately inflates the significance of uncertainties in biological pathways, inappropriately discounts the potential for public health improvements below the current NAAQS on the premise that accountability studies have not examined such levels yet, and inappropriately dismisses risk assessment as a tool. While the IPMRP acknowledges that there remain uncertainties in these realms, the Panel concludes that this is an extreme misinterpretation which runs counter to all reasonable scientific views of the available evidence. The IPMRP concludes that these arguments are not scientifically sound as outlined below.

To dispute the conclusion that the current PM<sub>2.5</sub> standards are not sufficiently protective, it would be necessary to discard the scientific findings from epidemiologic studies. A voluminous body of epidemiologic evidence, accumulated over more than three decades, has consistently shown adverse PM<sub>2.5</sub> health effects over a range of levels and averaging times. This includes hundreds of studies that quantitatively show an adverse effect of PM<sub>2.5</sub> exposure for mortality and multiple other health endpoints, have examined diverse populations and at-risk groups, have considered multiple exposure scenarios including natural experiments and accountability studies, have applied diverse designs, and have employed varied advanced analytic methods. Recent studies that are scientifically valid and policy relevant in this review provide new compelling evidence of effects at concentrations at and below the current primary PM<sub>2.5</sub> standards based on very large cohorts. It also would be necessary to inappropriately ignore conclusions drawn by EPA and CASAC multiple times since 1997 when an air quality standard for PM<sub>2.5</sub> was added. EPA concluded that there were serious health effects associated with PM<sub>2.5</sub> concentrations in areas that met the then (and now still) current PM<sub>10</sub> standard. Most recently in 2012, EPA again concluded the existing PM<sub>2.5</sub> standard was inadequate and thus strengthened the annual standard. The primary scientific evidence for these actions was

epidemiologic studies, supported by evidence from animal and controlled human studies. The current review is bolstered by ground-breaking new epidemiologic studies, based on far larger study populations, as a result of the emergence of new generation of models that quantify spatial variability in exposure concentrations and include populations that are not served by the existing monitoring network. These new studies reaffirm and substantially augment and strengthen the scientific evidence compared to the prior review. These new studies include multiple large U.S. cohort studies that show adverse effects of PM<sub>2.5</sub> on mortality. Several national policy-relevant cohort studies from Canada show mortality associations with long-term average exposures well below the current U.S. PM<sub>2.5</sub> standard. The IPMRP concludes that it is inappropriate to discard this voluminous and consistent body of epidemiologic evidence.

To dispute the conclusion that the current PM<sub>2.5</sub> standards are not sufficiently protective, it also would be necessary to discard the experimental evidence of the biological pathways and mechanisms of action for PM<sub>2.5</sub> health effects. Experimental evidence continues to accumulate that cardiovascular effects from exposure to PM<sub>2.5</sub> include endothelial dysfunction, arterial thrombosis, and arrhythmia. The strongest evidence is for endothelial dysfunction. Respiratory effects are supported by animal toxicological studies that suggest altered host defense, greater susceptibility to bacterial infection, and consistent evidence of respiratory irritant and inflammatory effects. For cancer, mechanisms include DNA damage, micronuclei formation, chromosomal abnormalities, differential expression of genes relevant to cancer pathogenesis and genomic instability. The IPMRP concludes that the growing body of animal and human controlled study scientific evidence since the last review augments and strengthens findings since the last review. Although uncertainties remain, the uncertainties do not outweigh robust inferences regarding biological pathways leading to PM<sub>2.5</sub> health effects based on the overall body of evidence.

To dispute the conclusion that the current PM<sub>2.5</sub> standards are not sufficiently protective, it also would be necessary to conclude that further decreases in PM<sub>2.5</sub> concentrations will not lead to beneficial public health impacts. It is a logical fallacy to claim that absence of evidence is evidence of absence. This fallacy underlies the proffered flawed rationale that because accountability studies have yet to be conducted at levels at or below the current standards, this is sufficient to call into question that there are benefits from reducing the current level of the standard. At levels somewhat higher than and overlapping with the current standard, existing accountability studies provide supporting evidence that there are increases in life expectancy and improvements in respiratory function in children associated with reductions in ambient PM<sub>2.5</sub>. The accountability studies listed in Table 3-3 of the draft PA are useful in supporting causality determinations of adverse effects of PM<sub>2.5</sub> at annual levels close to, and overlapping with, the current standard. Thus, they provide important insights related to risk reduction, even though they are not at low enough levels to serve as a basis for recommending alternative levels. While accountability studies have not yet been conducted in the range of the current or proposed alternative standards, the existing evidence that there is not a discernible threshold in PM<sub>2.5</sub> health effects supports a reasoned scientific judgment that there are public health benefits to lowering the current standard (as, of course, also shown in the numerous epidemiological studies showing health effects in areas with air quality distributions less than those allowed by the current annual and 24-hour standards). Such a judgment does not require that there must be policy-relevant accountability studies, even though they would be informative if they existed. Therefore, the IPMRP concludes that it is inappropriate to give weight to the lack of existing accountability studies below the current standard as a meaningful source of uncertainty in calling into question the current primary PM<sub>2.5</sub> standards.

To dispute the conclusion that the current PM<sub>2.5</sub> standards are not sufficiently protective, an implied flawed rationale is proffered on page 3-98 (lines 1-4) that uncertainties in the risk

assessment are so large as to render the risk assessment uninformative. As noted earlier, the Panel gives more weight to the evidence-based approach than to the risk-based approach in arriving at a finding that the current standards are not adequate to protect public health. The risk assessment provides support but is not necessary or essential to our finding. Nonetheless, taking uncertainties related to the risk assessment into due consideration, it is our expert scientific judgment that the risk assessment provides supporting information, as have risk assessments in past reviews. A claim that the risk assessment is not informative is only possible if one completely discards the epidemiologic evidence as irrelevant to estimating population risk, and/or disputes most of the methods used and assumptions made in the risk assessment. While the IPMRP believes that the risk assessment can be improved and has provided multiple suggestions in this regard, the Panel finds that the risk assessment approach is sound and the results are qualitatively informative for consideration of the adequacy of the current standard as a supplement to the findings based on the evidence-based approach. The Panel affirms that it is appropriate to base the risk assessment on the recent epidemiologic studies because these studies inform our understanding of population risk in the exposure range relevant to the current standards. The Panel also does not consider that the limitations of the risk assessment invalidate the qualitative conclusions that can be reached from its results, namely that the estimated magnitude of premature deaths attributed to PM-related mortality at the levels of the current primary PM<sub>2.5</sub> standards is unacceptably high. The IPMRP concludes that it is inappropriate to over-emphasize and inflate the significance of uncertainty in the risk assessment to the point of calling into question the key insights afforded by the assessment. However, the IPMRP also notes that, while the risk assessment is informative and supportive in providing the basis for qualitative insights regarding the magnitude of risk, more weight is given to the evidence-based approach in drawing conclusions.

Overall, the IPMRP concludes that in order to accept the current standards as adequate, multiple implausible and scientifically unjustifiable assumptions and conclusions are necessary. Applying Occam's razor – i.e., the more assumptions that are required, the more implausible the explanation – the IPMRP concludes that the arguments in favor of retaining the current standard are specious. The revised PA should acknowledge the implausibility of these assumptions or consider dropping them altogether.

**SCQ-3.6 What are the Panel's views on the conclusions in the draft PA regarding developing potential  $PM_{2.5}$  alternative standards with respect to:**

- a) The preliminary conclusion that the available information continues to support the  $PM_{2.5}$  mass-based indicator, remains too limited to support a distinct standard for any specific  $PM_{2.5}$  component or group of components, and remains too limited to support a distinct standard for the ultrafine fraction?**
- b) The preliminary conclusion to retain the annual and 24-hour averaging times?**
- c) The preliminary conclusion that it is appropriate to consider retaining the forms of the current annual and 24-hour  $PM_{2.5}$  standards, in conjunction with revised levels?**
- d) The preliminary conclusion that the range for alternative levels for the annual  $PM_{2.5}$  standard should begin below  $12 \mu\text{g}/\text{m}^3$  and extend as low as  $8 \mu\text{g}/\text{m}^3$ ?**
- e) The possible rationales for alternative annual  $PM_{2.5}$  levels of 12, 10, and  $8 \mu\text{g}/\text{m}^3$ ?**
- f) The preliminary conclusion that, in conjunction with a lower annual standard intended to protect against both short- and long-term exposures, the evidence does not support the need for a revised level for the  $PM_{2.5}$  24-hour standard?**
- g) The discussion of an alternative approach to lower the level of the 24 hour standard to  $30 \mu\text{g}/\text{m}^3$  to provide increased protection for both short- and long term exposures?**

The draft PA provides appropriate scientific rationales for retaining the current indicator, averaging time, and form for the primary  $PM_{2.5}$  standards. Based on the scientific evidence, as summarized in more detail in responses to SCG-3.3, SCG-3.4, and SCG-3.5, the Panel finds that annual levels above  $10 \mu\text{g}/\text{m}^3$  are not protective of public health. The draft PA provides an appropriate scientific rationale for annual levels between  $10 \mu\text{g}/\text{m}^3$  to  $8 \mu\text{g}/\text{m}^3$ . The Panel's scientific opinion regarding  $PM_{2.5}$  alternative standards is that an annual standard of 10 to  $8 \mu\text{g}/\text{m}^3$  and a 24-hour standard of  $30 \mu\text{g}/\text{m}^3$  to  $25 \mu\text{g}/\text{m}^3$  taken together as a suite of standards is appropriate, with the lower end of these ranges providing more protection against risk of premature mortality and other adverse effects due to exposure to  $PM_{2.5}$ .

**What are the Panel's views on the conclusions in the draft PA regarding developing potential  $PM_{2.5}$  alternative standards with respect to:**

- a) The preliminary conclusion that the available information continues to support the  $PM_{2.5}$  mass-based indicator, remains too limited to support a distinct standard for any specific  $PM_{2.5}$  component or group of components, and remains too limited to support a distinct standard for the ultrafine fraction?**

There is little new information since the last review to support consideration of changes to the indicator, form, or averaging times for the annual and daily NAAQS. Although there is not sufficient scientific evidence or analysis in the draft PA upon which to make a recommendation in this review cycle, a rolling 24-hour form would better reflect daily exposures than the current midnight to midnight 24-hour calendar day period, since some sources have a strong diel pattern, peaking overnight where a single ambient concentration high night is broken into two separate days under the current standard. This would require that nearly all monitoring sites



have valid continuous FEM PM<sub>2.5</sub> data, which is not currently the case; about 60% of the approximately ~900 PM<sub>2.5</sub> monitoring sites have valid FEM data. Thus, there is a need to improve the coverage of FEM monitors that measure continuous hourly ambient concentrations. It would be appropriate for UFP to be considered in the next review cycle as an additional indicator, contingent upon accumulation of additional quantitative evidence regarding exposure-response relationships, since it is described as “likely to be causal” for long-term nervous system effects. This would require development of an FRM for UFP and implementation of a UFP monitoring network which could be based upon the existing near-road network including pairing with existing nearby neighborhood or urban scale sites.

***b) The preliminary conclusion to retain the annual and 24-hour averaging times?***

The annual and 24-hour averaging times are appropriate and are supported by scientific studies of adverse health effects at these averaging times. The Panel concurs with the draft PA, page 3-101, lines 14-16, that “Epidemiologic studies continue to provide strong support for health effects associated with both long- and short-term PM<sub>2.5</sub> exposures based on annual (or multiyear) and 24-hour PM<sub>2.5</sub> average periods, respectively.”

There is limited evidence that suggests sub-daily PM exposures are important, but it is not sufficient to support a sub-daily averaging interval at this time. A sub-daily averaging time would require development of a reference and/or equivalent method for measurement of PM<sub>2.5</sub> unless the value of the 24-hour standard were reduced to protect against 4-hour to 12-hour exposures of concern. A rolling 24-hour form could provide additional protection against sub-daily exposures depending on the selected level. A 24-hour rolling average is typically more health protective than a 24-hour calendar average for a given level.

***c) The preliminary conclusion that it is appropriate to consider retaining the forms of the current annual and 24-hour PM<sub>2.5</sub> standards, in conjunction with revised levels?***

The forms of the current annual (3-year average) and 24-hour (98<sup>th</sup> percentile) primary PM<sub>2.5</sub> standards are appropriate in conjunction with revised levels. The Panel supports the rationale given in the draft PA for retaining these forms. Epidemiologic studies continue to provide strong scientific support for health effect associations with both long-term (annual, multiyear) and short-term (mostly 24-hour) PM<sub>2.5</sub> exposures. The form of the annual standard is appropriate for targeting protection against annual PM<sub>2.5</sub> exposures and offers protection in many areas of the country against 24-hour PM<sub>2.5</sub> exposures. Epidemiologic studies, with support from controlled human studies, provide scientific evidence of associated adverse effects at the 24-hour averaging time. The Panel concurs with the draft PA that “nothing in the evidence that has become available since the last review calls into question” the forms of the current standards. These forms are appropriate in conjunction with revised levels.

***d) The preliminary conclusion that the range for alternative levels for the annual PM<sub>2.5</sub> standard should begin below 12 µg/m<sup>3</sup> and extend as low as 8 µg/m<sup>3</sup>?***

The initial consideration in the draft PA of a range for an alternative annual primary PM<sub>2.5</sub> standard of 11 µg/m<sup>3</sup> to 8 µg/m<sup>3</sup> is a reasonable starting point given the robust new evidence of premature mortality down to at least 8 µg/m<sup>3</sup>, as covered in the draft ISA and this draft document (Pinault et al., 2016; Weichenthal et al., 2016a; Weichenthal et al., 2016b). However, as explained below, the scientific evidence supports 10 µg/m<sup>3</sup>, not 11 µg/m<sup>3</sup>, as the upper bound of the Panel’s recommended range. In determining the range of levels to be considered for a revised annual standard, the Panel concurred with the draft PA that it is appropriate to

consider the means of key epidemiologic studies, which is consistent with past practice in previous reviews. The Panel notes, however, that some studies have been re-analyzed based on truncated data (e.g., for ambient concentrations not exceeding the current standard) for which robust findings of adverse effect have been identified (Di et al., 2017a; Shi et al., 2016). Analyses based on “partial means” of truncated air quality distributions provide additional scientific support of adverse effects at levels below the current annual standard. The Panel also considered the scientific evidence from epidemiologic studies at ambient levels below the mean ambient level of the studies. For example, at the 25th percentile, or the 10th percentile, although the uncertainties are greater, there is variability in adverse effect with respect to variability in ambient concentration. Collectively, considering all of these factors, the Panel unanimously finds a scientific basis for  $8 \mu\text{g}/\text{m}^3$  as being the lower bound of annual ranges for which there is strong weight of scientific evidence of adverse effects. Although there is some evidence of adverse effects at levels below  $8 \mu\text{g}/\text{m}^3$ , the uncertainties at such lower levels become larger. The lower bound of  $8 \mu\text{g}/\text{m}^3$  for the annual primary  $\text{PM}_{2.5}$  standard is supported by U.S. based studies with additional support from Canadian studies. Multiple studies indicate that there may be risk below  $8 \mu\text{g}/\text{m}^3$ .

The Panel considered limitations of studies in arriving at these levels. Confounding by individual characteristics must be considered as an alternative explanation for observed associations in epidemiologic studies. In the key epidemiologic cohort studies, the estimated associations with  $\text{PM}_{2.5}$  are adjusted for individual life-style characteristics such as smoking, as in the Canadian (Pinault et al., 2016) and U.S. studies (Pope et al., 2015; Jerrett et al., 2016; Thurston et al., 2016; Turner et al., 2016). In national cohort studies where individual life-style characteristics are not available, indirect adjustment can be used drawing on other life-style surveys, such as in the CanCHEC study (Weichenthal et al., 2016a). In the U.S. Medicare cohort study (Di et al., 2017a) individual life-style characteristics were not available for the entire population. However, in a subset of the Medicare cohort, Di et al. showed that individual smoking and income levels were not associated with  $\text{PM}_{2.5}$  exposures, a necessary condition for confounding. The Panel found that mortality associations with long-term  $\text{PM}_{2.5}$  exposures were consistent after direct and indirect adjustment for individual life-style factors in all of these key U.S. and Canadian studies. Although not every study is able to control as well as possible for socioeconomic status at both the individual and neighborhood level, in those for which the data are available, the findings are robust to that adjustment. In studies of long-term exposure to particulate matter, there is neither rationale nor empirical support for concern over confounding by temperature. Consistency of results based on multiple studies that employ multipollutant models, among which there are differences in underlying factors such as the relative ambient mixtures of co-pollutants, population demographics, climatic zones, and distributions of housing characteristics, support the robustness of their results. Therefore, the expert scientific judgment of the Panel is that the available scientific evidence robustly supports the recommended range of levels.

**e) *The possible rationales for alternative annual  $\text{PM}_{2.5}$  levels of 12, 10, and  $8 \mu\text{g}/\text{m}^3$ ?***

The Panel finds that  $10 \mu\text{g}/\text{m}^3$  is the upper bound of the recommended range for the annual primary  $\text{PM}_{2.5}$  standard based on the scientific evidence. At this level, there is a very high degree of scientific confidence in the relationship between exposure to fine particles and adverse effects, based on consistent epidemiological findings from multiple multi-city studies, augmented with findings from single-city studies, at policy-relevant ambient concentrations at or below the levels of the current standards and that are supported by research from experimental models in animals and humans. The overall body of evidence supports the causal determinations for adverse health effects of fine particulate matter as set forth in the draft Integrated Science Assessment. The Panel considered whether  $11 \mu\text{g}/\text{m}^3$  should be an upper

bound of its scientifically-recommended range. For example, a key study by Shi et al. (2016) has a pseudo-design value near  $11 \mu\text{g}/\text{m}^3$ . However, as noted elsewhere in the draft PA, the PDVs are up to 10% higher than an actual design value. The far more compelling scientific rationale for rejecting  $11 \mu\text{g}/\text{m}^3$  as an upper bound is the strong epidemiologic evidence of premature mortality at this annual concentration. An annual concentration of  $11 \mu\text{g}/\text{m}^3$  would not be protective of public health.

Thus, the Panel finds, based on the scientific evidence, that the annual standard should be revised within a range of annual average concentrations of  $10 \mu\text{g}/\text{m}^3$  to  $8 \mu\text{g}/\text{m}^3$ , while retaining the indicator, averaging time, and form of the current annual standard. The choice of level within this range is a policy judgment at the discretion of the Administrator. A choice toward the lower end of the range would provide additional health protection compared to a choice at the higher end of the range. Based on currently available evidence and inferences, 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.

The draft Policy Assessment uses two approaches to assess the protection provided by alternative annual  $\text{PM}_{2.5}$  levels: the risk-based approach using 47 urban areas with downscaler rollback of ambient  $\text{PM}_{2.5}$  concentration to just meet alternative levels in each area for which health outcomes are predicted using BenMap, and the evidence-based (epidemiological study) approach where the risk of premature mortality is expressed as a hazard ratio for a  $10 \mu\text{g}/\text{m}^3$  increase in concentration. The Panel prefers the evidence-based approach for the reasons described under part (d). The evidence-based approach also demonstrates that certain sub-populations have different risk; in this case the Di et al. (2017a) chronic Medicare study shows that the relative risk for African Americans is three times higher than that of the entire population, with a hazard ratio of 1.21 per  $10 \mu\text{g}/\text{m}^3$  increase in  $\text{PM}_{2.5}$ . If the primary  $\text{PM}_{2.5}$  standards are intended to provide protection to sensitive sub-groups and not just the population as a whole, this is important information that is not taken into account in the risk-based approach and is, therefore, not adequately taken into account in the draft Policy Assessment.

Taking the strengths and limitations of the risk assessment into account, including its uncertainties, the risk assessment is useful and scientifically robust in illustrating that reductions in the level of the annual standard will lead to proportional reductions in premature mortality. At the level of the current standard, the estimated magnitude of premature deaths for the populations that were included in the selected study areas is unacceptably high, as detailed in responses to SCG-3.4 and SCG-3.5. The risk is linear with no threshold below the current standard down to an annual level of  $8 \mu\text{g}/\text{m}^3$  or lower. The Thurston et al. (2016) (not 2015 as in some of the tables) AARP cohort shows lower mortality rates; this may be in part due to the AARP cohort having higher than average socio-economic status than the population as a whole, and being somewhat younger (starting at age 55, not 65) than the Medicare cohort. The risk assessment is useful for providing qualitative support to our finding that the current standard is not adequate, with the evidence-based approach being the more compelling source of scientific evidence.

The draft PA does not give sufficient emphasis in its discussion of the risk analysis with regard to study results and corresponding risk estimates below  $8$  to  $9 \mu\text{g}/\text{m}^3$  annual average concentration, even though results at such levels are shown in Figure 3-12. The draft PA claims that there is insufficient information from studies at those low concentrations. However, Figure 3-8 of the draft PA shows that the annual level of  $\text{PM}_{2.5}$  for 25% of the Di et al. (2017) chronic mortality Medicare study population was below  $7 \mu\text{g}/\text{m}^3$ . This represents 115 million person-years of follow-up, a very large sample size that results in relatively robust mortality estimates

even at levels below  $7 \mu\text{g}/\text{m}^3$  (Di et al., 2017a, Figure 3a). Thus, there is a very large population with current annual PM exposures less than  $8 \mu\text{g}/\text{m}^3$  for which effects have been found. While the effect is lower at these lower concentrations, there is a suggestion of a supralinearity of the CR curve below  $7 \mu\text{g}/\text{m}^3$  (higher risk per unit PM exposure increase), and the overall mortality is large in this group because of its size. These issues are not clearly or adequately addressed in the draft PA. Although the Panel gave consideration to whether the lower end of the recommended range for the revised annual primary  $\text{PM}_{2.5}$  standard might be at  $7 \mu\text{g}/\text{m}^3$ , the Panel finds that there is not sufficient scientific certainty at this low of a level to support such a recommendation.

**f) *The preliminary conclusion that, in conjunction with a lower annual standard intended to protect against both short- and long-term exposures, the evidence does not support the need for a revised level for the  $\text{PM}_{2.5}$  24-hour standard?***

The Panel finds that the current  $\text{PM}_{2.5}$  24-hour standard is not adequate to protect public health, as explained above. The Panel concurs with the scientific rationale in the draft policy assessment for retaining the indicator, averaging time, and form of the current standard. Based on the scientific evidence, the Panel recommends that the level of the  $\text{PM}_{2.5}$  24-hour standard be revised to a range between  $30 \mu\text{g}/\text{m}^3$  to  $25 \mu\text{g}/\text{m}^3$ . In this regard, our scientific advice differs from that of the draft PA, with supporting details both above and below. In particular, the Panel notes that the 24-hour standard is controlling in some locations and, thus, in such locations provides health protection not adequately afforded by the annual standard alone.

When paired with an annual standard of  $10 \mu\text{g}/\text{m}^3$  or lower, the current  $\text{PM}_{2.5}$  24-hour standard of  $35 \mu\text{g}/\text{m}^3$  is not sufficient to provide adequate protection against short-term exposures in situations such as smoke from residential wood combustion in valleys, where  $\text{PM}_{2.5}$  is only elevated for part of the year. Exposures to smoke from residential wood combustion in several parts of the country may occur for 6 to 12 hours, typically overnight; high night-time  $\text{PM}_{2.5}$  concentrations are broken into separate days when calendar day (midnight to midnight) 24-hour averaging intervals are used.

The Panel notes that even at lower levels within its recommended range for the annual primary  $\text{PM}_{2.5}$  standard, the available scientific evidence indicates that the annual standard does not adequately protect against short-term exposures, including sub-daily exposures, in some parts of the U.S. These include locations with overnight exposures to smoke from residential wood combustion, as noted above. Furthermore, there are scientifically anticipated effects related to common exposure scenarios, such as short-term peaks in near-road exposures, especially during peak travel times, to particles across a range of sizes and chemical composition.

The Panel finds that the use of calendar-day 24-hour averages for the short-term standard may not be protective of public health, unless the level is set low enough to prevent potentially harmful peak exposures. Over time, a larger number of real-time FEM monitors have been placed in service that are capable of providing hourly-averaged  $\text{PM}_{2.5}$  concentration readings. Thus, the monitoring network has transformed such that it has the technical capability to support a 24-hour rolling average, calculated each hour. At a given level, a rolling average is typically more health protective than a calendar-day average. The Panel recommends that EPA conduct a comparative analysis of an hourly 24-hour rolling average versus the current 24-hour calendar-day average to assess the potential health protective benefits of a change in form. Without a supporting analysis, the Panel was unable to offer a recommendation for the rolling average form. Furthermore, the Panel recommends that data be collected and analyzed to

support consideration of sub-daily averaging times, with rolling average forms, in the next PM NAAQS review.

***g) The discussion of an alternative approach to lower the level of the 24 hour standard to 30 µg/m<sup>3</sup> to provide increased protection for both short- and long term exposures?***

For 24-hour exposures, there are numerous studies that find adverse effects at levels well below the current standard, within a range of 30 µg/m<sup>3</sup> to 25 µg/m<sup>3</sup> (Shi et al., 2016; Di et al., 2017b; Weichenthal et al., 2016a; Weichenthal et al., 2016b). The choice of the 47 urban areas does not include some areas of the country for which a 24-hour standard, rather than an annual standard, would be controlling. The draft Policy Assessment provides scientific support for a level of 30 µg/m<sup>3</sup> as an alternative to the current level of 35 µg/m<sup>3</sup> for the 24-hour primary PM<sub>2.5</sub> standard. Even with an annual level in the range of 10 µg/m<sup>3</sup> to 8 µg/m<sup>3</sup>, a 24-hour standard at 30 µg/m<sup>3</sup> may not be protective of acute health effects that could occur with sub-daily exposures, based on scientific evidence from controlled human studies. Furthermore, based on numerous epidemiologic studies for 24-hour average exposures, there is a continuum of adverse effects down to well below 25 µg/m<sup>3</sup>. Thus, 25 µg/m<sup>3</sup> is a 24-hour average level that is scientifically justifiable for consideration in setting a revised standard. However, there is no threshold for 24-hour daily average exposures; while a 24-hour level at 25 µg/m<sup>3</sup> would offer more protection than a 30 µg/m<sup>3</sup> level, it does not reduce risk to zero.

The choice of levels for the 24-hour standard is largely and predominately informed by multiple consistent epidemiologic studies of acute health effects based on daily metrics for exposure and health outcomes. However, the Panel notes that controlled human studies with high sub-daily exposures (2 hours at 24 to 300 µg/m<sup>3</sup> PM<sub>2.5</sub>) which exhibit subclinical effects are equivalent to 24-hour exposure concentrations that are policy relevant (Hemmingsen et al., 2015; Devlin et al., 2003; Gong et al., 2004; Tong et al., 2005). As such, these studies add support, but are not the primary factor informing, our expert scientific judgment that the current 24-hour average standard is not adequate to protect public health. PDVs should be calculated for the controlled human studies.

A secondary factor in identifying a range of alternative levels for the 24-hour standard is the argument that the annual standard is controlling and that the 24-hour standard is a backstop against acute adverse effects not otherwise controlled by the annual standard. In past reviews and in this review, there is an underlying notion that there is a typical mean ratio between annual and 24-hour levels. Thus, if the annual level is revised downward, the 24-hour level should be revised downward proportionally. A linearly proportional reduction in the 24-hour level implied by reducing the annual level, from 12 µg/m<sup>3</sup> to a range of 10 µg/m<sup>3</sup> to 8 µg/m<sup>3</sup>, would imply a range of 24-hour levels of 29 µg/m<sup>3</sup> to 23 µg/m<sup>3</sup>. However, the Panel views this as a secondary factor in the choice of levels, with more attention given to the scientific health-based rationale for choice of levels given above.

The Panel also considered a sub-daily averaging time, such as a 2 to 8 hour rolling average, calculated hourly. Such a standard would more directly protect against peak exposures such as near roadway or from residential wood combustion or so-called wildfires that are largely anthropogenic. A sub-daily standard could be based on the maximum daily X-hour average, where X is the selected averaging time, analogous to the current primary ozone standard. However, this is more appropriately a topic that should be seriously considered in the next review cycle, rather than this review cycle, given the lack of sufficient evidentiary support at this time upon which to make a recommendation.

**EPA-4. Chapter 4 – Review of the Primary PM<sub>10</sub> Standard: What are the CASAC views on the approach described in Chapter 4 to considering the PM<sub>10-2.5</sub> health effects evidence in order to inform preliminary conclusions on the primary PM<sub>10</sub> standard? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current primary PM<sub>10</sub> standard?**

**SCQ-4.1 To what extent does the Panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM<sub>10</sub> NAAQS review? Are there additional policy-relevant questions that should be addressed?**

**SCQ-4.2 What are the Panel’s views of the draft PA assessment of the currently available scientific evidence regarding the health effects associated with exposures to thoracic coarse particles, PM<sub>10-2.5</sub>?**

**SCQ-4.3 What are the Panel’s views on the draft PA preliminary conclusion that the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM<sub>10</sub> standard and that evidence supports consideration of retaining the current standard?**

Although new evidence is available since the last review for a broader range of health outcomes associated with short- and long-term exposures to thoracic coarse particulate matter (PM<sub>10-2.5</sub>), this evidence is subject to considerable uncertainty. The causality determinations in the draft ISA for PM<sub>10-2.5</sub> are no higher than “suggestive of, but not sufficient to infer, a causal relationship” for short-term respiratory, short-term cardiovascular, and short-term mortality effects, and “inadequate” to infer a causal relationship for other considered endpoints.

The draft PA appropriately discusses the strengths and limitations of the available scientific evidence regarding PM<sub>10-2.5</sub>. Multicity studies in Europe and Asia provide evidence of consistent associations between short-term exposure to PM<sub>10-2.5</sub> and premature mortality. However, more policy-relevant research is needed to better quantify the adverse effects of PM<sub>10-2.5</sub>. PM<sub>10-2.5</sub> can penetrate to the airways past the vocal cords, which should be acknowledged and discussed in the draft PA, and can help explain why there is some evidence attributing asthma exacerbation to PM<sub>10-2.5</sub> exposure.

The Panel concurs with the draft PA that PM<sub>10</sub> is an appropriate choice at this time for the indicator for PM<sub>10-2.5</sub>. However, PM<sub>10</sub> is an imperfect indicator of PM<sub>10-2.5</sub>. The Panel recommends movement away from PM<sub>10</sub> and toward PM<sub>10-2.5</sub> as the indicator. The use of PM<sub>10</sub> as an indicator for PM<sub>10-2.5</sub> dates to a time when there was not yet a reliable monitoring method specific to PM<sub>10-2.5</sub>. Nationwide, PM<sub>10-2.5</sub> sites are <20% of the ~1564 PM<sub>2.5</sub> sites, insufficient to capture the needed temporal and spatial variations.

EPA’s lack of adequate support for PM<sub>10-2.5</sub> measurements (e.g., network design, ambient monitoring, and chemical speciation) hinders the assessment of the PM<sub>10-2.5</sub> relationships to health effects. Such measurements are essential to reduce uncertainties in causality determination (e.g., approaches to estimating PM<sub>10-2.5</sub>; measurement errors and lack of biological plausibility).

Since 2000, 24-hour PM<sub>10</sub> concentrations have decreased by ~30% with the majority of PM<sub>10</sub> sites measuring below 75 µg/m<sup>3</sup>. The 3-year average of annual 98<sup>th</sup> percentiles of 24-hour PM<sub>10-2.5</sub> concentrations for 2015-2017 are mostly less than 30 µg/m<sup>3</sup>, in line with the observed nationwide PM<sub>2.5</sub> to PM<sub>10</sub> ratios of 0.5-0.6.

The Panel concurs with the assessment in the draft PA that “the available evidence supports maintaining a PM<sub>10</sub> standard to provide some measure of protection against PM<sub>10-2.5</sub> exposures” (p 4-15, lines 9-10). The Panel concurs with the draft PA that it is scientifically reasonable to retain, without revision, at least the *level of protection* afforded by the current PM<sub>10</sub> standard. However, as noted below, this is not the same as retaining the current *level* of the standard.

The draft PA does not mention CASAC’s advice regarding the PM<sub>10</sub> standard in its 2010 ‘closure’ letter on the second external review draft of the Policy Assessment in the prior review (Samet, 2010b). At that time, EPA and CASAC considered a different form of the PM<sub>10</sub> standard based on the 98<sup>th</sup> percentile rather than the current one exceedance per year on average over three years. CASAC advised that “a 98th percentile level between 75 and 80 µg/m<sup>3</sup> is comparable in the degree of protection afforded to the current PM<sub>10</sub> standard.” CASAC further advised that “[w]hile recognizing scientific uncertainties, CASAC supports a lower level to provide enhanced protection, somewhere in the range of 75 – 65 µg/m<sup>3</sup>.” Thus, CASAC recommended consideration of a revised standard that would afford more health protection than the current standard. A second draft of the PA should acknowledge and discuss this prior advice. The Panel is supportive of consideration of ranges under the current form that have similar levels of protection as those recommended by CASAC in the last PM NAAQS review.

The draft PA does not address the impact of recommended reductions in the level of the 24-hour primary PM<sub>2.5</sub> standard with respect to the level of protection afforded by the primary PM<sub>10</sub> standard. Because PM<sub>2.5</sub> is a component of PM<sub>10</sub>, accounting for 50%-60% of PM<sub>10</sub> mass on a national average as noted above, a reduction in the level for the 24-hour primary standard for PM<sub>2.5</sub>, as recommended by this Panel, would lead to less protection from an unchanged primary PM<sub>10</sub> standard. This is because retaining the same primary PM<sub>10</sub> standard would allow proportionately more PM<sub>10-2.5</sub> mass as the primary PM<sub>2.5</sub> standard is revised downward. Thus, to retain the same public health protection, consideration should be given to revising the primary PM<sub>10</sub> standard downward.

***EPA-5. Chapter 5 – Review of the Secondary Standards: What are the CASAC views on the approach described in Chapter 5 to considering the evidence for PM-related welfare effects in order to inform preliminary conclusions on the secondary standards? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current secondary PM standards?***

The general approach employed in Chapter 5 begins by noting that relatively little new information is available on PM-related welfare effects on materials, climate and visibility. This disregards important new information on visibility preference indices (see response to SCQ-5.2(a) below). In developing a “rationale” for supporting conclusions on the current secondary standards, Chapter 5 begins with the 2012 Administrator’s observations that combining the most lenient end of the considered range with the most lenient end of the considered level of an alternative secondary NAAQS provided little added protection over the current NAAQS. It then presents these previous conclusions as if they represented the current state of the science. They do not, nor were they supported by CASAC advice provided during the 2012 review (see for example, Samet, 2010a&b).

**SCQ-5.1 To what extent does the Panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the secondary PM standards? Are there additional policy-relevant questions that should be addressed?**

Generally, the questions posed in Chapter 5 reflect many of the important policy-relevant issues for secondary standards. One additional important question that should be raised is whether a single level of PM light extinction (or PM<sub>2.5</sub> mass) is appropriate for protecting visibility in all urban and rural areas in all regions of the country. Questions should also be raised about whether a 24-hour averaging time or a 90th percentile form are appropriate for protecting visibility. Several of these elements of the alternative 2012 secondary NAAQS considered and rejected by the Administrator were not consistent with current science or with CASAC advice in the two previous (2006 and 2012) PM NAAQS reviews (see for example: Hopke, 2004; Henderson, 2006; Samet, 2010a&b).

**SCQ-5.2 What are the Panel's views of the draft PA evaluation of the currently available scientific evidence with respect to the welfare effects of PM. Does the assessment appropriately account for any new information related to factors that influence:**

**a) Quantification of visibility impairment associated with PM<sub>2.5</sub> and examination of methods for characterizing visibility and its value to the public?**

The concept that there is a single level of “acceptable” visibility is flawed. Visibility preferences are likely to vary regionally, from one urban area to another and from urban to rural areas, depending on the nature of the scenes and landscape features typically viewed in those areas. While people in a given area may rate a certain level of visibility as acceptable, this does not imply that they would not realize a welfare gain from further improvements in visibility (Boyle et al., 2016; Haider et al., 2019; Yao et al., 2019). The relatively small number of currently available visibility preference studies have shown that there are different levels of “acceptable” visibility levels in different study areas when visibility impairment was expressed in terms of fixed levels of light extinction.

An important recent meta-analysis of these available visibility preference studies conducted by William Malm and colleagues (Malm et al., 2011, 2019; Malm, 2013, 2016; Molenaar and Malm, 2012) addresses the limitations with the concept that there is any specific level of light extinction that is universally acceptable. This important work was entirely omitted from the draft ISA and from the draft PA. Malm's recent work evaluated a large number of visibility preference indicators and found that the apparent contrast of distant, prominent but not necessarily dominant, scene elements was a much better and more consistent predictor of “acceptable” visibility, than any specific level of light extinction. Across all the currently available visibility preference studies, as the apparent contrast of distant, prominent scene elements approached an apparent contrast level of about -0.04 (i.e. very little contrast), 50% of respondents found the visibility unacceptable. In simpler terms, as the visual range approaches the distance of distant scenic elements, people everywhere find the visibility unacceptable. It would be a relatively straightforward GIS exercise to characterize typical average and/or maximal viewing distances across different urban/suburban/rural areas and regions. The Agency should include such calculations, along with associated extinction levels in the second drafts of the ISA and PA.

In addition to this recent work on visibility preference, the draft PA and draft ISA also neglect a relatively large body of recent (and historical) research on the economic effects of scenic views



on property values. A review of this literature could provide an additional approach for evaluating improvements (or degradation) in visibility regardless of any fixed definition of “acceptability”. See for example Jeong et al., 2019; Mittal and Byahut, 2017; Nicholls and Crompton, 2018; Walls et al., 2015; and others.

Regarding the quantification of visibility impairment associated with PM<sub>2.5</sub>, the draft PA advocates 24-hour, filter-based, calculated light extinction as the preferred indicator of PM visibility effects. This is contrary to various CASAC recommendations during the 2012 NAAQS review (Samet, 2010a&b), which advised the Agency to consider:

- A. measuring PM light extinction directly and continuously to support an hourly or multi-hour daylight-only averaging time(s), or if the Agency still finds this unfeasible:
- B. using the relatively sparse PM speciation data to calculate seasonal (or monthly) regional species and f(RH) values to combine with the much denser continuous PM<sub>2.5</sub> monitoring network to calculate hourly PM light extinction, or
- C. simply use the hourly PM<sub>2.5</sub> as the basis for a sub-daily (hourly or multi-hour) daylight-only indicator, which would intentionally remove the variable influence of water from the regulatory metric.

In comments during the 2006 review, CASAC also concluded that the current 35 µg/m<sup>3</sup> daily standard was inadequate to protect visibility, and recommended a secondary NAAQS with a PM<sub>2.5</sub> mass indicator, 4 to 8-hour daylight averaging time, 20 to 30 µg/m<sup>3</sup> level, and 92nd to 98th percentile form (Hopke, 2004; Henderson, 2006). Note also that CASAC comments during the 2012 review reiterated that the current NAAQS was inadequate for protecting visibility, observing that “the levels of the current PM<sub>2.5</sub> and PM<sub>10</sub> standards are too high, and their averaging times are too long, to guard against levels of visual air quality considered adverse over the short (hour or less) time periods during which changes in visual air quality are perceptible.” CASAC further noted that a form as lenient as the 90th (to 98th) percentile only be considered if the averaging time was for the single worst hour of the day, recommending the 95th to 98th percentile range if combined with multi-hour, sub-daily daylight averaging time (Samet, 2010a). The combinations of indicator, averaging time, level and form recommended by CASAC in the past two NAAQS reviews are all considerably more protective than the current NAAQS and the “most lenient possible combination” of elements considered and rejected in the 2012 review, and repeated again in the current draft PA. A second draft of the PA should systematically address these issues while taking into account the implications of revisions to the 24-hour PM<sub>2.5</sub> standard recommended by the Panel, which may have co-benefits with respect to welfare effects.

***b) The effects of PM<sub>2.5</sub> components on climate?***

The effects of the mix of PM species on climate remain complex, multi-directional and uncertain. It is not clear if a secondary standard would be the best way to address this issue.

***c) The effects of fine and coarse particles on materials?***

Chapter 5 presents some interesting new work on adverse effects of PM deposition on the efficiency of solar panels, although this work may not yet lend itself to specific quantitative relationships with PM<sub>2.5</sub> and or PM<sub>10</sub> to support consideration of secondary standards.

**SCQ-5.3 What are the Panel's views of the draft PA preliminary conclusion that the currently available scientific evidence does not call into question the protection afforded by the current secondary PM standards against PM welfare effects and that it is appropriate to consider retaining the current secondary PM standards without revision?**

The Panel strongly disagrees with the draft PA preliminary conclusion that the currently available evidence supports retaining the current secondary standards without revision. As indicated above and with more detail in individual comments (see especially comments from Richard Poirot), the Panel finds that all elements -- indicator, averaging time, level and form -- have not been well-justified in the draft PA and are not consistent with current scientific evidence. Therefore, a second draft of the PA is needed that revisits these issues and provides sufficient supporting information for a reasonable range of alternatives to support formulation of advice by CASAC (if augmented with the appropriate expertise by reinstating the disbanded CASAC PM Review Panel) and the public, including the IPMRP.

**EPA-6. Chapters 3 to 5: What are the CASAC views regarding the areas for additional research identified in Chapters 3, 4 and 5? Are there additional areas that should be highlighted?**

The current review must be based upon existing information; however, there are several areas that could inform future reviews of the primary and secondary PM standards and help reduce some of the uncertainties associated with this process.

Future research needs include the following:

- Air quality monitoring and reporting for sub-daily and short-term levels of exposure for both near-roadway and more generic sites.
- Development of Federal Reference Methods for measurements of ultrafine particles and for black carbon.
- Development of an appropriate monitoring network for ultrafine particles and black carbon; the network should include near-roadway sites as well as other sites.
- To improve the scientific basis for the next review, EPA is urged to evaluate and expand the PM<sub>10-2.5</sub> network, along with speciation of PM<sub>10-2.5</sub> including multi-elements, major ions, carbon (including carbonate carbon), and bioaerosols.
- Characterize PM<sub>10-2.5</sub> in different health-relevant exposure environments (e.g., city center, suburban, roadside, agricultural, and rural areas) for mass, elements (including potential toxic species), carbonaceous materials (including selected organic compounds and carbonate), water-soluble ions, and bioaerosols (including endotoxins, 1,3 beta glucan, and total protein).
- More detailed monitoring for organic components of PM; there is also a need to develop less costly and more easily implemented ways of measuring the ambient levels of these components.
- Detailed examination of the distributions of short-term exposure levels over time.
- Research should continue to define in more detail the physiological bases for adverse health responses to PM and its components. Such research would help establish appropriate exposure averaging times for future consideration as well as indicate sub-clinical markers that could predict adverse health response. Particular attention needs to

be given to mechanisms that could explain relationships between PM exposures and neurological, metabolic, and autoimmune disease.

- Additional comparative toxicological studies designed to facilitate extrapolation from animal and cellular studies to humans.
- Alternative exposure metrics need to be explored in studies of health effects of PM. How important are peak exposures as opposed to average exposures in explaining observed health responses? This includes study of sub-daily exposure levels. What is the appropriate time average for peak exposures? Do current average measures adequately limit exposures to peak levels? The importance of relative changes in exposure in terms of risk reduction needs further research. How important are past exposures in explaining responses to current levels; indeed the correct question to ask is: what are the impacts of current exposures given past exposures? This is particularly important when health outcomes, such as cancer which develops over an extended period of time, and cross-sectional designs are considered. These designs compare exposures and health responses across geographic entities. Although there are changes in air quality over time, the relative ordering of air quality across geographic entities changes minimally. What is the latency of response? Tied to this is the issue of cumulative exposure, which should be examined.
- Better characterization of the performance of hybrid modeling approaches to estimate PM exposures over different averaging times, and evaluation of alternative modeling approaches.
- Additional health studies are needed of the effects of PM components on health. Greater attention needs to be given to organic components of PM and to trace metals. Additional focus on the impacts of near-road exposures are warranted. Studies are needed that further examine the role of PM from various sources on health responses.
- Appropriate epidemiological studies designed to look at the health impacts of ultrafine particle exposure are needed.
- Define efforts to better include the concept of pseudo-design values into epidemiological studies and controlled human studies.
- Greater consideration of the health impacts of the coarse fraction of PM, especially for asthmatic and respiratory responses.
- Research to quantify the acute and chronic health effects of particulate matter produced by combustion of biomass, including residential wood combustion and wildfire smoke.
- Studies regarding to what extent and how SOA from biogenic hydrocarbons are controllable (e.g., through effects of sulfate, nitrogen oxides on biogenic SOA formation).
- Health research tends to be focused on one pollutant at a time even when several pollutants are measured, but they are most often considered independently. Studies that facilitate the sorting out of response to the various components in a multi-pollutant study are needed. The potential impact of joint exposure to more than one pollutant is needed; this includes some examination of the importance of sequencing exposures to various pollutants. This research should also include further efforts to understand the impacts of differential exposure error.
- People spend more of their time in indoor environments. Indoor PM levels can be high in these environments. How important are these? If they are not as important, why?

What is the health impact of joint indoor and outdoor exposures? Are health responses to outdoor PM levels greater when indoor levels are high?

- The use of microenvironmental exposure modeling to account for infiltration of ambient particles to enclosed environments, and implications for explaining variability in concentration-response functions between cities should be explored.
- PM clearly impacts visibility, which can influence emotional well-being. Studies to examine this association are needed.
- Additional support is needed to enhance photo-based air quality visualization tools (for example to add additional urban areas and clouds to the WinHaze model). Support is also needed to conduct visibility preference studies, using consistent, best practices, over a wide range of urban and suburban areas throughout the country.
- The Panel notes that the recent emergence of newer causal methods for controlling for confounding may be appropriate for PM health effects modelling, and recommends future development of models designed to assess effect modification by PM co-pollutants and joint exposures to address this area of uncertainty.

### **Additional Consensus Statement: Draft Integrated Science Assessment**

In addition to responding to the charge questions on the draft Policy Assessment, the concerns of the Panel regarding the draft Integrated Science Assessment are summarized here.

In our December 10, 2018 letter to CASAC and the EPA docket for the draft Integrated Science Assessment (Frey et al., 2018), the Panel offered consensus advice on numerous issues related to the draft ISA. The failure of EPA to provide a second external review draft of the ISA compromises the credibility and integrity of the NAAQS review process. This is because there were many important scientific issues raised regarding the first external review draft that require revision and iteration prior to their application in risk and exposure assessment and prior to their interpretation in the policy assessment. Although the Panel found that the draft ISA was a comprehensive scientific document, the Panel identified numerous areas for which refinement or revision was needed as detailed in our December 10, 2018 letter to CASAC. These areas include low cost sensors, air quality, contrasts between PM<sub>2.5</sub> and UFP, coarse PM, PM components, onroad and near-road microenvironments, mixtures and copollutants, study selection, transparent application of the causal framework, more in-depth treatment of specific issues related to PM<sub>2.5</sub> and mortality, more explanation and possible reconsideration of the causal determination for short-term exposure to coarse PM and respiratory adverse effects, more explanation and possible reconsideration of the causal determination for long-term exposure to UFP and central nervous system effects, and reconsideration of the at-risk causal finding for populations with pre-existing cardiovascular or respiratory disease. Members of the IPMRP also provided extensive individual comments that were attached to the December 10, 2018 letter from the Panel.

In our March 27, 2019 letter to CASAC (Frey et al., 2019), the Panel noted that “the framework for causal determination, including terminology, and the overall plan for development of the ISA, was reviewed by CASAC in 2016.” The Panel noted that “the various considerations in developing causal determinations are explained in the Preamble to the ISAs and have been considered already in CASAC’s review of the Draft Integrated Review Plan.” The Panel further noted that “[w]hile there may be opportunities for EPA staff to improve the clarity and transparency of the explanations of the inferences it makes and the conclusions it draws, this is not a fundamental limitation of the underlying framework but rather a matter of routine scientific review and iteration to improve the clarity and transparency of the final document.”

Normally, in prior review cycles, there is a second external review draft of the ISA concurrent with a first review draft of the Risk and Exposure Assessment (REA). In this review cycle for PM, EPA has not produced a separate draft REA, but instead has subsumed the REA into the draft PA. Typically, in a normal review cycle, the draft PA would not be released until after EPA has finalized the ISA and completed a second draft of the REA. The typical sequence in a normal review cycle was intended to protect the science assessments from being commingled with the policy assessment, so that the scientific basis could be established irrespective of later policy interpretations. In the current review cycle, the fact that the ISA is not completed prior to external review of the draft PA provides EPA leadership with the opportunity to change the ISA to support pre-determined policy outcomes in the final PA. This is a completely unacceptable situation.

The draft PA has elected to retain the causality determination framework for health effects attributed to exposures of varying durations to particular indicators, and to retain the causality framework for at-risk populations. The Panel concurs.

The Panel expresses its concern regarding the footnote to Table 3-1, on page 3-18 of the draft Policy Assessment, to the effect that “we recognize that the final ISA will reflect the EPA’s consideration of CASAC advice and that, based on CASAC advice, some or all of these causality determinations could differ in the final ISA. The final PA will reflect these updates.” This footnote is inappropriate in a draft PA because the scientific issues should have been resolved prior to development of the draft PA. CASAC has already admitted, explicitly, that it is not qualified to offer these judgments, because it lacks the breadth, depth, and diversity of expertise for review of the PM NAAQS (see the April 11, 2019 letter from CASAC to the Administrator). Expert scientific judgment must be conditioned on appropriate domain knowledge (see Dr. H. Christopher Frey’s individual comments for more details) which is lacking in the CASAC.

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# Appendix C

**Individual Comments by  
Independent Particulate Matter Review Panel Members  
on the  
EPA’s Policy Assessment for the Review  
of the  
National Ambient Air Quality Standards  
for  
Particulate Matter  
(External Review Draft – September 2019)**

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## Dr. Peter Adams

### **EPA-2. Chapter 2 – PM Air Quality: To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for the review?**

SCQ-2.1 What are the Panel's views regarding whether the draft PA accurately reflects and communicates the air quality related information most relevant to its subsequent evidence-based assessment of the health and welfare effects studies, including uncertainties, as well as the development of the risk assessment for current and alternative standards? In particular, do the following sections accurately reflect and communicate current scientific understanding, including uncertainties, for: (a) relationships between annual and daily distributions of PM; (b) the review of hybrid modelling approaches used to estimate exposure in some studies and the risk assessment; and (c) information on background levels of various PM indicators?

Overall, I found that Chapter 2 was clearly presented, provided useful context for the review, and accurately summarized and communicated relevant knowledge of the atmospheric behavior of PM. In particular, I found that Figures 2-10 and 2-11 and associated discussion provided useful and relevant evidence about the relationship between annual and daily PM levels. Similarly, Section 2.3.3 provided a good overview of the strengths and weaknesses of hybrid modeling approaches for exposure assessment.

I note that information about ultrafine PM was very sparse in this report. I urge EPA to consider dedicating more resources to modeling, monitoring, and exposure assessment for ultrafine PM.

Regarding background levels of PM, this is a somewhat harder question. While useful information was presented, I noted a tendency to label some kinds of PM as natural and/or background when it might, in fact, be a mix of natural and anthropogenic. This includes wildfires and biogenic SOA. More detailed notes on this are below.

Page 2-3: Wildland fires are partly natural sources but partly anthropogenic as well, depending on the origin of the fire. This becomes relevant again in Section 2.4 on Background PM.

Page 2-3: Similarly, it is not straightforward to say whether biogenic SOA is natural or anthropogenic. The VOC precursor is natural (well, even this is debatable for any managed land). But there is a literature of work pointing out that biogenic SOA levels are higher due to human activity for at least two reasons: 1) ozone is enhanced by anthropogenic activities and is a key oxidant for many biogenic VOCs and 2) some SOA yield are NO<sub>x</sub>-dependent and most NO<sub>x</sub> is anthropogenic. Hence, separating natural from anthropogenic biogenic SOA is non-trivial. This becomes relevant again in Section 2.4 on Background PM.

Section 2.4.3: The text describes the measured organic matter at IMPROVE sites in the Southeast as an "upper bound" of natural biogenic aerosol, and it is indeed an upper bound. The fact that these IMPROVE sites have all

demonstrated significant decreases in organic matter concentrations strongly suggests that much of the organic matter is controllable. It strikes me as highly unlikely that additional emissions controls would not result in further decreases even in biogenic SOA for the reasons described above.

Otherwise, I present some more minor notes of statements that could be revised or clarified but do not substantially hinder the overall success of the document.

Page 2-9: “Anthropogenic SO<sub>2</sub> and NO<sub>x</sub> are the predominant precursor gases in the formation of secondary PM<sub>2.5</sub>, and ammonia also plays an important role in the formation of nitrate PM by neutralizing sulfuric acid and nitric acid.”

I think it is wrong, or at least an over-simplification, to call SO<sub>2</sub> and NO<sub>x</sub> “predominant” and relegate ammonia and VOCs to supporting roles. In many US locations, there is more organics (mostly SOA) in PM<sub>2.5</sub> than sulfate. Hence, VOCs are important. Sulfate has declined in importance over the past 10-15 years – and in some locations has not been important for a while. NO<sub>x</sub>/nitrate are very important in some locations, really not important in others. The current text acknowledges an “important role” for ammonia, but by many measures, PM<sub>2.5</sub> concentrations are more sensitive to ammonia than NO<sub>x</sub> emissions.

Page 2-18: Section 2.2.5 mentions particle count measurements but does not elaborate to the same degree as the section does for other measurements (aetholometer, EC/OC).

Pages 2-21 and 2-22: The text gives a somewhat too simple view of PM<sub>2.5</sub> concentrations (highest in west, lower in east). Except for a few locations in the west (CA’s central valley, LA, and others), the west is cleaner than the east. There are more people breathing air just below the annual-average NAAQS (i.e. in the 10-12 µg/m<sup>3</sup> range) in the east than in the west.

Page 2-29: “The draft ISA describes a two-peaked diurnal pattern in urban areas, with morning peaks attributed to rush-hour traffic and afternoon peaks attributed to a combination of rush hour traffic, decreasing atmospheric dilution, and nucleation (U.S. EPA, 2018, section 2.5.2.3, Figure 2-32).”

I cannot believe that nucleation has any impact on PM<sub>2.5</sub> mass concentrations. Rather, the draft probably means to say efficient oxidation in the afternoon of precursor gases, which condense (rather than nucleate) onto existing particles.

**EPA-5. Chapter 5 – Review of the Secondary Standards: What are the CASAC views on the approach described in Chapter 5 to considering the evidence for PM-related welfare effects in order to inform preliminary conclusions on the secondary standards? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current secondary PM standards?**

I found the approach and rationale EPA took in reaching the preliminary conclusions to be reasonable.

SCQ-5.1 To what extent does the Panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the secondary PM standards? Are there additional policy-relevant questions that should be addressed?

I found the questions to be sufficient and relevant.

SCQ-5.2 What are the Panel's views of the draft PA evaluation of the currently available scientific evidence with respect to the welfare effects of PM. Does the assessment appropriately account for any new information related to factors that influence:

- a) Quantification of visibility impairment associated with PM<sub>2.5</sub> and examination of methods for characterizing visibility and its value to the public?
- b) The effects of PM<sub>2.5</sub> components on climate?
- c) The effects of fine and coarse particles on materials?

I found that the draft PA did a good job of summarizing the state of knowledge at the time of the last NAAQS review, now, and the new information that has become available in between. I found this to be the case for visibility and climate effects but note that I do not consider myself an expert on material damage.

SCQ-5.3 What are the Panel's views of the draft PA preliminary conclusion that the currently available scientific evidence does not call into question the protection afforded by the current secondary PM standards against PM welfare effects and that it is appropriate to consider retaining the current secondary PM standards without revision?

I found the draft PA preliminary conclusion to be appropriate and well supported.

Lastly, I note some minor issues that could be revised and clarified in the PA but do not substantially impair it from serving its purpose.

Page 5-5: "In addition, at the time of the proposal, the Administrator recognized that suitable equipment and performance-based verification procedures did not then exist for direct measurement of light extinction and could not be developed within the time frame of the review (77 FR 38980-38981, June 29, 2012)."

This statement confuses me since nephelometers and aetholometers exist and could do the job. This also seems to contradict statements made on the bottom of page 5-11 about available measurement methods.

Page 5-25: "The IPCC AR5, taking into account both model simulations and satellite observations, reports a radiative forcing from aerosol-radiation interactions (RFari) from anthropogenic PM of  $-0.35 \pm 0.5$  watts per square meter (Wm<sup>-2</sup>) (Boucher, 2013), which is slightly reduced compared to AR4."

Here “reduced” is confusing. The effect is reduced in absolute magnitude but increased from -0.5 to -0.35 W/m<sup>2</sup> from AR4 to AR5. This could be revised for clarification.

Page 5-26: “While research on PM-related effects on climate has expanded since the last review, there are still significant uncertainties associated with the accurate measurement of PM contributions to the direct and indirect effects of PM on climate.”

I think it’s more appropriate to say “accurate estimation” given the number of modeling studies involved.

Page 5-29: “Such uncertainties include those related to our understanding of: • The magnitude of PM radiative forcing and the portion of that associated with anthropogenic emissions; and,”

Although the term “radiative forcing” can sometimes be used slightly different ways, the most common and general definition is the difference in the Earth’s energy balance due to the presence (versus absence) of anthropogenic emissions. Hence, radiative forcing is, by definition, anthropogenic. In contrast, it’s common to say “radiative effect” when one means the net result of anthropogenic and natural aerosols. A similar statement is made on page 5-40 and should be remedied there.

## Dr. John L. Adgate

**EPA-1. Chapter 1 – Introduction: To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for the review?**

The information in Chapter 1 of the draft Policy Assessment (PA) is clearly presented for the most part: it addresses the implications of the available scientific evidence and provides some useful context, including the purpose, legislative requirements, history, and key elements and case law related to the Clean Air Act that govern the development of NAAQS. The review leaves out elements of the recent policy changes, the functioning of the review process, and timeline of the review that are important parts of the peer review process for the PA and the documents that feed into it. The PA document would be strengthened if it provided a summary of the timeline of the overall review in contrast to past reviews, and stated whether important related documents, such as the draft Independent Science Assessment (ISA) and earlier planning documents (e.g., the REA), will be released in final peer reviewed form prior to the finalization of the PA. These documents were part of previous comprehensive reviews prior to the changes implemented by the Administrator in 2017 and 2018. Outlining those changes and their rationale would make section 1.4 of the PA complete and the overall timeline clearer.

**EPA-3. Chapter 3 – Review of the Primary PM<sub>2.5</sub> Standards: What are the CASAC views on the approaches described in Chapter 3 to considering the PM<sub>2.5</sub> health effects evidence and the risk assessment in order to inform preliminary conclusions on the primary PM<sub>2.5</sub> standards? What are the CASAC views regarding the rationales supporting the preliminary conclusions on the current and potential alternative primary PM<sub>2.5</sub> standards?**

Chapter 3 is well written and addresses the charge questions on the Primary PM<sub>2.5</sub> Standards, and summarize the policy-related issues and the most important weight of evidence findings identified in the draft Independent Science Review. Table 1 on page 3-18 is a useful summary, though footnote 15 implies that conclusions on the 3 “likely to be causal” endpoints may be reversed or disregarded in the final PA based on CASAC’s commentary on the validity of these determinations. Given that CASAC itself has asked for additional scientific expertise on particulate matter health studies, some CASAC members have called for a reinstatement of the PM subcommittee, and recent CASAC communications indicate lack of consensus on a number of scientific and science policy issues, the language of the footnote indicating that the PA would be finalized based on advice from CASAC seems imponderable.

**SCQ-3.1 Does the Panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM<sub>2.5</sub> review? Are there additional policy-relevant questions that should be addressed?**

The policy questions posed in the chapter address the central questions on adequacy of the current annual and 24 hour PM<sub>2.5</sub> standards and related issues, such as what is known, not known, and key scientific issues and uncertainties. The chapter context

could be strengthened by noting health impacts on vulnerable and/or sensitive subpopulations,

Comments on Figures/Tables:

Many of the figures/tables do not stand alone as comprehensible units as they have undefined acronyms and in some cases incomplete titles or other descriptors that are not clear without extensive review of the text elsewhere in the document (e.g., “hybrid model” in Figure 3-8, “pseudo-design” in Figure 3-9). The document would be more readable if all graphics were at the high image quality.

Table 3-2 on controlled human exposure studies should include the number of exposed/unexposed individuals in each study.

**SCQ 3.4 What are the Panel’s views on the quantitative risk assessment for PM<sub>2.5</sub> including:**

In general this section is less clearly written than other parts of the PA. It is also jargon dense, often without defining key terms used multiple times and does not concisely summarize the key features and conclusions from the text and tables that make up Appendix C.

**f) The choice of health outcomes and studies selected for developing concentration-response functions for long and short-term effects?**

The choice of the three health outcomes presented in this section is not clearly articulated. Nonetheless, the studies selected for developing the C-R response functions are based on large well designed studies included in prior analyses and present epidemiological evidence for total mortality, ischemic heart disease mortality, and lung cancer mortality. The first two endpoints have more extensive evidence of causality per the summary in this review and were vetted in prior reviews, while the evidence for lung cancer mortality is less robust and the designation of “likely to be causal” based on judgment of the less robust findings related to individual study power and other factors, such as latency. Inclusion of this less robust endpoint that likely has greater uncertainty in its C-R function estimate provides an opportunity to assess the effect of using endpoints with weight of evidence determinations that are more uncertain.

**g) The selection criteria for the 47 urban areas and PM<sub>2.5</sub> air quality scenarios analyzed?**

The selection criteria for the 47 urban areas are based on availability of monitoring data and geographical diversity is reasonable given the range of health outcomes assessed in large studies and the observed differences in response in different locations inside the US. The third criteria, “PM<sub>2.5</sub> air quality concentrations” is unclear as the text describes the need for adjustment, but doesn’t clearly describe how these three criteria are assessed and or balanced in the process of decision-making. Nonetheless, this approach is likely broad enough to provide a representative risk assessment based on the population, though even a cursory glance of Figure 3-10 indicates that large parts of the central, northern, and western US are were not included in the areas assessed. In the end the approach appears to be sufficiently broad and include areas with



large populations, so it will allow for examination of estimated effects below the existing standards as well as the examination of the shape of the C-R response curve for long and short-term health endpoints.

- h) The hybrid modeling approach used for quantifying exposure surrogates across an area and adjusting air quality for alternative standard levels, as supplemented by interpolation/extrapolation?**
- i) The characterization of variability and uncertainty in the risk assessment? &**
- j) The robustness and validity of the risk estimates?**

**[text below responds to both d and e]**

The text describing this process on 3-83 is fairly brief and points to Appendix C but does not present the key findings or conclusions in a comprehensible way. The goals of this analysis need to be more clearly stated, and text on the rationale for the different risk modelling approaches articulated up front. While the general approach of upper bound estimates and use of sensitivity analysis are justified, as is the use of qualitative assessment, the process of selecting concentration-response functions, how the sensitivity analysis will be conducted and the range of plausible values is incompletely described in the body of the PA and thus the quality of this analysis is unclear. The subsequent summary of associated mortality under alternative standards and exposure reduction scenarios has results in the range that would be expected, though the process is hard to follow and key features of the appendix tables cited are not well described. In the end the lack of clarity in the approach here reduces confidence in the validity of the results presented.

**SCQ-3.5 What are the Panel's views on the draft PA preliminary conclusion that, taken together, the available scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary PM<sub>2.5</sub> standards?**

Overall, the preliminary conclusion that the weight of evidence from various study types and analyses presented support questioning whether the current standards are sufficiently protective of public health. The overall strength of evidence from a longstanding body of evidence has been further bolstered with new studies from a range of disciplines. This strong evidence on mortality and morbidity endpoints, coupled with emerging evidence for less extensively studied health endpoints, such as nervous system effects, and observation of health effects at or below current standards are scientifically credible. Furthermore, since it is likely that some populations are at increased risk due to geographic location, proximity to sources, or population characteristics (such as age or prior disease status) that increase their susceptibility, the conclusion that the existing standards may not provide an adequate margin of safety is warranted.

**Mr. George Allen**

General comment. It remains unclear how EPA will address the CASAC's April 11, 2019 comments on the draft PM ISA in the final ISA. These comments assume there will not be any substantial changes to the causal findings as presented in the draft ISA that would result in how the draft ISA findings are used in this draft PA.

## Chapter 2, Air Quality.

### Hybrid Modeling.

In the context of this review of health based standards, the air quality section on hybrid modeling approaches to PM<sub>2.5</sub> is the most important, since this is the area where substantial improvements in characterizing ambient PM<sub>2.5</sub> exposures over large areas have been made since the last PM NAAQS review. The performance of four different approaches are summarized, with the Bayesian downscaler 12 km model and the machine learning 1 km model having better overall performance. All models had degraded performance at low PM concentrations and in rural areas, although for use in health effect studies, uncertainties in annual average concentrations below ~ 6 to 7 µg/m<sup>3</sup> are less important.

Of particular relevance for this review is the performance of the machine learning approach for daily PM<sub>2.5</sub> with a 1 km grid used by Di et al. from the Harvard-Chan School of Public Health, since this was used in the pair of Di et al. chronic and acute mortality papers from 2017. The ability to predict PM<sub>2.5</sub> at the 1 km scale provides improved estimates in urban areas, which is important since much of the US population is urban and PM<sub>2.5</sub> tends to be higher in urban areas.

### Near-road PM.

A useful summary of the increase in PM<sub>2.5</sub> at near-road sites is given, showing an average increment over urban background of less than 1 µg/m<sup>3</sup>. Briefly noted in section 2.2.5 are other particle measurements at some of the near-road network sites, including black carbon (BC) and ultra-fine particle concentration measurements. It is worth noting that although BC is being measured at many near-road sites, it is not required to be reported to AQS under current regulations, and some agencies still do not report it.

### Re-purposing the near-road network from NO<sub>2</sub> to PM.

There are approximately 75 near-road monitoring sites that were originally deployed with NO<sub>2</sub> as the primary pollutant of interest. That turned out to be unnecessary, since there are no near-road sites even close to being out of compliance with the NO<sub>2</sub> NAAQS. Even exceedances of the 1-h 100 ppb standard are unusual. This doesn't mean there is no issue with near-road pollution health effects though, with particles being the most likely driver of the observed increase in several different health endpoints including cardio-vascular effects. EPA should reconsider how to use the existing near-road monitoring network infrastructure in the context of characterizing a range of on-line particle metrics at a subset of near-road sites, including UFP, lung-deposited surface area (using charge-based measurements), black carbon and total aerosol carbon (and OC by difference), and speciation of tire and brake wear emissions (including iron and copper) using 1 to 2-hour automated XRF methods. Coarse PM is elevated in the near-road environment and should also be measured using continuous methods. To quantify the increase of these pollutants relative to urban background, matching measurements could be made at NCore sites in the same urban area, preferably within a few km of the near-road site.

Relationship between annual and daily PM<sub>2.5</sub> design values.

This is an important analysis, given that EPA continues to recommend that the daily PM<sub>2.5</sub> NAAQS not be changed and continued to be used only as a backstop, with the annual PM<sub>2.5</sub> NAAQS as the primary control mechanism. While it is true that most sites that are in compliance with the current annual NAAQS of 12 have daily design values less than 35, there is a subset of sites where the daily NAAQS DV is greater than 35 and the annual is less than 12. A common driver of this situation is winter woodsmoke from residential space heating, where elevated levels of PM<sub>2.5</sub> occur only during the heating season. An extreme example of this scenario is the North Pole (Fairbanks) AK valley monitoring site, in severe non-compliance for PM<sub>2.5</sub> because of winter woodsmoke. The ratio of the 2016-2018 daily DV to annual average is 5.1, substantially larger than the 35/12 ratio of 2.9. For the annual NAAQS to provide equivalent protection of the daily NAAQS at this location, it would have to be 7 µg/m<sup>3</sup>. If the annual PM NAAQS is reduced, the daily should not be left unchanged unless an annual NAAQS of less than 8 µg/m<sup>3</sup> is chosen.

Issues with FRM and FEM PM<sub>2.5</sub> monitor comparisons.

Monitoring agencies continue to struggle with getting their continuous FEM PM<sub>2.5</sub> monitor performance within acceptable levels for them to be used to demonstrate compliance with the PM<sub>2.5</sub> NAAQS. This problem goes back to how the FRM is run for FEM testing requirements; it is well known that FRM filters can lose up to 10% of their non-water mass over the 177 hours allowed before post-sampling weighings are done. Dirk Felton described this issue in 2009 in an AWMA Environmental Manager article "Is It Time to Upgrade the PM<sub>2.5</sub> Federal Reference Method?", available at <http://pubs.awma.org/gsearch/em/2009/2/felton.pdf>. From a programmatic perspective it is unlikely that the FRM or FEM certification process will be changed to resolve this performance difference. EPA could allow instrument specific correction factors to reduce the bias relative to the FRM of most of the more than 900 FEM sites to the point where current data, and to some extent historical data, would be of sufficient quality for comparison to the 24-hour NAAQS. This becomes important for consideration of a change to the averaging interval of the daily standard to a rolling 24-hour average, similar to how the ozone NAAQS is an 8-hour daily maximum value.

Background PM.

This section covers sources of background (non-anthropogenic, domestic) PM well, with estimates of background PM from 0.5 to 3 µg/m<sup>3</sup>, with the upper end of that range probably driven by secondary organic aerosol (SOA). Other than wind-blown dust, SOA is the largest source, especially in the southeast from the reaction of photochemical oxidants with biogenic hydrocarbons (isoprene, terpenes). This document treats all of this source as natural, but since some of the photo-oxidant load is anthropogenic, perhaps some of the SOA should be considered that as well. Smoke from wildfires, especially in western states, could be considered anthropogenic to some extent, since human activity accounts for some portion of wildfire events. This could include climate change-related effects of drier and hotter weather, as well as ignition events from power transmission lines. The 2018 Camp fire in California is a good example of this kind of event.

Chapter 3, Section 3.4.2, Potential PM<sub>2.5</sub> alternative standards

There is little new information since the last review to support serious consideration of changes to the indicator, form, or averaging times for the annual and daily NAAQS. There is some

discussion of UFP as an additional indicator since it is described as Likely to be causal for long-term nervous system effects, but it is unclear if this association is independent of PM<sub>2.5</sub> which is also Likely to be causal. As noted in the draft PA, there is a very large body of research showing PM<sub>2.5</sub> mortality effects since the last PM review. The most robust work is the pair of chronic and acute studies of the Medicare population by Di et al. from the Harvard-Chan School of Public Health. In addition to having a 61 million person cohort with a median follow-up of 7 years and hybrid-modeled daily PM<sub>2.5</sub> 1x1 km exposure estimates for the entire continental US, the combination of chronic and acute mortality analysis on the same data set provides increased confidence that the analytical methods used are robust, since potential confounders for the chronic and acute analysis are different. These studies justify serious consideration of annual PM<sub>2.5</sub> values down to 8 µg/m<sup>3</sup>. While these studies are an important part of EPA's analysis, the agency is still using the "study area" approach for the REA. When you have robust exposure and mortality estimates for the entire country, this approach seems too limited.

The draft PA looks at a range of annual PM<sub>2.5</sub> between 8 and less than 12 (e.g., 11), and performs risk assessments at 11, 10, and 9 µg/m<sup>3</sup> (Table 3-7, page 3-88). Table 3-8 presents % risk reduction for these concentrations relative to 12. Since the CR curve is assumed to be linear within this range, the reductions are not large: 21 to 27% across all table categories. The Di and Pope all-cause mortality estimates for the 47 urban study areas are ~ 50,000/year - a very large number from a public health perspective. Reducing this by ~ 25% is still a very large number, and does not reflect mortality on a national scale; the 47 urban study areas represent about 1/3 of the total population (Table C-2).

The risk analysis mostly ignores or de-emphasizes study data below 8 to 9 µg/m<sup>3</sup>, saying there is insufficient information from studies at those low concentrations. However, figure 3-8 shows that average pm<sub>2.5</sub> for 25% of the Di et al. chronic mortality study population was below 7 µg/m<sup>3</sup>. This represents 115 million person-years of follow-up, a very large sample size that results in relatively robust mortality estimates even at levels below 7 µg/m<sup>3</sup> (see Di et al., NEJM 2017 Figure 3a). There is a very large population with current annual PM exposures less than 8 µg/m<sup>3</sup>, and while the effect is lower with lower concentrations and there is a suggestion of flattening of the CR curve below 7 µg/m<sup>3</sup>, the overall mortality is large in this group because of its size. This issues is not clearly addressed in the draft PA.

Figure 2 of the Di et al. 2017 NEJM chronic mortality study presents another measure of concern: the three times higher risk for African Americans compared to the general population.

This is not addressed in the risk assessment. If standards are set for what we think is appropriate for the general population, the 13% of the over 65 population that is black will be at substantially elevated risk relative to the general population.

#### Daily PM2.5 NAAQS.

There is no reasonable rationale to leave the daily PM2.5 NAAQS unchanged if the annual is reduced to 10 µg/m<sup>3</sup> or lower. Yes, it is appropriate to have the annual NAAQS be the primary control, but in addition to providing protection for short-term sub-daily peak exposures, one reason to keep the daily NAAQS at least somewhat relevant is that EPA's PM2.5 health messaging (AQI) is based only on the daily standard. Other than for wildfire events, at 35 µg/m<sup>3</sup> health messaging is almost never more than yellow/moderate. That messaging communicates little to no risk at concentrations that EPA says causes more than 50,000 premature deaths annually. Health messaging should not excessively discourage exercise, and as long as PM2.5 health messaging doesn't routinely communicate code orange (unhealthy/sensitive groups, at the level of the daily standard) or red (unhealthy, substantially above the daily standard), this should not be an issue.

Typo: Thurston 2015 in many Chapter 3 tables should be 2016.

#### Black Carbon (BC) health effects.

The 2018 Draft Integrated Science Assessment for PM mentions BC in the context of both short-term respiratory and cardiovascular effects. It is not mentioned in any of the long-term exposure categories, and unlike UFP for the first time, does not rise to the level of inclusion in any of the tables of causality. This is surprising since there is a growing body of literature that suggests BC is a good indicator of traffic-related air pollution (TRAP) health effects, if not causal of the cardio-vascular health effects observed in the near-road environment. BC can serve as a delivery vehicle for semi-volatile components of mobile-source exhaust since it is small enough to penetrate deep into the lung. BC particles can have a coating of fresh semi-volatile organic carbon material on their surface. They have a large surface area relative to their mass since the size of fresh tailpipe BC [~ 0.25 µm] is about where surface area distributions peak. A partial list of literature on BC health effects since the 2009 ISA is included below; none of these are included in the 2018 draft PM ISA. BC should be included in future tables of causality, since it would seem to be at least "somewhat suggestive" of having a causal health effect. Vermeulen et al. (2013) is included here since it used EC (a similar metric to BC) as the indicator for diesel engine exhaust, and points to a large body of literature linking cancer to EC or BC long-term exposures.

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## Dr. John Balmes

### **Charge Question SCQ-3.1**

*Does the Panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM<sub>2.5</sub> review? Are there additional policy-relevant questions that should be addressed?*

In general, the questions posed in the chapter capture most of the policy-relevant issues. One area that deserves more attention is the relatively greater exposure to PM<sub>2.5</sub> of communities of color and low socioeconomic status (SES) for which there is considerable evidence. These communities also tend to have greater vulnerability to adverse health effects of PM<sub>2.5</sub> exposure. The chapter briefly alludes to the greater exposure and vulnerability of poor people of color when spatial averaging is discussed, but the need to protect the health of this population deserves greater attention in the draft PA.

### **Charge Question SCQ-3.2**

*What are the Panel's views on the relative weight that the draft Policy Assessment gives to the evidence-based (i.e. draft PA, section 3.2) and risk-based (i.e. draft PA, section 3.3) approaches in reaching conclusions and recommendations regarding current and alternative PM<sub>2.5</sub> standards?*

The evidence-based approach to whether the current and alternative PM<sub>2.5</sub> standards protect public health using the air quality distributions of the epidemiological studies that demonstrate associations between exposures to PM<sub>2.5</sub> and adverse health effects is appropriate. The second approach using “pseudo-design values” to determine whether PM<sub>2.5</sub> concentrations in epidemiological study areas would have exceeded the current or alternative standards also adds to the assessment.

The description of the risk-based approach is more difficult to follow, especially regarding the adjustments that were made for areas “requiring either a downward adjustment to air quality or a relatively modest upward adjustment.” The method by which exposure reductions based on a hybrid approach using both measured concentrations and modeled estimates are developed both for the current and alternative standards is again somewhat difficult to follow.

The evidence-based approach deserves more weight, but the fact that the risk-based approach produces similar information is reassuring.

### **Charge Question SCQ-3.3**

*What are the Panel's views on the evidence-based approach, including:*

*a) The emphasis on health outcomes for which the draft ISA causality determinations are “causal” or “likely causal”?*

The emphasis on health outcomes that the draft ISA identified as “causal” or “likely causal” is appropriate, although the lack of treatment of respiratory outcomes and long-term exposures with the risk-based approach is disappointing.

*b) The identification of potential at-risk populations?*

Again, people of color and low SES should also be identified as a potential at-risk population.

*c) Reliance on key multicity epidemiology studies conducted in the US and Canada for assessing the PM<sub>2.5</sub> levels associated with health effects?*

European multi-city epidemiological studies should also be considered.

*d) Characterizing air quality in these key studies using two approaches: the overall mean and 25th/75th percentiles of the distribution and the “pseudo design value” reflecting a monitor with the highest levels in an area?*

Mean PM<sub>2.5</sub> concentration may not be the best way to characterize the exposure of the populations in epidemiological studies that demonstrate associations with adverse health effects. Some of the statements about pseudo-design values are hard to understand such as “For studies with 25th percentiles  $\leq 12.0 \mu\text{g}/\text{m}^3$ , at least 25% of the study area population lived in locations likely to have met the current annual standard over the study period (i.e., in at least 25% of health events occurred in such locations”. How do we know this?

*e) The preference for continuing the use of an annual PM<sub>2.5</sub> standard as the principal means of providing public health protection against the bulk of the distribution of short- and long-term PM<sub>2.5</sub> exposures?*

The argument for the use of an annual standard as the primary approach to protecting public health is logical and well-stated. That said, high short-term exposures to PM<sub>2.5</sub> from catastrophic wildfires remain a major driver of health impacts even if these are not regulated by EPA.

*f) The draft PA conclusions on the extent to which the current scientific information strengthens or alters conclusions reached in the last review on the health effects of PM<sub>2.5</sub>?*

These conclusions are appropriate based on the review of the health effects literature in the draft ISA.

*g) Whether the discussions of these and other issues in Chapter 3 accurately reflect and clearly communicate the currently available health effects evidence, including important uncertainties, as characterized in the ISA?*

While the discussion of Chapter 3 accurately reflects the currently available health effects evidence, communication of important uncertainties, such as the impacts of high peak sub-24-hour exposures, is not always clear. High sub-24-hour peak exposures are increasingly occurring as a result of wildfires in the Mountain West.

### **Charge Question SCG-3.5**

*What are the Panel’s views on the draft PA preliminary conclusion that, taken together, the available scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary PM<sub>2.5</sub> standards?*

The preliminary conclusion that the current may not be adequate to protect the public health with a sufficient margin of safety is reasonable given the evidence reviewed in the draft ISA.

## Dr. Kevin J. Boyle

Here, I refer to the charge questions for Chapter 5 of the report.

PA-5. Chapter 5 – Review of the Secondary Standards: What are the CASAC views on the approach described in Chapter 5 to considering the evidence for PM-related welfare effects in order to inform preliminary conclusions on the secondary standards? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current secondary PM standards?

SCQ-5.1 To what extent does the panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the secondary PM standards? Are there additional policy-relevant questions that should be addressed?

**Comment:** I think that it is good that additional attention was given to urban areas where the largest share of the populace resides without overlooking rural residents (p. 5-14, lines 1-6) Consideration of regional variation is also important (p. 5-14, 5-15).

However, there are important missing components to adequately consider public welfare that I outline below.

SCQ-5.2 What are the Panel's views of the draft PA evaluation of the currently available scientific evidence with respect to the welfare effects of PM. Does the assessment appropriately account for any new information related to factors that influence:

a) Quantification of visibility impairment associated with PM<sub>2.5</sub> and examination of methods for characterizing visibility and its value to the public?

**Comment:** The use of “*acceptable*” visibility is a fundamentally flawed policy concept (p.15, line 25 – p. 17, line 9). What is acceptable in an urban area with a certain baseline visibility may not be acceptable in a rural area with a higher baseline of visibility. This is not just a dichotomy between urban and rural residents. Urban residents may expect greater visibility when they travel to a rural area for vacation, and rural residents may consider urban visibility a forgone condition. An additional question is whether the visibility standard should be higher in some locations such as already the case in Class I visibility areas, national parks and wilderness areas.

The more concerning element is that while people may rate a certain level of visibility as acceptable, this does not imply that they would not realize a welfare gain from further improvements in visibility (Boyle et al., 2016; Haider et al., 2019; Yao, 2019). Compromised visibility can also affect property values (Walls, Kousky and Chu, 2015). In short, the question is never posed or answered to consider if there are net public benefits, improved welfare, for enhancing visibility beyond the acceptable level. Further, the acceptability studies were focus groups with small numbers of participants.

- Ely et al. (1991) conducted 17 focus groups of members of civic organizations in Denver, CO for a total of 214 participants (about 12-13 people per group).
- BBC Consulting (2002) conducted 27 focus groups in Phoenix, AZ for a total of 385 participants ( about 14 people per group).

- Pryor (1996) conducted four classroom exercises in British Columbia, CAN with 180 university students (about 45 students per class).
- Abt (2001) conducted a single focus group in Washington< DC with nine participants.

The Ely and BBC studies represent initial research that would be conducted at the beginning of a well-designed national preference study with one exception. The focus groups would be conducted at several locations around the U.S., not in single cities. The Pryor study presents an interesting investigation to learn about preferences for visibility, but is not indicative of national preferences in the U.S. Finally, the Abt study represents the first step in study design from which no firm policy implications could be drawn. Johnston et al. (2017) discuss best practices in the conduct of an economic preference study to evaluate public welfare gains and losses and the use of focus groups in the design of such studies. The American Association for Public Opinion Research's Best practices for Survey Research include the recommendation that "(a)ll questions should be pretested to ensure that questions are understood by respondents, can be properly administered by interviewers or rendered by web survey software and do not adversely affect survey cooperation" (<https://www.aapor.org/Standards-Ethics/Best-Practices.aspx#best6>, accessed September 23, 2019). The conduct of focus groups is a key step in this process to learn how best to present visibility images and query subjects about visibility in the implementation of a national visibility preference study. Thus, the above studies present evidence of the importance of visibility but do not present enough information to support national policy decisions.

The report states that the "... preliminary conclusions for the Administrator's consideration is that it is appropriate to consider retaining the current secondary PM standards, without revision. In so concluding, we recognize, as noted above, that the final decision on this review of the secondary PM standards to be made by the Administrator is largely a public welfare judgment, based on his judgment as to the requisite protection of the public welfare from any known or anticipated adverse effects." (p. 39, lines 21-26) This conclusion is based on flawed logic because an implicit premise of the report is that there are no societal benefits beyond what some small and incomplete studies found as acceptable.

- b) The effects of PM<sub>2.5</sub> components on climate?

**Comment:** The report concludes that "(w)hile evidence in this review suggests that PM influenced temperature trends across the southern and eastern U.S. in the 20th and 21st century, uncertainties continue to exist and further research is needed to better characterize the effects of PM on regional climate in the U.S." (p. 28, lines 25-28). It seems questionable to me to treat ecological effects and climate separately, which has been done by partitioning ecological impacts to a separate assessment. While this is not my area of expertise, it seems logical to ask if induced changes in climate over time will have ecological impacts that are not observed today.

- c) The effects of fine and coarse particles on materials?

**Comment:** The report concludes that “(w)hile some new evidence is available with 21 respect to PM-attributable materials effects, the data are insufficient to conduct quantitative analyses for PM effects on materials in the current review” (p. 5-35, line 20-22). The report is unclear on what literature was reviewed and there is evidence outside of the U.S. on the cost of soiling from air pollution (e.g., Besson, 2017; Grøntoft, 2019

SCQ-5.3 What are the Panel’s views of the draft PA preliminary conclusion that the currently available scientific evidence does not call into question the protection afforded by the current secondary PM standards against PM welfare effects and that it is appropriate to consider retaining the current secondary PM standards without revision?

**Comment:** I have several major concerns.

First, the framing of the policy from a welfare perspective using “acceptable”, by default, leads to the conclusion that no further protection is required. From a welfare perspective, the question is never posed to ask if welfare would be enhanced if protection was increased.

Second, given the uncertainties in the current state of knowledge the question is never posed to inquire if further protection is warranted until the uncertainties are resolved. The “what if nothing is done” question is never explored in any substantial manner to explore how large or small the consequences might be from holding the current standard.

Finally, in addition to advocating for a “better characterization” of the scientific knowledge, it would be appropriate to recommend a precautionary principle in setting policy until the visibility impacts and resulting welfare impacts are better understood (Kiebel et al., 2001). A safe minimum standard would call greater emphasis on protection of the environment, visibility here, so long as the social costs of doing so are not unreasonable (Bishop, 1978).

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## Dr. Judith Chow

### **EPA-2. Chapter 2 – PM Air Quality: To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for the review?**

SCQ-2.1 *What are the Panel's views regarding whether the draft Policy Assessment accurately reflects and communicates the air quality related information most relevant to its subsequent evidence-based assessment of the health and welfare effects studies, including uncertainties, as well as the development of the risk assessment for current and alternative standards? In particular, do the following sections accurately reflect and communicate current scientific understanding, including uncertainties, for: (a) relationships between annual and daily distributions of PM; (b) the review of hybrid modelling approaches used to estimate exposure in some studies and the risk assessment; and (c) information on background level of various measures of PM?*

Chapter 2 documents particulate matter (PM) emission sources, ambient monitoring methods and networks, as well as ambient air urban and non-urban PM concentrations. The chapter provides useful information, but several key areas deserve additional discussion including: 1) clarification of discrepancies in source types and percent contributions to gaseous precursors (i.e., SO<sub>2</sub>, NO<sub>x</sub>, NH<sub>3</sub>, and VOCs) and primary PM emissions; 2) documentation of the zones of representation of ambient monitoring sites for PM exposure assessments; 3) specification of the relationship between annual average and 98<sup>th</sup> percentile 24-hour PM<sub>2.5</sub> concentrations; and 4) exclusion of exceptional events in the PM<sub>10</sub> analysis.

- **Sources of PM Emissions (Section 2.1.1)**

Total PM<sub>2.5</sub> emissions are estimated at ~5.4 million tons/year (similar to the <5400 Ktons/year in the draft ISA with different units), but the aggregation of the seven source types in the draft PA (U.S. EPA, 2019) varies from that in the draft ISA (U.S. EPA, 2018a); both are based on the 2014 National Emissions Inventory (NEI, U.S. EPA, 2018b). Figure 2-2 (page 2-5) shows that the “Dust” source (including agriculture, construction, and road dust) and “Agriculture” (tilling) source each account for 18% of the total PM<sub>2.5</sub> emissions in the PA, which differs from the 13% “Unpaved Road Dust” and 19% “Agriculture- Crops & Livestock Dust”) emissions in the ISA. As agricultural tilling results in suspended PM dust, it should be part of the agricultural dust. The rationale to assign agricultural dust to the “Dust” source and agricultural tilling to the

“Agriculture” source needs to be explained.

Aggregation of different dust types or subtypes should be documented. Separation of “Dust” source emissions into paved and unpaved road dust and construction dust provides insight on the magnitude of suspended PM for each source subtype. This information is useful to evaluate source contributions by receptor modeling source apportionment and has been applied in the development of State Implementation Plans (SIPs).

Table 1 compares the percent contributions of seven source types between the draft PA and ISA for both annual PM<sub>2.5</sub> and PM<sub>10</sub> emissions. It shows the inconsistency in definition of source types and source subtypes between the PA and ISA. Similar discrepancies are found for the percent distribution of PM<sub>10</sub> emissions. Given that ~75% of the PM<sub>10</sub> emissions are attributed to “Dust” and “Agriculture” sources, it would be helpful to illustrate the source subtype contributions.

As PM<sub>10</sub> consists of PM<sub>2.5</sub>, the percent distribution of major emission sources to PM<sub>10-2.5</sub> should be given to provide some perspective on major source contributions to the coarse particle size fraction. It should also be noted that fugitive dust emission estimates are highly inaccurate and do not agree with source apportionment contributions at receptors (Watson and Chow, 2000). Emissions of precursor gases (i.e., SO<sub>2</sub>, NO<sub>x</sub>, NH<sub>3</sub>, and VOCs) also differ between the draft PA and ISA. For SO<sub>2</sub>, the 79% “Stationary Fuel Combustion” source in Figure 2-5a (page 2-10) is 6% higher than the 73% “Fuel Combustion” source (sum of Electric Generation and Industrial Boilers in Figure 2-4 [page 2-15] of the draft ISA); for NO<sub>x</sub>, the 58% “Mobile” source in Figure 2-5b is 4% higher than the 54% in the draft ISA (Figure 2-4b); and for NH<sub>3</sub>, the 80% “Agriculture” source (Figure 2-5c) is 22% higher than the 58% “Agriculture- Livestock Waste” source in the draft ISA (Figure 2-4c).

The most confusing discrepancies concern VOC emissions. The naming convention changes from “VOC” in the ISA to “Anthropogenic VOCs” in the PA. Both documents report annual average VOC emissions of 17 million tons per year (page 2-9 of draft PA and page 2-13 of draft ISA). Figure 2-5d of the PA attributes 24% of VOC to “Mobile” sources, this is four times higher than the 6% in the ISA (Figure 2-4d). The 71% of VOCs attributed to the “Biogenics-Vegetation and Soil” source type in the draft ISA is not included in the draft PA. Discrepancies between the two EPA reports need to be resolved.

Since these emission estimates serve as input to air quality models, consistent source types and emission estimates should be used. Reasons for different percent contributions of precursor gases and PM emissions, based on the same 2014 NEI, should be clarified.

- **Ambient PM Monitoring Methods and Networks (Section 2.2)**

Discussions of the spatial scales and monitors that characterize mobile and stationary source emissions (pages 2-12 and 2-13) are not consistent with the community monitoring zones (CMZ) defined by the U.S. EPA (1998) network design document. Zones of representation are defined as: microscale (<100 m), middle scale (~100-500 m), neighborhood scale (0.5-4 km), and urban scale (4-50 km) (40 CFR, Part 58, Appendix D). The statement for PM<sub>10</sub> monitoring that “...the network design criteria emphasize monitoring at middle and neighborhood scales to effectively characterize the emissions from both mobile and stationary sources...” from pages 2-12 and 2-13 is misleading as most of the PM<sub>10</sub> sites represent urban-scale community exposures. Only the near-road PM<sub>2.5</sub> or PM<sub>10</sub> sites can represent micro- and middle-scale monitoring.

The zone of representation for each monitor is important for exposure assessment and epidemiological studies that use data from compliance monitoring stations. Emission source zones of influence and receptor site zones of representation need to be defined for exposure assessment.

It appears that network-wide annual PM<sub>2.5</sub> concentrations have been reduced from 8.6 µg/m<sup>3</sup> during 2013-2015 (Table 2-4, pages 2-48 of ISA) to 8.0 µg/m<sup>3</sup> during 2015-2017 (page 2-24 of PA). Apparently, PM<sub>2.5</sub> concentrations have continuously declined nationwide with a ~30% reduction since 2000. It would be helpful to provide statistics on the number of sites included in each concentration bracket for the annual and 98<sup>th</sup> percentile 24-hour PM<sub>2.5</sub> concentrations in Figure 2-8 (page 2-23), especially for locations with annual averages between 8-10 µg/m<sup>3</sup> and 10-12 µg/m<sup>3</sup>.



Not much information is given to illustrate relationships between annual and daily PM<sub>2.5</sub> distributions. It is not clear why most sites exhibit high correlation coefficients between the trends in annual average PM<sub>2.5</sub> concentrations and trends in 98<sup>th</sup> percentile of 24-hour PM<sub>2.5</sub> concentrations at individual sites (Figure 2-10, page 2-25). The implications of these high correlations, especially for eastern U.S. and in coastal California sites, need to be explained. The 24 hour PM<sub>10</sub> NAAQS is 150 µg/m<sup>3</sup>, not to be exceeded more than once per year averaged over three years. However, only the average second highest 24-hour PM<sub>10</sub> concentrations during 2015-2017 (Figure 2-16, page 2-33) and 2000-2017 national trends (Figure 2-17, page 2-34) are presented. As many western sites exceeded the 150 µg/m<sup>3</sup> PM<sub>10</sub> NAAQS, days with exceptional events should be excluded in these presentations to provide a better perspective of potential areas with elevated PM<sub>10</sub> concentrations. As elevated PM<sub>10</sub> concentrations occur episodically (e.g., wildfires and dust storms), a summary of PM<sub>10</sub> levels on standard exceedance days should be given. Prolonged biomass burning can result in adverse health effects, sampling periods, and locations with elevated PM<sub>10</sub> concentrations should be specified. Although it appears that the majority of the PM<sub>10</sub> sites showed levels <75 µg/m<sup>3</sup> during 2015-2017, maximum (instead of second highest) 24-hour PM<sub>10</sub> concentrations should be given to provide information on sites and locations with potential exceedances of 24-hour PM<sub>10</sub> NAAQS over the three year period.

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Table 1  
Comparison of percent source type contributions to total PM<sub>2.5</sub> and PM<sub>10</sub> emissions between draft PA<sup>a</sup> and ISA<sup>b</sup>

Total PM<sub>2.5</sub> Emissions (5.4 million tons/year)

<b>Source Type</b>	<b>Draft PA (U.S. EPA 2019)<sup>a</sup></b>	<b>Source Type</b>	<b>Draft ISA (U.S. EPA 2018)<sup>b</sup></b>	<b>Difference (PA minus ISA)</b>
Fires	32%	Wildfires	17%	--
		Prescribed Fires	15%	--
Dust	18%	Unpaved Road Dust	13%	+5%
		Agriculture- Crops & Livestock		
Agriculture (Tilling)	18%	Dust	19%	-1%
Stationary Fuel Combustion	14%	Fuel Comb- Residential Wood	6%	+8%
Industrial Processes	5%		0%	+5%
Mobile Sources	7%		0%	+7%
	0%	Waste Disposal	4%	-4%
Misc.	6%	Other	26%	-20%

Total PM<sub>10</sub> Emissions (13 million tons/year)

<b>Source Type</b>	<b>Draft PA (U.S. EPA 2019)<sup>a</sup></b>	<b>Source Type</b>	<b>Draft ISA (U.S. EPA 2018)<sup>b</sup></b>	<b>Difference (PA minus ISA)</b>
Fires	11%	Wildfires	6%	--
		Prescribed Fires	5%	--
Dust	47%	Unpaved Road Dust	39%	-8%
	0%	Paved Road Dust	5%	-5%
Agriculture (Tilling)	28%	Agriculture- Crops & Livestock Dust	30%	+2%
Stationary Fuel Combustion	5%	Fuel Comb- Residential Wood	0%	+5%
Industrial Processes	4%		0%	+4%
Mobile Sources	3%		0%	+3%
Misc.	2%	Other	15%	-13%

<sup>a</sup>U.S. EPA (2019) Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft. U.S. Environmental Protection Agency, Research Triangle Park, NC, USA; based on Figures 2-2 and 2-3.

<sup>b</sup>U.S. EPA (2018) Integrated Science Assessment for Particulate Matter, External Review Draft. U.S. Environmental Protection Agency, Research Triangle Park, NC, USA; based on Figures 2-2 and 2-6

**EPA-4. Chapter 4 – Review of the Primary PM<sub>10</sub> Standard: What are the CASAC views on the approach described in Chapter 4 to considering the PM<sub>10-2.5</sub> health effects evidence in order to inform preliminary conclusions on the primary PM<sub>10</sub> standard? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current primary PM<sub>10</sub> standard?**

SCQ-4.01 *To what extent does the Panel find that the key policy questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM<sub>10</sub> NAAQS review? Are there additional policy-relevant questions that should be addressed?*

Little information is given in Chapters 2 and 4 to evaluate the adequacy of the 24-hour PM<sub>10</sub> NAAQS to protect public health and welfare. Little progress has been made since the previous ISA (U.S. EPA, 2009). Equal weight and effort should be dedicated to each criteria pollutant in evaluating the NAAQS. However, different approaches are used for PM<sub>10-2.5</sub> as compared to PM<sub>2.5</sub> for causality determination. It is not clear why the draft PA did not include evaluations of PM<sub>10</sub> distributions in locations with epidemiological studies; comparison of experimental exposures with ambient air quality; or quantitative assessments of PM<sub>10-2.5</sub> health risks. As PM<sub>10</sub> includes PM<sub>2.5</sub>, the key policy questions should reflect the policy-relevant issue for PM<sub>10-2.5</sub> that highlights different properties in the PM<sub>2.5</sub> and PM<sub>10-2.5</sub> size fractions.

SCQ-4.02 *What are the Panel's views of the draft PA assessment of the currently available scientific evidence regarding the health effects associated with exposures to thoracic coarse particles, PM<sub>10-2.5</sub>?*

Although only a few new short-term PM<sub>10-2.5</sub> exposure studies were presented in the draft ISA (Table 11-9 on pages 11-100 to 101), these demonstrate consistent positive associations with total (nonaccidental) mortality (U.S. EPA, 2018). The long-term exposure to PM<sub>10-2.5</sub> and mortality (Table 11-11 on pages 11-119 to 120 of ISA) resulted in inconsistent outcomes. The lack of available scientific evidence is mainly due to a lack of PM<sub>10</sub> and PM<sub>10-2.5</sub> monitoring. Nationwide, there are 391 FRM and 365 FEM PM<sub>10</sub> sites as compared to 624 FRM and 579 FEM PM<sub>2.5</sub> sites for integrated 24-hour and hourly PM concentrations, respectively. In addition, there are 361 PM<sub>2.5</sub> monitors, not approved as FEMs, operated to report the AQI. Therefore, the total number of PM<sub>10</sub> sites is less than 50% of the PM<sub>2.5</sub> sites. This results in a dearth of PM<sub>10</sub> data, and is therefore, PM<sub>10-2.5</sub> (coarse) concentrations.

Although a PM<sub>10-2.5</sub> FRM was specified in the 2006 PM NAAQS review, little effort has been made over the last decade to better understand the temporal and spatial variations or the composition of PM<sub>10-2.5</sub>. As of 2018, there are only 279 PM<sub>10-2.5</sub> sites in the AQS database, less than 20% of the PM<sub>2.5</sub> sites. In addition to the commonly measured multielements, major ions (e.g., nitrate, sulfate, and ammonium), and organic and elemental carbon, speciation of PM<sub>10-2.5</sub> components should also include carbonate carbon and bioaerosols (e.g., endotoxin, 1,3-β-glucan, and total protein), prominent in PM<sub>10-2.5</sub> fractions (e.g., Chow et al., 2015) that may be associated with health effects.

*SCQ-4.03 What are the Panel's views on the draft PA preliminary conclusion that the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM<sub>10</sub> standard and that evidence supports consideration of retaining the current standard?*

Given the lack of measurements and resources, it is not surprising that the same key uncertainties (e.g., approaches to estimating PM<sub>10-2.5</sub>; measurement errors; potential for confounding by co-pollutant; and lack of biological plausibility) in causality determination are given in the previous (U.S. EPA, 2009) and current (U.S. EPA, 2018) ISA assessments. Figure 2-16 (page 2-33) shows that the average second highest 24-hour PM<sub>10</sub> concentration during 2015-2017 was 56 µg/m<sup>3</sup> (ranging 18-173 µg/m<sup>3</sup>). The majority of the sites measured below 75 µg/m<sup>3</sup>, with the exception of those in the southwestern U.S. The annual second highest 24-hour PM<sub>10</sub> concentrations in Figure 2-17 (page 2-34) show a downward trend of ~30% from 2000-2017, and are <75 µg/m<sup>3</sup> after 2007. The 98<sup>th</sup> percentile PM<sub>10-2.5</sub> concentrations for 2015-2017 (Figure 2-20, page 2-36) are mostly less than 30 µg/m<sup>3</sup>, consistent with nationwide PM<sub>2.5</sub> to PM<sub>10</sub> ratios of 0.5-0.6 for the second highest PM<sub>10</sub> concentrations during 2015-2017 (Figure 2-19, page 2-35). Therefore, 24-hour average PM<sub>10</sub> concentration of 60-75 µg/m<sup>3</sup> with a 24-hour PM<sub>10-2.5</sub> of 30 µg/m<sup>3</sup> most represents community exposure.

Given that 24-hr PM<sub>10</sub> concentrations have decreased by ~30% since 2000 and a positive association between PM<sub>10</sub> and health effects is still present, it is hard to justify retaining the 24-hour PM<sub>10</sub> NAAQS at the current level (150 µg/m<sup>3</sup>) and form (not to be exceeded more than once per year on average over a three-year period), which has not been revised since 1987 (see Table 1-1, pages 1-6).

More analyses are needed to test the association of lower (e.g., 60-75 µg/m<sup>3</sup>) 24-hour PM<sub>10</sub> concentrations with health effects and to demonstrate that the 24-hour PM<sub>10</sub> NAAQS of 150 µg/m<sup>3</sup> promulgated over 30 years ago is still adequate to protect public health.

***EPA-5. Chapter 5 – Review of the Secondary Standards: What are the CASAC views on the approach described in Chapter 5 to considering the evidence for PM-related welfare effects in order to inform preliminary conclusions on the secondary standards? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current secondary PM standards?***

*SCQ-5.01 To what extent does the Panel find that the key policy questions posed in this chapter appropriately reflect the important policy-relevant issues for the secondary PM standards? Are there additional policy-relevant questions that should be addressed?*

*SCQ-5.02 What are the Panel's views of the draft PA evaluation of the currently available scientific evidence with respect to the welfare effects of PM. Does the assessment appropriately account for any new information related to factors that influence:*

*d) Quantification of visibility impairment associated with PM<sub>2.5</sub> and examination of methods for characterizing visibility and its value to the public?*

- e) *The variable effects of PM<sub>2.5</sub> and its light absorbing and scattering components on climate?*
- f) *The effects of fine and coarse particles on materials?*

SCQ-5.03 *What are the Panel's views of the draft PA preliminary conclusion that the currently available scientific evidence does not call into question the protection afforded by the current secondary PM standards against PM welfare effects and that it is appropriate to consider retaining the current secondary PM standards without revision?*

- **Visibility Effects (Section 5.2.1)**

The analysis of visibility effects is mainly based on outdated (2005-2008 vs. 2011-2014) data and doesn't provide new information that might influence evaluation of light extinction and visibility. To achieve consistent and objective quantification of regional haze, the Regional Haze Rule (Section 308 of Protection of Visibility, 40 CFR Part 51, Subpart P, Sections 51.300-51.309) uses PM<sub>2.5</sub> chemical components to estimate particle light extinction (Watson 2002). Information on spatial interpolation of average light extinction by major chemical component for the most recent period (e.g., 2015-2017) should be compared with that from the last review to provide some perspective on overall changes.

As shown in Hand et al (2019), the organic mass (OM) to OC ratio increased across the network after 2011, highest in the east during summer, unrelated to the influence of particle bound water. The effects of visibility from changes in PM<sub>2.5</sub> composition over the past decade needs to be addressed. The reanalysis of three versions of IMPROVE light extinction algorithms (Malm et al., 1994; Pitchford et al., 2007; Lowenthal and Kumar, 2016) should provide IMPROVE 2015-2017 reconstructed light extinction coefficients ( $b_{ext}$ , Mm<sup>-1</sup>) by chemical components with monthly average PM<sub>2.5</sub> concentrations, to compare with those of 2005-2008 period. The revised IMPROVE algorithm (Pitchford et al, 2007) uses different scattering coefficients for the large and small sulfate, nitrate, and OM concentrations. The 20 µg/m<sup>3</sup> cut-off was selected to separate the large vs. small components. Owing to the nationwide reduction in PM<sub>2.5</sub> mass and sulfate concentrations, the "20 µg/m<sup>3</sup>" cut-off in the revised IMPROVE algorithms (Pitchford et al., 2007; Lowenthal and Kumar, 2016) may no longer be applicable. A reexamination with concentration levels more relevant to current air quality should be used to develop a more representative IMPROVE light extinction algorithm.

The draft PA suggests expanding the number and geographic coverage of "Preference" studies in urban, rural, and Class I areas to account for differences in population preference based on the scenic views. The "magnitude of scenic values" or the "ability of the public perception on visibility degradation" is judgmental and qualitative at best. Efforts should be put on science-based visibility estimates.

- **Key Uncertainties and Areas for Future Research (Section 5.4)**

New measurement techniques that can be used to estimate the radiation balance or climate change should be discussed. The newly developed multiwavelength (e.g., 405, 532, and 870 nm) Photoacoustic Extinctionmeter (PAX) provides high resolution aerosol optical measurements (Droplet Measurement Technologies, Boulder, CO) and is more advanced than the teleradiometers and telephotometers listed in the draft PA. Both the photoacoustic system and the dual and seven wavelength aethalometers (AE22 [370 and 880 nm] and AE33 [370 to 950 nm], Magee Scientific, Berkeley, CA, USA) can be used to estimate brown carbon (BrC),

organic carbon that absorbs light at a low wavelength (~300-400 nm). Estimates of BrC are included in the most recently released report by the Intergovernmental Panel on Climate Change (IPCC, 2019)

Starting with PM<sub>2.5</sub> filter samples from January 2016, the IMPROVE network reports seven wavelength (i.e., 405-980 nm) optical measurements along with the OC and EC analysis (e.g., Chen et al, 2015; Chow et al, 2015; 2018; 2019) that demonstrate the impact of BrC during fire episode. These data can be used to address changes in OM/OC ratios; develop revised IMPROVE algorithm; improve emissions inventory estimates; and provide data for climate assessment.

These data are also useful for determining natural visibility conditions related to the U.S. Regional Haze Rule; examining the effectiveness of emission reduction strategies for wood burning; and identifying exceptional events that cause exceedances of air quality standards. The draft PA should most represent state-of-the-art measurement techniques.

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Dr. Douglas W. Dockery

**SCQ-3.2 What are the panel's views on the relative weight that the draft Policy Assessment gives to the evidence-based (i.e. draft PA, section 3.2) and risk-based (i.e. draft PA, section 3.3) approaches in reaching conclusions and recommendations regarding current and alternative PM<sub>2.5</sub> standards?**

Section 3.2 provides a well-structured and clearly presented synthesis of the evidence for the health effects of PM exposures. There is no evidence for a discernable population threshold. Two approaches are used to attempt to draw out information relevant to recommending or evaluating current and alternative PM<sub>2.5</sub> standards.

In the first approach, the PM<sub>2.5</sub> air quality distributions over which epidemiologic studies support health effect associations and the degree to which such distributions are likely to occur in areas meeting the current (or alternative) standards are evaluated. Key studies are characterized based on the intuitive notion that the measures of association (exposure-response functions) are most precise at the mean of the exposure distribution. This misses the point that power is a function of the variance of exposure, not the mean. However, evaluating studies based on mean does show evidence for PM<sub>2.5</sub> effects for studies with mean exposures below the current PM<sub>2.5</sub> standards.

In the second approach, PM<sub>2.5</sub> design values (“pseudo-design values”) are calculated where possible for epidemiologic study sites. These calculations attempt to determine if these epidemiologic study areas would have met or violated the current or alternative standards during study periods. It is an interesting to examine whether the PM<sub>2.5</sub> exposure measures used in the epidemiologic studies (whether directly measured or estimated) would differ from the observed PM<sub>2.5</sub> from regulatory monitoring. Indeed, it is clear that regulatory monitoring by targeting compliance will produce values higher than monitoring or hybrid methods targeted on estimating population exposures. Ultimately, this approach also provides evidence for PM<sub>2.5</sub> effects in communities not violating the current standard.

Section 3.3 is a risk assessment that estimates population-level health risks associated with PM<sub>2.5</sub> air quality “requisite” to protect the public health, that is “just meeting” the current standards. Given the evidence based conclusions of effect below the current standards from the epidemiology, risks associated with PM<sub>2.5</sub> air quality adjusted to simulate “just meeting” alternative annual and 24-hour standards with lower levels are estimated. Although characterized as representative of the US population, this risk assessment is limited to 47 urban areas with monitored PM<sub>2.5</sub> above or marginally below the current NAAQS. Multiple urban areas affected by “special” circumstances such as wildfires, seasonal local wood smoke, and “uncertain” measurements are excluded. A multistep process is used to estimate exposure reductions for each monitoring site to achieve targeted alternative based on a hybrid model of monitored and CMAQ model surfaces. The observed exposure response functions for a limited set of health outcomes (“causal” and “likely to be causal”) are applied using BENMAP to estimate expected numbers of events. There is some quantitative, but largely qualitative

assessment of uncertainty. While this risk assessment is limited in scope, and not clearly described, the approach is sound and the numbers of preventable deaths at the current standard or alternative levels of the standard are informative. In particular, the risk assessment shows there are substantial numbers of deaths even in these limited analyses due to existing PM<sub>2.5</sub> exposures at the current standard. There would be substantial numbers of deaths prevented if stricter alternative levels of the PM<sub>2.5</sub> standard were in place. Moreover, the numbers of preventable deaths attributable to the annual standard are much larger than those attributable to the 24-hour standard. This supports the notion that the annual standard is the controlling limit.

While the evidence-based approach synthesizes the scientific evidence for adverse effects of PM<sub>2.5</sub> across the full range of exposures, the risk-based approach provides context for exposures and expected benefits from the current and alternative levels of the PM<sub>2.5</sub> standards. The consistency and coherence of the results of these two approaches is important in showing the PM<sub>2.5</sub> current standards are not protecting the public health adequately, and in providing guidance on possible alternative levels.

**SCQ 3.3 What are the panel’s views on the evidence-based approach, including:**

**a) *The emphasis on health outcomes for which the draft ISA causality determinations are “causal” or “likely causal”?***

The focus on the health outcomes which are “causal” or “likely causal” is entirely appropriate, and well supported by the synthesis of the evidence in the ISA. (Note that the risk assessment approach only considers a subset of these health outcomes, see SCQ 3.4 a).

**b) *The identification of potential at-risk populations?***

Section 3.2.2 (page 3-42) on “Potential At-Risk Populations” is remarkably succinct. It would be helpful to structure this discussion around the multiple pathways that people could be at risk because of exposure, susceptibility, ameliorating personal characteristics, and community context.

The evidence continues to be that the young, the old, and those with pre-existing chronic conditions have increased susceptibility. In addition, minority and economically disadvantaged populations have higher exposures and less ability to modify their exposure, to obtain appropriate health care, or to modify lifestyle (e.g. moving or improving nutrition) to ameliorate response. The conclusion is correct that “*the groups at risk of PM<sub>2.5</sub>-related health effects represent a substantial portion of the total U.S. population*” (page 3-43, line 19).

**c) *Reliance on key multicity epidemiology studies conducted in the US and Canada for assessing the PM<sub>2.5</sub> levels associated with health effects?***

While there have been many important and informative epidemiologic studies from Europe and Asia as well as from North America, since the last review. All of these studies are important in defining the scientific basis for the adverse effects of PM<sub>2.5</sub>

exposures. However, the evidence from the multicity US and Canadian epidemiologic studies is adequate (and compelling) to assess the health effects of PM<sub>2.5</sub>. The US studies are the most informative in assessing relevant PM<sub>2.5</sub> exposures for standard setting. The Canadian studies are particularly informative in showing adverse effects at PM<sub>2.5</sub> exposures below the current US standards. One might ask about the relevance of the Canadian studies. The population in Canada tend to be in the southern provinces which are further south than many US cities. While the 49th parallel is often thought of as the border between the US and Canada, the vast majority of Canadians (roughly 70%) live below it.

**d) Characterizing air quality in these key studies using two approaches: the overall mean and 25<sup>th</sup>/75<sup>th</sup> percentiles of the distribution and the “pseudo design value” reflecting a monitor with the highest levels in an area?**

It is commendable to examine the distribution of the underlying PM<sub>2.5</sub> exposure data used in epidemiologic studies (page 3-51). Indeed there is useful information to be gained, particularly in considering how informative these studies are in the lower exposures ranges. However, characterizing these studies based on the mean exposure is based on a mis-understanding of the statistics.

The statement that epidemiologic studies provide the strongest support for reported health effect associations over the part of the distribution corresponding to the bulk of the underlying data (page 3-51, line 2-3) has some intuitive validity. However, extending that to say the associations are “strongest” at the mean is flawed. Figure 3-2 (page 3-52) from Lepeule et al (2012) is used to show that the confidence intervals are smallest at the center of the distribution of exposures (where there is the most data), and widest at the extremes. This is true, but this does not mean that the association is strongest (or alternatively has the smallest confidence interval) at the center of the distribution. The plotted confidence intervals show the uncertainty around the expected hazard ratio at each exposure, and indeed these are larger where there is less data (or less exposure measures). In simple statistics, the error of the expected value is inversely proportional to the square root of the number of data points. Thus confidence intervals are wider where there is less data. However, the association is determined by the slope of the fitted line (not the expected value at any given point). In linear regression, the uncertainty (confidence interval) of the slope is inversely proportional to the square root of the number of data point times the standard deviation of the exposure. Thus the important characteristics is not the mean of the exposure distribution but the standard deviation or heterogeneity of the exposures. Studies with large differences in exposures are more precise than studies with little variation in exposure. A study with large numbers but no variation in exposure would produce a very precise estimate of the health indicator, but provide no information on the slope or association with exposure. Thus the parameter that should be examined in Figures 3-3, 3-4, 3-5, 3-6 and Table 3-3 is the variance or other index of heterogeneity (e.g. IQR) of exposure. Likewise for Figure 3-7 and 3-8. Here it is positive that 25<sup>th</sup> and 10<sup>th</sup> percentiles are considered when available as well as the mean or median. Indeed these percentiles would be a much more informative statistic to use in this risk assessment, but only a handful of these percentiles are available. Note that in these two figures, the arithmetic

means are compared for the short and long term studies. They show similar means for both types of exposures. However, the variances and therefore the 10<sup>th</sup> and 25<sup>th</sup> percentiles should be very different, and cannot be directly compared. For the short-term studies variance is between daily PM<sub>2.5</sub> concentrations, and the number of data point is number of days. For long-term studies variance is between annual mean PM<sub>2.5</sub> concentrations, and the number of data points is the number of cities or spatial locations. Thus the short term studies will tend to have much larger variances than the long term studies.

There is a significant logical misinterpretation of the “pseudo design values”.

Throughout the PA there are statements such as “50% of the study area populations lived in locations with pseudo-design values below these concentrations, or 50% of the health events occurred in such locations.” This would appear to state that 50% of the population experiences such pseudo-design values, and equivalently 50% of the health events occur in these locations. Neither of these interpretations can be supported by the data. These statements ignore the base populations associated with each exposure.

**e) The preference for continuing the use of an annual PM<sub>2.5</sub> standard as the principle means of providing public health protection against the bulk of the distribution of short- and long-term PM<sub>2.5</sub> exposures?**

The logic for this has not changed since the 2009 review. There is some additional discussion of this issue in the PA, which concludes there is no reason to modify this approach. However, the increased frequency of wildfires and associated acute exposures to anomalously high, short term episodes of PM<sub>2.5</sub> raises the importance of examining these effects in the evidence based analyses. (Note the risk assessment analyses explicitly exclude these events from consideration.)

**f) The draft PA conclusions on the extent to which the current scientific information strengthens or alters conclusions reached in the last review on the health effects of PM<sub>2.5</sub>?**

What are the changes in the evidence since the last review?

- Experimental studies (both controlled human and animal toxicology) providing evidence of causal pathways. Notably, some of these examine the same physiological and clinical indicators as in the epidemiologic studies. Exposures/doses in these experimental studies are higher than typically experienced as ambient exposures by populations in the community, requiring extrapolation. On the other hand, these exposures are now much closer (within an order of magnitude) of ambient 24 hour exposures. Note in particular that controlled human exposures are limited to a few hours. When these short, high exposure periods are extrapolated to 24-hour averages, the net exposure is often comparable to commonly observed ambient levels.
- The hybrid methods combining information from stationary monitors, land use regression, chemical transport model and remote sensing data to estimate exposures have allowed the epidemiology studies to examine not only populations

living near a fixed monitoring station, but across larger regions or across the entire country. Thus, studies now include complete samples of the population, not just those in urban areas where there were networks of air pollution monitors. Importantly rural populations which were previously unmonitored are included. These rural populations tend to have lower exposures to PM<sub>2.5</sub>, and therefore extend the range of observations to levels substantially below those included in the 2009 review. The national Canadian cohort studies have been particularly informative about effects at low PM<sub>2.5</sub> levels. However, the national cohort studies in the US have been able to examine associations restricting to communities with exposures below the current annual NAAQS.

- The hybrid methods have also improved the spatial resolution of the PM<sub>2.5</sub> estimates for epidemiologic analyses. These improved PM<sub>2.5</sub> exposure estimates have reduced exposure misclassification, increased the effective sample size, and provided stronger, more precise associations.

All of these advances have strengthened the evidence for health effects of PM<sub>2.5</sub> exposures.

**g) Whether the discussions of these and other issues in Chapter 3 accurately reflect and clearly communicate the currently available health effects evidence, including important uncertainties, as characterized in the ISA?**

The evidence for effects of sub-daily peak exposures to PM<sub>2.5</sub> are in my opinion undervalued in the PA and the ISA. The PA concludes that there is insufficient evidence for consideration of averaging times less than 24-hours. However, this lack of evidence is largely driven by the current form of the PM<sub>2.5</sub> NAAQS based on annual and 24-hour averages. The epidemiologic studies are largely based on exposure measurement methods that follow the EPA FRMs and NAAQS. Thus, few studies have considered sub-daily exposures. Consideration of peak versus 24-hour mean is not equivalent to examining PM<sub>2.5</sub> associations in the previous hour(s). As the Integrated Science Assessment notes, there are a limited number of studies which show increased risk of cardiovascular events (myocardial infarctions and arrhythmias) associated with PM<sub>2.5</sub> exposures in the previous hours. Likewise, controlled human exposure studies show changes in clinical cardiac indicators after PM<sub>2.5</sub> exposures of only an hour or less. Wildfire exposures while lasting multiple days, are usually brief (sub-daily) but intense in a given location because of shifting winds and moving sources. Understanding the effects of these specific short, intense exposures is challenging, but increasingly important.

**SCQ 3.4 What are the panel's views on the quantitative risk assessment for PM<sub>2.5</sub> including:**

- a) **The choice of health outcomes and studies selected for developing concentration-response functions for long and short-term effects?**

The risk assessment was nominally based health outcomes determined to be “causal” or “likely to be causal”. As determined in the ISA there were “causal” associations for PM<sub>2.5</sub> with Mortality

and Cardiovascular Effects, and “likely causal” for Respiratory, Cancer, and Nervous System effects. However, only a subset of these are included in the risk assessment calculations (see table below).

Health Outcome	Exposure Duration	Causal Determination	Risk Assessment
Mortality	Long & Short	Causal	All Cause Mortality (Long & Short)
Cardiovascular Effects	Long & Short	Causal	Ischemic Heart Disease Death (Long only)
Respiratory Effects	Long & Short	Likely to be Causal	
Cancer	Long	Likely to be Causal	Lung Cancer Deaths (Long only)
Nervous System Effects	Long	Likely to be Causal	

Notably not included:

- Cardiovascular effects (long term) other than IHD mortality, such as cerebrovascular (stroke).
- Any short-term cardiovascular effects (short term), other than IHD mortality
- Respiratory effects either long or short term; mortality or morbidity
- Cancer mortality other than lung cancer
- Nervous system effects (morbidity)

Compare this to the Global Burden of Disease analyses which have developed risk assessment estimates for mortality from All Causes, Ischemic Heart Disease (IHD), Cerebrovascular Events (Stroke), Lower Respiratory Infections (LRI), Chronic Obstructive Pulmonary Disease (COPD) and Lung Cancer.

Presumably because of the time and resource constraints, the risk assessment is limited to a subset of the relevant health end-points. This implies that any findings of increased risk will be an underestimate of the true net risk.

***b) The selection criteria for the 47 urban areas and PM<sub>2.5</sub> air quality scenarios analyzed?***

Urban areas were selected for the risk assessment to be in some sense a representative sample of the US population. Three criteria are given for the selection of the 47 urban areas:

- *Available ambient monitors: “areas with relatively dense ambient monitoring networks”* This is not defined.
- *Geographical Diversity: “areas that represent a variety of regions across the U.S. and that include a substantial portion of the U.S. population”* Again not defined and there is not evidence that this actually was used as selection criteria. Some regions

were (e.g. northwest) were explicitly excluded. The population (>30 yrs) of these areas ranges from ~12 million to ~0.1 million. Thus, while a substantial fraction of the US population (~1/3) is included in these risk estimates, the sample is skewed towards large urban areas.

- *PM<sub>2.5</sub> air quality concentrations: “areas requiring either a downward adjustment to air quality or a relatively modest upward adjustment (i.e., no more than 2.0 µg/m<sup>3</sup> for the annual standard and 5 µg/m<sup>3</sup> for the 24-hour standard). In addition, ... we excluded several areas that appeared to be strongly influenced by exceptional events.”* In other words, areas with PM<sub>2.5</sub> above or modestly below the NAAQS were included in the initial screen (10/30 criteria). There were multiple adjustments to the air quality data for apparent non-representative values. 56 areas met the initial 10/30 criteria, but 9 (20%) were excluded for influence of wildfires (7 areas), one for anomalous local conditions (Eugene, OR), and another “uncertain” projections (Phoenix, AZ).

Overall, these selection criteria are ill defined with post-hoc adjustments that undermine the basis describing these 47 urban areas as representative of the US population. Nevertheless, these urban areas do provide a basis for this risk assessment and do not invalidate the results. By explicitly excluding consideration of impact of wildfires, and local and seasonal sources (wood burning), these risk assessments will underestimate the total net health burden from PM<sub>2.5</sub>.

**c) The hybrid modeling approach used for quantifying exposure surrogates across an area and adjusting air quality for alternative standard levels, as supplemented by interpolation/extrapolation?**

The objective was to provide scaling factors to bring the values at the highest monitor in selected urban areas into compliance with current or proposed alternative standards. In this case, the chemical transport model calculations were matched to regulatory monitoring to estimate the degree adjustment needed to meet current or alternative standards. Frankly, following the logic and process for this modeling was almost impossible, either in the text or the appendix. A more detailed flow chart in the text may have been helpful. While the overall approach appears to be sound, not being able to understand the details of the method does not provide confidence in the calculations.

Note that the “hybrid” model used here for assessing regulatory compliance is not in any sense comparable to the “hybrid” models used for exposure estimation in the epidemiology studies. It would be beneficial in the PA not to describe these very different approaches as “hybrid models”.

**d) The characterization of variability and uncertainty in the risk assessment?**

The characterization of the uncertainties and variability of the risk assessment is ad hoc. Alternative exposure response functions were considered, including their individual

confidence intervals. However, generally the highest value was cited, with no assessment of a central value or range of values across alternative exposure-response functions. Alternative approaches for achieving standards (PM primary and PM secondary) were considered, but effectively no consideration of uncertainties in exposure estimates. Recall also that only a subset of health outcomes found to be “causal” or “likely to be causal” are considered, so estimated numbers will be a subset of expected health numbers. This does not diminish the conclusion that there are substantial numbers of premature deaths in the United States among populations exposed to PM<sub>2.5</sub> at or below the current standards.

**e) The robustness and validity of the risk estimates?**

The risk assessment was limited in scope, only a fraction of the US population living in urban areas was examined, and the description of the methods was difficult to follow. Nevertheless, the approach was sound and the calculated numbers of premature deaths is a conservative (that is underestimate) of the true expected numbers of deaths and other adverse health events.

**SCQ-3.5 What are the panel’s views on the draft PA preliminary conclusion that, taken together, the available scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary PM<sub>2.5</sub> standards?**

The scientific evidence from the epidemiologic studies with supporting experimental evidence from controlled human exposure studies and animal toxicology is unambiguous in showing effects of PM<sub>2.5</sub> at levels below the current primary standards.

The air quality analysis of mean values and distributions of PM<sub>2.5</sub> values in the key epidemiologic studies, comparing to design values, and examination of “pseudo-design values” addresses some secondary questions in extrapolating from the epidemiologic studies to practical control issues. These analyses confirm that the epidemiologic studies are showing health effects at PM<sub>2.5</sub> levels defined either by the epidemiologic exposure measures or appropriate design values which are at or below the current annual and 24-hour standards.

The risk assessment approach was appropriate although not clearly presented. The risk assessment itself was limited to a subset of the “causal” and “likely to be causal” health effects, and limited to a subset of the US population with PM<sub>2.5</sub> ambient concentrations above or slightly below the current standards. Thus, the risk assessment, which is built on the epidemiologic evidence and the air quality analyses, provides conservative (that is underestimates) of likely net numbers of adverse health events attributable to PM<sub>2.5</sub> levels around the current standard. The risk assessment findings of substantial number of PM<sub>2.5</sub> attributable deaths provides important context for the evidence-based analyses.

Together these approaches provide coherent and consistent evidence that the current PM<sub>2.5</sub> annual and 24-hour standards do not provide adequate protection of the public health.



**EPA-6. Chapters 3 to 5: What are the CASAC views regarding the areas for additional research identified in Chapters 3, 4 and 5? Are there additional areas that should be highlighted?**

Sub-Daily PM<sub>2.5</sub> Exposures: The PA concludes that there is insufficient evidence for consideration of averaging times less than 24-hours. However, this lack of evidence is largely driven by the current form of the PM<sub>2.5</sub> NAAQS based on annual and 24-hour averages. Epidemiologic studies are largely based on exposure measurement methods which follow the EPA FRMs and NAAQS. Thus, few studies have considered sub-daily exposures. Consideration of peak versus 24-hour mean is not equivalent to examining PM<sub>2.5</sub> associations in the previous hour(s). As the Integrated Science Assessment notes, there are a limited number of studies which show increased risk of cardiovascular events (myocardial infarctions and arrhythmias) associated with PM<sub>2.5</sub> exposures in the previous hours. Likewise, controlled human exposure studies show changes in clinical cardiac indicators after PM<sub>2.5</sub> exposures of only an hour or less. As continuous PM data becomes available, it is important to examine associations with these sub-daily exposures. Note that wildfire exposures are usually brief (sub-daily) but intense, so understanding the effects of these specific exposures is challenging, but increasingly important.

## Mr. Henry (Dirk) Felton

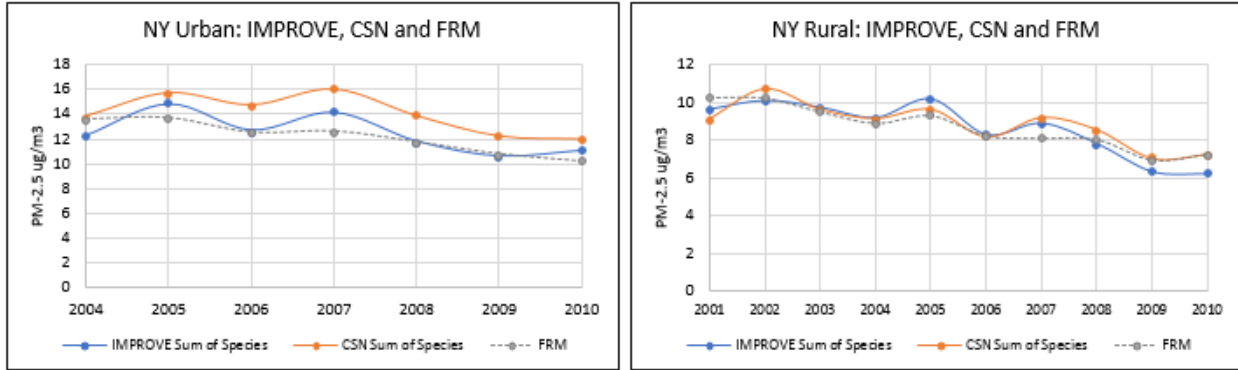
### SCQ 2.1

The draft PA does not provide a clear and concise summary of air quality. When data from different monitoring programs are discussed, inconsistent date ranges are used. The PM data are presented as design values from 2015-2017, ultrafine data are presented for 2014-2015, IMPROVE data are presented from 2004 and 2016 and the analysis on background PM used 2016 IMPROVE data. These data sets from different time periods were then compared to model results for 2011 and source categories from the 2014 NEI. Taking data from different date ranges reduces the validity of the conclusions that can be drawn. For instance, 2016 was a year that included the Fort McMurray wildfire in Alberta Canada. That year should not have been singled out as a representative year to look at background PM. The number of acres burned varies from year to year so a longer dataset should be used.

The plots used to show the NEI for PM-2.5 and PM-10 were not very helpful. Pie charts showing national average emissions don't provide information specific to regions, urban or rural regions or for areas with high or low ambient concentrations.

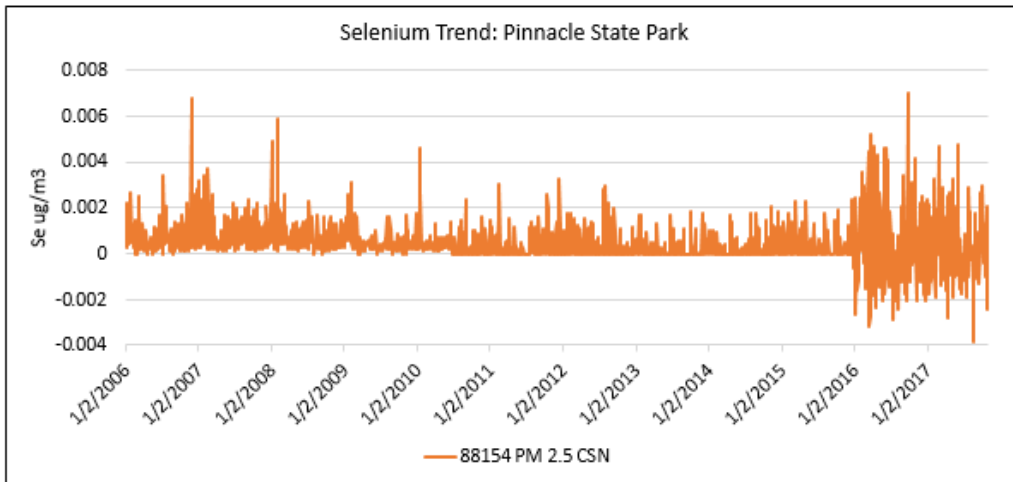
The draft PA also provided very little information about the components of PM-2.5. The National plots only included four species and no elemental data and no mass balance analysis was provided.

The draft PA's summary of air quality should address the shortcomings of the CSN program. This program was originally designed with six objectives linked to assessing PM-2.5 components over time so States could develop and track SIPs and related control programs. One objective included comparing the mostly urban CSN data with the mostly rural IMPROVE program. Over time, the CSN sampling protocol and the analysis methods for some of the species have been changed to more closely align with the equipment and methods used in the IMPROVE program. These changes have been to the detriment of the State Agencies who need this data to align as closely as possible with the equipment and protocols related to the PM-2.5 FRM. NYSDEC operated collocated CSN and IMPROVE sites to assess the differences between the programs. The two methods were in better agreement at the rural site where volatile species including OC were lower. At the urban site where the accuracy of the species data were critically important for source attribution, SIP development and control strategy tracking, the CSN results were too high in comparison to the PM-2.5 FRM.



Data from the South Bronx and from Pinnacle State Park

The CSN program has also been impacted by contractual changes. In late 2015, the CSN laboratory contract was awarded to a different laboratory and this has negatively impacted many of the elemental results. Some low concentration elements have been useful because they can be linked to specific source categories. This data has been used to identify local and out of State source impacts so they can be addressed appropriately. In the plot below, Selenium which has been used to identify coal combustion does not have a useful trend after the change in laboratories.



Selenium CSN Data from Pinnacle State Park

The CSN program is a valuable resource but it has been compromised by competing interests and as a result correction factors have to be applied to various species and some of the elemental data can no longer be used to detect trends. This program needs to be redesigned to make it more representative of the PM-2.5 in urban areas where ambient concentrations are likely to be closer to the primary NAAQS.

**SCQ 3.3**

**d)** Setting a health-based standard that only attempts to limit detrimental health effects for the population within the 25<sup>th</sup> and the 75<sup>th</sup> percentile of annual PM concentrations does not represent an adequate margin of safety for at least one quarter of the population. In fact, the admission that the level based on this analysis would only protect a portion of the population against “an array of serious health effects, including premature mortality and increased hospitalizations for cardiovascular and respiratory

effects” shows that little attention is paid to susceptible populations and no protections are afforded for health effects short of hospitalization and mortality.

### SCQ 3.5

The draft PA addresses each element of the NAAQS individually: indicator, averaging time, form and level. The problem is that the analyses of PM concentration and health effects that accompany each element do not examine each element in isolation. The analyses that accompany the discussion about levels only examine studies that conform to either the averaging time and form of the annual or 24-hour standard. No effort was made to examine health effects resulting from data collected using other averaging times or forms. With this kind of limit: “blindness” on analyses, there is no opportunity to demonstrate the need for a sub daily or alternate form of the standards.

### SCQ 3.6

**a)** The current PM-10 and PM-2.5 standards are set to protect against respiratory and circulatory system health impacts. Ultrafine particles (UFP) have an additional central nervous system (CNS) health exposure pathway that is not controlled by a standard. A new standard should be set to reduce exposures to higher UFP levels. Some of the largest sources of UFP are combustion sources including stationary and motor vehicles. Motor vehicle emissions can be high from HDD vehicles that have damaged or poorly maintained emission control systems. Vehicle brake and tire wear are also sources that impact most of the population. Setting a UFP standard with a short averaging time would help drive improved controls on sources including HDD vehicles and would reduce exposures in near road communities.

**b)** The averaging times of the existing PM standards do not adequately protect populations exposed to elevated PM concentrations (UFP, PM-2.5, PM-10) typically found near roadways during weekday morning commuting hours. These impacts are often the highest exposures in many communities and are more evident near roadways with a higher proportion of HDD vehicles.

The beginning and end times for the averaging time of the 24-hr standard are also not adequate to protect against residential heating and recreational wood smoke impacts. The occurrences of these emissions typically begin in the evening and end in the early morning. The midnight to midnight form of the 24-hour standard effectively cuts these impacts into two which in many cases ends up reducing the regulatory impact by averaging additional cleaner hours of two days. Monitoring data have shown that exceedances of the 24-hour standard would be more frequent if the standard were based on noon to noon or on a rolling 24-hour average basis.

**f)** A lower annual standard does not do enough to reduce the impact from short-term or sporadic sources such as wood smoke from building heating, agricultural burning or industrial activity. Impacts from these sources can have very significant impacts on smaller scales in urban or rural communities. These emissions must be controlled if they impact fewer people just as much as the sources that impact larger scales. Another disadvantage of lowering just the annual standard is that it may increase the number of times when there is a  $10 \mu\text{g}/\text{m}^3$  change in concentration. Health effects have been found to occur when there are  $10 \mu\text{g}/\text{m}^3$  changes in air quality in relatively clean and in relatively polluted cities. To prevent these harmful swings in air quality, the daily standard must be lowered in conjunction with or prior to lowering the annual standard.

**GC-4**

Peaks in background PM are often the result of wildfire emissions or dust storms. These sporadic emissions should not be included in a discussion of peak background PM relative to a NAAQS because these emissions can be excluded from attainment consideration using the exceptional events policy.

Peaks in concentrations resulting from anthropogenic emissions do need to be included in NAAQS data assessments. In urban areas where PM-2.5 concentrations are closer to current NAAQS, contributions from background PM sources are smaller and less relevant.

## H. Christopher Frey

These comments build upon written comments that I submitted to CASAC and EPA as an attachment to a consensus letter from the Independent Particulate Matter Review Panel (IPMRP) on December 10, 2018,<sup>22</sup> as individual comments to CASAC and EPA on March 26, 2019,<sup>23</sup> and as part of a consensus letter from the IPMRP on March 27, 2019.<sup>24</sup>

### Process Issues

Since 2017, numerous changes have been made to the scientific review process for the National Ambient Air Quality Standards (NAAQS), including changes that affect the membership and composition of the EPA Clean Air Scientific Advisory Committee (CASAC). These changes have been made without advance notice to, or input from, the full chartered CASAC, EPA staff, or the public. The changes include: (a) imposing non-scientific criteria for appointing CASAC members related to geographic diversity and affiliation with governments; (b) replacing the entire membership of the chartered CASAC in a period of one year; (c) banning recipients of scientific research grants while allowing persons affiliated with regulated industries to be members of CASAC; (d) ignoring statutory requirements for the need for a thorough and accurate scientific review of the NAAQS in setting a review schedule; (e) reducing the number of drafts of a document for CASAC review irrespective of whether substantial revision of scientific content is needed; (f) commingling science and policy issues; (g) depriving CASAC of the needed breadth, depth, and diversity of scientific expertise for the PM NAAQS review by disbanding the CASAC PM Review Panel; (h) depriving CASAC of the needed breadth, depth, and diversity of scientific expertise for the ozone NAAQS review by refusing to form a CASAC Ozone Review Panel; and (i) creation of an ad hoc “pool” of consultants that fails to address the deficiencies created by disbanding the CASAC PM Review Panel and not forming a CASAC Ozone Review Panel. Each one of these changes harms the quality, credibility, and integrity of the NAAQS review for both PM and ozone.

EPA should appoint members to CASAC and its review panels based on the need for breadth, depth, and diversity of scientific expertise, not geographic diversity and government affiliation. Consistent with Federal peer review guidance, EPA should allow leading researchers who hold EPA scientific research grants to serve, subject to previously existing requirements that such

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<sup>22</sup> Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, “CASAC Review of EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018),” 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014-0859, December 10, 2018.  
[https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/\\$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf)

<sup>23</sup> Frey, H.C., “Public Comment: Deficiencies of Procedure and Expertise Must Be Corrected,” Written Comment to the Clean Air Scientific Advisory Committee,” U.S. Environmental Protection Agency, Washington, DC, March 26, 2018,  
[https://yosemite.epa.gov/sab/sabproduct.nsf/46BBA443B9D953A9852583C9004F1F00/\\$File/Frey+Written+Public+Comments+to+CASAC+190326+Final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/46BBA443B9D953A9852583C9004F1F00/$File/Frey+Written+Public+Comments+to+CASAC+190326+Final.pdf)

<sup>24</sup> Frey, H.C., A.V. Diez Roux, P. Adams, G. Allen, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R. McConnell, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, “03-07-19 Draft CASAC Review of EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018),” 19 page letter submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, March 27, 2019.  
[https://yosemite.epa.gov/sab/sabproduct.nsf/A491FD482BB83BEE852583CA006A2548/\\$File/Written+Comments+from+17+Members+of+the+CASAC+PM+Review+Panel+that+was+Disbanded+on+October+11+2018+rev.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/A491FD482BB83BEE852583CA006A2548/$File/Written+Comments+from+17+Members+of+the+CASAC+PM+Review+Panel+that+was+Disbanded+on+October+11+2018+rev.pdf)

persons do not deliberate on their own work. EPA should recognize that there is a learning curve to service on CASAC and, therefore, value in appointing members to staggered terms and reappointing members to a second three-year term. EPA should allow adequate time for the scientific review. EPA should not combine assessment documents in a review unless this is consistent with a final Integrated Review Plan that has been agreed to by CASAC. EPA should allow for the likelihood that complex scientific and policy documents such as an Integrated Science Assessment, Risk and Exposure Assessment, and Policy Assessment may need substantial revision and re-review. EPA should better manage the timing of key milestones in the NAAQS review process so as not to selectively take time away from CASAC as a means to compensate for delays created by EPA elsewhere in the review. EPA should not introduce policy considerations until the scientific issues have been adequately settled. EPA should continue to follow the successful practice, proven for four decades, of augmenting CASAC with the expertise it needs via review panels that deliberate interactively with members of the chartered CASAC. EPA should not make ad hoc changes to the NAAQS review process in the middle of a review. If EPA wishes to make changes to the NAAQS review process, it should do so in a systematic manner similar to that employed in 2006, when EPA staff, CASAC, and others had an opportunity to provide input.

CASAC does not have adequate breadth, depth, and diversity of scientific expertise and experience needed to conduct thorough reviews based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to the Particulate Matter NAAQS.

**Emphasis has been placed on geographic diversity, not scientific expertise**, in appointing members of CASAC, per an October 31, 2017 memorandum by former Administrator Scott Pruitt.<sup>25</sup> This policy has been implemented by Administrator Scott Wheeler in appointing members to CASAC on October 31, 2017 and by Administrator Andrew Wheeler in appointing five members to CASAC on October 10, 2018.<sup>26</sup> In revising criteria for membership on EPA Federal Advisory Committees, the October 31, 2017 memorandum from former Administrator Pruitt, EPA should have recognized that such committees may serve different purposes, and should have acknowledged Federal guidance on peer review. The membership criteria for a scientific review committee should not be the same as the membership criteria for a stakeholder committee.

**Emphasis has been placed on affiliation with state, local, and tribal governments, not scientific expertise**, in appointing members of CASAC, per October 31, 2017 memorandum by former Administrator Scott Pruitt. Although by law CASAC must have at least “one person representing State air pollution control agencies,” CASAC must also have sufficient expertise to do its job. As of October 10, 2018, with the new appointments by Administrator Wheeler, CASAC had four members from state agencies (Georgia, Texas, Alabama, and Utah) and had another appointee who was affiliated with a Federal agency. Having four members from state agencies does not make CASAC four times better. CASAC is less scientifically qualified than it would otherwise have been had the appointments been made, instead, based on selecting the best scientists.

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<sup>25</sup> Pruitt, E.S., “Strengthening and Improving Membership on EPA Federal Advisory Committees,” Memorandum, U.S. Environmental Protection Agency, October 31, 2017. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>

<sup>26</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-act-committee>

**A policy to have more member turnover** on CASAC, per the October 31, 2017 memorandum by former Administrator Scott Pruitt, has led to 100% turnover in just one year. In his October 10, 2018 appointments to CASAC, Administrator Wheeler replaced five CASAC members with five people who had never served on the chartered CASAC. Coupled with the appointments a year earlier by Administrator Pruitt of a chair and a member with no prior CASAC experience, as of October 2018 the chair and members of the chartered CASAC had a grand total of two person-years of experience on the CASAC, and little to no institutional memory of how CASAC operates. The new policy to enhance member turnover fails to acknowledge that there are benefits of continuity and knowledge provided by having some previous members continue to serve. Under this new policy, **well-qualified scientists have been “rotated” off of the CASAC, in favor of new members without needed subject matter expertise and without prior experience** on CASAC or CASAC review panels, selected instead for their affiliation or geographic location. CASAC is now the most inexperienced and unqualified that it has been in its history.

**Banning recipients of EPA research grants from serving on CASAC**, per the October 31, 2017 memorandum by former Administrator Scott Pruitt, is clearly intended to keep top academic researchers from serving on CASAC. The memorandum states that “no member of an EPA federal advisory committee currently receive EPA grants,” but that this “principle should not apply to state, tribal, or local government agency recipients of EPA grants.” This is inconsistent with the Federal Advisory Committee Act and inappropriate for four reasons. One is the obvious inconsistency of implying that receiving a grant creates a conflict of interest for one but not another class of persons. The second is the longstanding recognition that **receipt of a peer-reviewed scientific research grant, for which the Agency does not manage the work nor control the output, is not a conflict of interest**. Per the Office of Management and Budget (OMB): “When an agency awards grants through a competitive process that includes peer review, the agency’s potential to influence the scientist’s research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist’s ability to offer independent scientific advice to the agency on other projects.”<sup>27</sup> A 2013 report by the EPA Office of Inspector General reaffirmed that receipt of an EPA research grant is not a conflict of interest.<sup>28</sup> However, there can be situations in which a member of an advisory committee should recuse themselves from discussions that might pertain to their own work. Thus, third, the CASAC has had recusal policies in place for dealing with this issue and situations in which a member’s work may come up for deliberation. Fourth, **the memorandum does not acknowledge that persons with financial or professional ties to regulated industries have, at the very least, the appearance of conflict of interest**.

**Former EPA Administrator Pruitt signed a memorandum on May 9, 2018 that made major changes to the scientific review process for the NAAQS.**<sup>29</sup> The memo is replete with

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<sup>27</sup> Office of Management and Budget, “Final Information Quality Bulletin for Peer Review,” *Federal Register*, 70(10):2664-2677 (January 14, 2005), <https://www.govinfo.gov/content/pkg/FR-2005-01-14/pdf/05-769.pdf>

<sup>28</sup> EPA, “EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees,” Report No. 13-P-0387, Office of Inspector General, U.S. Environmental Protection Agency, Washington, DC, September 11, 2013. <https://www.epa.gov/sites/production/files/2015-09/documents/20130911-13-p-0387.pdf>

<sup>29</sup> Pruitt, S.E., “Back to Basics Process for Reviewing National Ambient Air Quality Standards,” Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 9, 2018. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>



cherry-picking of incomplete information that fails to accurately characterize the previously existing NAAQS review process, including its strengths. The memorandum emphasizes that the Clean Air Act requires that NAAQS be reviewed every five years, but fails to emphasize the statutory mandate for a thorough and accurate scientific review. For those NAAQS reviews for which EPA entered into a consent decree or was under court order to complete a review, the court-supervised schedules have taken into account the need for EPA staff to develop assessment documents and for CASAC to review the documents and advise the Administrator. Thus, the memorandum fails to acknowledge that courts have recognized that the time needed for a thorough and accurate scientific review can be taken into account in setting schedules that go beyond the five year time frame. Instead, EPA is self-imposing a schedule that compromises the quality, credibility, and integrity of the scientific review and is doing so in a manner beyond what courts have historically imposed.

The memorandum gives the misleading impression that delays in the review process are attributed to CASAC. Based on analysis that I submitted as part of my individual member comments attached to the IPMRP's December 10, 2018 letter to CASAC, I showed that the duration of CASAC activities in a NAAQS review cycle is far less than the total duration of the review cycle. A key factor that increases the duration of CASAC's involvement in a review cycle is delay in EPA providing CASAC with assessment documents for review. Furthermore, the memorandum omits any discussion of the more salient factors that have led to delays in the NAAQS review process related to decisions made by the EPA, not CASAC, as detailed below. EPA should not impose a reduced duration schedule for the scientific review that compromises the scope and quality of the scientific review. The duration of a review cycle is dependent on the following:

- (1) EPA controls the duration of time between the conclusion of a prior review cycle and the initiation of the subsequent review cycle;
- (2) EPA decides the allocation of resources for development of assessment reports by EPA staff that are part of the scientific review process;
- (3) EPA decides when to release a draft document for CASAC review;
- (4) EPA has been responsible for delays in providing draft assessments to the CASAC for review;
- (5) Whether a draft EPA document requires further iteration depends on its initial scientific quality; and
- (6) EPA has control over the timing of the NAAQS review process from the time that it receives closure on advice from CASAC until it promulgates a final decision.

Although the May 9, 2018 memorandum gives some attention to the last point in the list above, it fails to account the first five listed EPA-driven factors that lead to delays in review cycles. **Based on incomplete and erroneous diagnosis of leading causes of delay**, and without due consideration for statutory requirements as described above, including the need for a "thorough review" based on the "latest scientific knowledge" of the "kind and extent of... effects," **the May 9, 2018 memorandum inappropriately targets measures to reduce the duration of CASAC's engagement in the review process.**

The late 2020 deadline for completing the particulate matter review given in the May 9, 2018 memorandum is contrary to EPA's own final Integrated Review Plan for the PM NAAQS

review<sup>30</sup> and 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, even if the CASAC were supported by a robust panel of experts in the multiple disciplines involved. Furthermore, the quality and credibility of the review depends on whether CASAC is augmented with an appropriately constituted PM Review Panel.

On October 10, 2018, then acting EPA Administrator Wheeler eliminated the CASAC PM Review Panel by press release,<sup>31</sup> with a follow-up email from the SAB office on October 11, 2018. This was done without advance notice and without prior consultation with the panel or the CASAC. There is no precedent for disbanding a review panel in the middle of a review cycle.

The actual reason as to why Administrator Wheeler disbanded the PM Review Panel and refused to form an Ozone review panel has likely not yet been publicly disclosed. Two general talking points have emerged from EPA leadership regarding the elimination of review panels for PM and ozone. One is that the CASAC is the sole advisory body charged with advising EPA per the Clean Air Act. The other is that the panels needed to be eliminated to ‘streamline’ the review process. Both of these talking points are specious.

The talking point that only CASAC should advise the Administrator is specious because in fact it has only been the CASAC that has advised the Administrator throughout the history of CASAC. Per CASAC’s charter with the U.S. Congress:<sup>32</sup>

“EPA, or CASAC with the Agency’s approval, may form subcommittees or workgroups for any purpose consistent with this charter. Such 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.”

Thus, **it has always been the chartered CASAC, not its panels, that advise the EPA.** It has been long-standing practice since the 1970s to augment the 7-member CASAC with additional independent experts, so as to have the breadth and depth of expertise required to conduct a “thorough review” based on the “latest scientific knowledge,” consistent with requirements of the Clean Air Act, as detailed in my individual comments attached to the IPMRP letter to CASAC dated December 10, 2018. **It is not sufficient, as the Administrator suggested, to state that the 7 member committee meets the minimum requirements of the law.**

The talking point that panels must be eliminated to streamline the review process is specious because, **without the panels, CASAC does not have the breadth, depth, and diversity of**

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<sup>30</sup> EPA, “Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter,” EPA-452/R-16-005, U.S. Environmental Protection Agency, Research Triangle Park, NC, December 2016. <https://www3.epa.gov/ttn/naaqs/standards/pm/data/201612-final-integrated-review-plan.pdf>

<sup>31</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-act-committee>

<sup>32</sup> United States Environmental Protection Agency Charter, Clean Air Scientific Advisory Committee, Filed with Congress, June 5, 2019, [https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/\\$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf)

**expertise to conduct scientific review consistent with the Clean Air Act requirements for being accurate and thorough.** Thus, the panels are essential. Secondly, the panels do not slow down CASAC's review time. They work in parallel and concurrently with the chartered CASAC.

The EPA released the external review draft of the Integrated Science Assessment (ISA) on October 15, 2018, five days after disbanding the CASAC PM Review Panel.<sup>33</sup> The Federal Register notice announcing that the draft ISA was available for public review was dated October 16, 2018 and published on October 23, 2018.<sup>34</sup>

Compared to the chartered CASAC, the PM review panel had more experts, covered more scientific disciplines, and had multiple experts who provide diversity of perspectives in many key disciplines, such as epidemiology, toxicology, and human clinical studies, among others.

After receiving public comments at its December 2018 and March 2019 public meetings on the draft ISA, CASAC requested in its April 11, 2019 letter to the Administrator that it review a second draft of the Integrated Science Assessment for Particulate Matter, and that it be augmented with the expertise necessary for such a review by either reappointing the disbanded PM review panel or appointing a similar panel.<sup>35</sup> In a July 25, 2019 letter to CASAC, the Administrator refused these requests.<sup>36</sup> **The Administrator stated that there will not be a second external review draft of the ISA.** The Administrator did not directly address any rationale for why he did not reappoint the disbanded panel or form a similar panel. Instead, the Administrator decided to appoint a "pool" of "subject matter" consultants. As described below, **the "pool" of consultants does not address deficiencies created by the same Administrator when he disbanded the PM review panel.**

The lack of a second draft of the ISA is highly problematic, particularly because the draft Policy Assessment is based on scientific evidence from the ISA. In prior NAAQS reviews, it has been typical practice that CASAC reviews a second and sometimes third draft (as in the cases of the most recent lead and ozone reviews) of the ISA. It has been typical practice that CASAC has had the opportunity to review a draft Policy Assessment **AFTER** it has completed reviews of draft ISAs. This sequence was by design. A key principle of the 2006 revisions to the NAAQS review process, which were modified in part in 2007 and 2009, is that the scientific foundation of

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<sup>33</sup> EPA, "Integrated Science Assessment for Particulate Matter (External Review Draft)," EPA/600/R-18/179, U.S. Environmental Protection Agency, Research Triangle Park, NC, October 2018.  
[https://yosemite.epa.gov/sab/sabproduct.nsf/0/932D1DF8C2A9043F852581000048170D/\\$File/PM-1STERD-OCT2018.PDF](https://yosemite.epa.gov/sab/sabproduct.nsf/0/932D1DF8C2A9043F852581000048170D/$File/PM-1STERD-OCT2018.PDF)

<sup>34</sup> EPA, "Integrated Science Assessment for Particulate Matter (External Review Draft)," *Federal Register*, 83(205):53471-53472 (October 23, 2019). <https://www.govinfo.gov/content/pkg/FR-2018-10-23/pdf/2018-23125.pdf>

<sup>35</sup> Cox, L.A. (2019), "CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)," EPA-CASAC-19-002, Letter to A. Wheeler, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, April 11, 2019.  
[https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf)

<sup>36</sup> Wheeler, A.R. (2019), Letter to L.A. Cox, EPA Clean Air Scientific Advisory Committee, from Administrator, U.S. Environmental Protection Agency, Washington, DC, July 25, 2019,  
[https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002\\_Response.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf)

the review must be established before addressing policy issues.<sup>37,38,39</sup> Failure to do 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.**

In this review cycle for PM, there are significant areas of indicated need for revision for the draft ISA based on comments from the Independent Particulate Matter Review Panel and members of the public. Thus, neither CASAC nor the public will have an opportunity to see how unresolved issues in the draft ISA that might have impacted the PA will be handled in a final version of the ISA. The final version of the ISA will not be available until after this EPA forces CASAC to conclude its involvement in this review cycle.

The Administrator announced a “pool” of 12 subject matter experts in an EPA press release on September 13, 2019.<sup>40</sup> The pool of 12 are intended to respond to written questions from the chartered CASAC for both the PM and ozone NAAQS reviews. In contrast, the disbanded PM review panel had 20 experts in addition to the chartered CASAC. At the same time that the Administrator disbanded the CASAC PM Review Panel on October 10, 2018, he also announced that he would not form a CASAC Ozone Review Panel. This was despite the fact that EPA had requested nominations for a CASAC Ozone Review Panel in a Federal Register notice on July 27, 2018.<sup>41</sup> In the prior ozone NAAQS review, which was completed in 2015, the CASAC was augmented with 15 additional experts to form an ozone review panel. Thus, **the total number of augmented experts for the prior ozone review and the current PM review through 2018 was 35. Twelve people is not an adequate number to cover the breadth, depth, and diversity of scientific expertise and experience needed for review of both ozone and PM.**

**The use of a “pool of subject matter experts” rather than a review panel to augment the chartered CASAC is unprecedented.** Review Panels augment and report through the chartered CASAC, working in parallel and in collaboration with the members of the chartered CASAC. Members of review panels are nominated by the public and the nominations are subject to public comment. The SAB staff office reviews, vets, and appoints members of review panels. Members of review panels participate in meetings with members of the chartered CASAC, and deliberate interactively with members of the chartered CASAC on complex subject matter. The chartered CASAC is ultimately responsible for the content of advice sent to the Administrator, but the formulation of that advice is informed based on deliberations with panelists who provide the breadth, depth, and diversity of needed scientific expertise.

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<sup>37</sup> Peacock, M., “Process for Reviewing National Ambient Air Quality Standards,” Memorandum to George Gray and Bill Wehrum, U.S. Environmental Protection Agency, Washington, DC, December 7, 2006.

<sup>38</sup> Peacock, M., “Modifications to Process for Reviewing National Ambient Air Quality Standards,” Memorandum, U.S. Environmental Protection Agency, Washington, DC, April 17, 2007

<sup>39</sup> Jackson, L., “Process for Reviewing National Ambient Air Quality Standards,” Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 21, 2009.  
<https://www3.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf>

<sup>40</sup> EPA, “Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts,” News Release, U.S. Environmental Protection Agency, Washington, DC, September 13, 2019.  
<https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts>.

<sup>41</sup> EPA, “Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel,” *Federal Register*, 83(145): 35635- 35636 (July 27, 2018). <https://www.govinfo.gov/content/pkg/FR-2018-07-27/pdf/2018-16116.pdf>

In contrast, **there was no opportunity for public comment on the nominees for the pool of subject matter experts.** The decision regarding appointments of ad hoc consultants to serve as subject matter experts was made by the Administrator, not by the SAB Staff Office. The General Accountability Office has documented irregularities in the process since 2017 by which appointments have been made to EPA advisory committees, including the CASAC.<sup>42</sup>

**Appointments made directly by the Administrator are subject to political considerations** and can disregard input from EPA career staff in the Science Advisory Board Staff Office regarding scientific considerations in selecting members and consultants. All interactions between CASAC and the subject matter experts are done only in writing. **Subject matter experts are not allowed to participate in deliberative meetings with CASAC.** For example, subject matter experts are not allowed to, unless invited in writing by the chair or designees of the chair, respond to all charge questions that might be of interest to the consultant. If a member of the pool of experts offers written comments that are inaccurate, are out of scope, or have other problems, there is not an effective mechanism for interaction that might have led to more relevant and refined input. Moreover, the composition of the pool of consultants does not provide CASAC the breadth, depth, and diversity of expertise needed for review of either the ozone or the PM NAAQS. **The appointment of consultants by the Administrator is not correcting the deficiencies in CASAC's ability to conduct a thorough review that have resulted from disbanding the PM Review Panel.**

**EPA should reinstate the disbanded PM review panel and appoint an ozone review panel. These panels should be appointed by the director of the SAB staff office, not by the Administrator, per established procedures in place prior to interference by the current EPA Administrator.**

In attempting to alter the NAAQS review process, if any changes are warranted, EPA should have followed the kind of open and transparent process undertaken in 2006, which included input from EPA career staff, the chartered CASAC, and members of the public. Such a process would lead to a better understanding of the key needs and challenges of NAAQS review and perhaps effective ideas for reviews which are more timely.

As a result of the many deleterious, unprecedented, and unwarranted changes to the CASAC described above, CASAC has transitioned from a committee of nationally and internationally recognized researchers at the leading edge of their fields toward a committee composed predominantly of stakeholders chosen based on geographic location and affiliation with state government, rather than scientific expertise first and foremost. **CASAC does not have adequate breadth, depth, and diversity of scientific expertise and experience needed to conduct thorough reviews based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to the Particulate Matter NAAQS.** This is generally true given that CASAC is comprised of only seven members, whereas these reviews require multiple experts in each of many scientific disciplines. This is even more true given that the current CASAC was appointed based primarily on geography and affiliation, and not by scientific discipline, in accordance with the October 31, 2017 memo by former Administrator Pruitt. According to November 7, 2018 "determination" memorandum from the EPA SAB office, the CASAC has no epidemiologists,<sup>43</sup> even though epidemiology is a key scientific discipline related

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<sup>42</sup> GAO, EPA Advisory Committees: Improvements Needed for the Member Appointment Process, GAO-19-280, General Accountability Office, Washington, DC. <https://www.gao.gov/assets/710/700171.pdf>

<sup>43</sup> Yeow, A., "Determinations Associated with the Clean Air Scientific Advisory Committee (CASAC) Review of the Particulate Matter (PM) National Ambient Air Quality Standards (NAAQS)," Memorandum to T.H. Brennan, Science

to both the ozone and PM reviews. The CASAC lacks adequate coverage of many other disciplines, such as exposure assessment, welfare effects, and other areas, and lacks depth in areas for which CASAC has historically and necessarily engaged multiple experts, such as toxicology and controlled human studies.

**The Administrator should reinstate the disbanded CASAC PM Review Panel or should form a similar panel to augment CASAC for the current review of the PM NAAQS. The Administrator should form a CASAC Ozone Review panel to augment the CASAC for the current review of the ozone standard. The EPA should reaffirm and continue the established and successful practice, demonstrated for four decades, of augmenting CASAC with expert panels for each NAAQS review.**

To promote transparency of the review and opportunity for public input consistent with long-standing practice, the CASAC should have a longer time frame for its deliberations, consistent with historic practice in the last decade, and should not have the public meeting process truncated to meet shortened deadlines that resulted from EPA delays in starting the current review. The current self-imposed review schedule for the PM NAAQS review is contrary to the final PM IRP. It has fewer public meetings of CASAC and, therefore, fewer opportunities for public comment. For the ozone NAAQS review, the EPA is planning that CASAC will have only one face-to-face meeting to simultaneously review the draft ISA and draft PA, which even more severely limits opportunities for public comment compared to prior review cycles.

EPA's focus on rushing the scientific review of both the PM and Ozone NAAQS is clearly hypocritical. Although the Administrator has emphasized the need to meet the five year statutory mandate of the Clean Air Act for NAAQS review, not only has the Administrator not acknowledged that courts have allowed adequate time for scientific review when EPA has missed such deadlines, but the Administrator has been silent regarding the timing of reviews for carbon monoxide, lead, nitrogen dioxide, and sulfur oxides. For example, the most recent review of the carbon monoxide NAAQS concluded on August 31, 2011. The most recent lead review concluded on October 18, 2016. The most recent nitrogen dioxide review concluded on April 6, 2018. Why has the EPA not started new review cycles for these pollutants? **Delays by EPA in starting review cycles or developing assessment documents should not infringe on the duration of review and comment activities by CASAC and the public.**

### **Decision Context for NAAQS Review May Not Be Redefined by CASAC**

CASAC may not redefine the policy and decision context of NAAQS review. This context is set forth by Congress in the Clean Air Act, including but not limited to the following excerpts. From Section 108:

The NAAQS must address "air pollution which may reasonably be anticipated to endanger public health or welfare"

"Air quality criteria for an air pollutant 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

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Advisory Board, U.S. Environmental Protection Agency, Washington, DC, November 7, 2018.  
[https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/64C246444C9CC319852584430045E365/\\$File/Determination%20memo-Chartered%20CASAC%20PM-110718.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentCASAC/64C246444C9CC319852584430045E365/$File/Determination%20memo-Chartered%20CASAC%20PM-110718.pdf)

ambient air, in varying quantities.” and “any known or anticipated adverse effects on welfare”

And from Section 109:

The Administrator “shall complete a thorough review of the criteria” published under Section 108.

“National primary ambient air quality standards, prescribed under subsection (a) shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.”

Note that nowhere does the Clean Air Act state that EPA should take a risk-neutral or risk-seeking attitude toward risk, nor that EPA should limit its assessment only to those studies that individually can demonstrate manipulative causality consistent with particular quantitative causal tests and inference methods. The language of the Clean Air Act means that EPA cannot throw out studies according to arbitrary “quality” criteria if that would compromise the ability to conduct a thorough review and account for the full scope of review as mandated in the Act.

### **The Role of Expert Judgment in Scientific Review of the NAAQS**

In the current review process the Administrator has arbitrarily and capriciously done away with the CASAC PM Review Panel. **Given the important role of expert judgment in CASAC’s work, it is essential that CASAC be augmented with additional experts in the multiple scientific disciplines needed for this review.** Furthermore, there must be multiple experts in key areas, such as air quality physics and chemistry, exposure assessment, toxicology, controlled human studies, epidemiology, and others, to have a diversity of perspectives to assure that judgment is based on the large body of relevant scientific evidence using accepted inference methods. For four decades, CASAC has been augmented with expert panels as documented by Frey et al. (2018) and others<sup>44,45,46</sup>. Augmented panels advise the CASAC and supplement it with the expertise it needs. Absent such augmented expertise, the chartered CASAC is scientifically unqualified to conduct a review consistent with language in the Clean Air Act.

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<sup>44</sup> Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Samat, E.A. Sheppard, B. Turpin, and S. Vedal, “CASAC Review of EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018),” 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014-0859, December 10, 2018, Appendix E. [https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/\\$File/PMRP+Letter+to+CA+SAC+181210+Final+181210.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CA+SAC+181210+Final+181210.pdf)

<sup>45</sup> Bloomer, L., and J. Goffman, “The Legal Consequences of EPA’s Disruption of the NAAQS Process,” Environmental and Energy Law Program, Harvard Law School,” undated, <http://eelp.law.harvard.edu/wp-content/uploads/Legal-Consequences-of-NAAQS-Changes.pdf>, accessed 10/7/19

<sup>46</sup> Bachmann, J., “Written Statement for the Public Meeting of the EPA Chartered Science Advisory Board, Re: 5/31 SAB Discussions about EPA Planned Actions and their Supporting Science,” Environmental Protection Network, May 29, 2018, <http://www.scientificintegrityinstitute.org/EPATransBachmann052918.pdf>

**Expert judgment requires judgment by domain experts.<sup>47,48</sup> Given that this CASAC lacks experts in the appropriate scientific domains, it is unqualified to offer such judgments.**

Given that this CASAC lacks expertise in many key disciplinary areas, especially epidemiology, and that EPA arbitrarily and capriciously disbanded the CASAC PM Review Panel a few days before the Draft ISA was released, thereby depriving CASAC of the needed expertise, this CASAC is not in a credible position to offer judgments regarding causal determinations.

Expert judgment should be based on conditioning of available evidence and inference methods. The conditioning step is substantially more credible when it is based on a group of experts with breadth and depth of expertise, and diversity of perspectives. EPA had such a group in the form of the CASAC PM Review Panel and yet arbitrarily and capriciously dismissed that panel without prior notice and without public consultations with CASAC.

There are well known biases in expert elicitation, some of which are cognitive and some of which are motivational. An example of a motivational bias is the so-called “expert bias,” which is when people who are not the relevant experts pretend that they are to make themselves appear to be important experts. Another well-known motivational bias is when an “expert” wants to influence the outcome of a scientific review process to achieve a particular policy or regulatory outcome. Such biases might be indicated, for example, when members of a scientific review committee earn their living based on funding from regulated industries, and offer opinions that are consistent with policy outcomes of interest to their funders. Motivational biases also arise when an expert has taken strongly stated public positions previously, as a result of which it becomes more difficult for that person to change their views.

Biases can be counter-acted. The approach to counter-act “expert” bias is to engage experts who have relevant expertise and to make sure that there is breadth and depth of needed expertise, as well multiple experts in key scientific disciplines who have diverse opinions. In contrast, if the goal is to undermine the science review process, efforts could be made to promote and enhance “expert” bias. This can be done, for example, by doing away with a group of domain experts, as EPA has done by eliminating the CASAC PM Review Panel, and instead placing the review in the hands of a group that lacks the breadth and depth of expertise, and diversity of perspectives, to properly condition the review. A corollary is that “true” experts are usually the first to admit that they are not qualified to undertake a particular review and to call for the inclusion of additional experts. Persons who are over-confident of their own expertise or who seek to be perceived as an expert in an area for which they are not are unlikely to want to cede their position to experts.

An example of over-confidence is the inability of a person to admit to any limitations of methodologies that they advocate while emphasizing only limitations but not strengths of other methodologies. For example, advocates of new quantitative methods should acknowledge limitations related to problem selection, data selection, limitations of the methodology itself, and challenges with interpretation of results. As a simple example, consider the use of statistical methods to making inferences regarding a statistic. There is judgment regarding how to structure the analysis, what data to select (including geographic area, time period, spatial and

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<sup>47</sup> EPA, Expert Elicitation Task Force White Paper, Science and Technology Policy Council, U.S. Environmental Protection Agency, Washington, DC, August 2011. [https://www.fwspubs.org/doi/suppl/10.3996/052017-JFWM-041/suppl\\_file/10.3996052017-jfwm-041.s7.pdf](https://www.fwspubs.org/doi/suppl/10.3996/052017-JFWM-041/suppl_file/10.3996052017-jfwm-041.s7.pdf)

<sup>48</sup> Morgan, M.G., and M. Henrion, *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press, 1990.



temporal resolution, and so on), what analysis methods to use, what criteria to use in hypothesis testing, and how to interpret the results.

One way to counter-act motivational biases related to experts who want to influence the outcome is, preferably, to not include persons with clear conflicts of interest as part of an expert advisory committee, especially in a regulatory context. This would typically exclude people with financial ties to regulated industries who have a vested interest in the outcome of the review process, and would also include people who have strongly stated prior positions that imply pre-judgment of the policy-relevant outcomes and people who work at agencies with publicly stated perspectives on issues under deliberation for which there is also a close reporting and line of management relationship. Such persons could still participate in the process as stakeholders via public comments.

In contrast, if the goal is to undermine the science review process, efforts could be made to promote and enhance motivational bias. A way to promote and enhance motivational biases is to have fewer experts and include among them persons who are susceptible to such biases. This is what EPA has done in doing away with the CASAC PM Review Panel and with recent changes to the composition of the CASAC.

**It is evident that the recent changes to the NAAQS review process have undermined prior measures that were in place to avoid or mitigate motivational biases. Changes to the NAAQS review process and to the CASAC since 2017 clearly produce bias.**

### **History of CASAC Advice on the Framework for Causal Determinations**

CASAC has reviewed the Framework for Causal Determinations in each NAAQS review cycle for a decade. Early work on development of the framework is evident in CASAC's comments on the second external review draft of the Integrated Science Assessment for Oxides of Nitrogen in 2008 (Henderson, 2008):

In regard to the Agency's approach to synthesis of the evidence and causal inference, an extensive Annex has been prepared that reviews a number of relevant frameworks. The background is a useful foundation for informing the selected approach for assessing available evidence and should be extended to justify the adopted framework. Based on this Annex, the Agency has made changes in Chapter 1 that are responsive to prior critiques. In particular, there is a description of literature selection; an approach to evaluating evidence for inferring causality is provided; and a reasonable set of descriptors of strength of evidence for causation is offered.

The CASAC made recommendations for improvement in the framework, such as to include consideration of publication bias, model selection bias, concentrations relevant to ambient levels, and common-causes (Henderson, 2008a).

Similarly, in 2008, the CASAC, augmented by subject-matter-experts to form the CASAC Sulfur Oxides Primary NAAQS Review Panel, likewise found that an early version of the framework in the first draft of the Sulfur Oxides ISA was promising but needed revisions (Henderson, 2008b):

The hierarchy of causal claims used in Chapter 5 is appropriate, but the criteria used to satisfy each of the categories of causal strength are not well specified and in some cases do not comport with best scientific practice. This aspect of the chapter can be improved, especially with

respect to criteria of coherence of evidence and robustness of conclusions. A complete description of the approach to causal inference should be provided in a revised ISA.

In its review of the second draft of the Sulfur Oxides ISA, CASAC found that (Henderson, 2008c):

*Chapter 1 has been improved, particularly by drawing on recent reports that offer models of approaches for causal inference and classification schemes for the weight of evidence for inferring causation. The ISA utilizes a five-level hierarchy for causal determination to be consistent with the Guidelines for Carcinogen Risk Assessment (EPA, 2005). We concur with using the five levels but recommend that the descriptions be changed to better reflect the level of certainty or confidence in the classification of the level of evidence.*

CASAC further advised that EPA “should avoid using statistical significance as a criterion for evidence interpretation,” and should improve “the presentation of the epidemiological concepts of effect modification and confounding that are particularly challenging in the face of multi-pollutant mixtures.”

In 2009, CASAC offered the following endorsement of the framework in its review of the first external review draft of the ISA for particulate matter (Samet, 2009a):

*The evidence is thoughtfully synthesized in a transparent fashion; the framework for classifying the strength of evidence has continued to evolve, and it provides transparency in documenting how determinations were made with regard to causation. The CASAC is particularly pleased that the Agency has adopted a uniform descriptive language for various levels of confidence in making causality determinations. We support the five-level hierarchy developed for causal determinations, and recommend it as the model for future ISAs.*

The CASAC went on to further state (Samet, 2009a): “The CASAC regards the framework for causal determination and judging the weight of evidence, as presented in Chapter 1, to be appropriate.”

In its review the second external review draft of the PM ISA, CASAC further stated (Samet, 2009b): “CASAC also commends EPA for the continued evolution of the process for evidence evaluation. The five-level classification of strength of evidence for causal inference has been systematically applied; this approach has provided transparency and a clear statement of the level of confidence with regard to causation, and we recommend its continued use in future ISAs.”

In 2009 the CASAC CO Review Panel advised EPA “as EPA receives comments on this framework when reviewed by various panels of CASAC, EPA should strive for consistency across documents” (Brain and Samet, 2009).

In 2010, the CASAC CO Review Panel found that (Brain and Samet, 2010): “EPA Framework for Causal Determination, now incorporates a detailed description of the criteria for causal determination. The introductory sentence to Section 1.6.3 clearly describes the process of moving from association to causation, requiring the elimination of alternative explanations for the association”. The CASAC went on to recommend more detail regarding confounding and

effect modification, and improved presentation of epidemiologic concepts include related to “available methods to control for confounding in the design and analysis phase of a study.”

In 2011, the Clean Air Scientific Advisory Committee (CASAC) augmented with additional experts to form the Ozone Review Panel reviewed the 1st draft of the Ozone ISA and stated (Samet, 2011):

*The CASAC continues to support the use of the EPA’s framework for causal determination that was first used in the ISA for particulate matter. This framework provides a comprehensive and transparent approach for evaluating causality. Based on long-standing approaches in public health, as brought together in a recent National Academy of Sciences (NAS) Institute of Medicine (IOM) report, the framework employs a two-step approach that first determines the weight of evidence in support of causation and then characterizes its strength in a standard scheme for causal classification. The second step further evaluates the available quantitative evidence regarding concentration-response relationships and the duration, level and types of exposures at which effects are documented. The EPA’s adoption of this framework has greatly improved the consistency and transparency of its assessment as compared to the approach seen in past reviews.*

The CASAC went on to further state “Panel members were largely satisfied with the framework for causal determination” while offering recommendations for further improvements pertaining to terminology, use of the “so-called Hill criteria” as a “guide to thinking about the data to ensure that relevant aspects of the data are adequately considered and taken as a whole rather than used as a checklist,” and that the “criteria not be ranked in any way; their relative importance will depend on the specific context and specific issue under consideration.”

In its review of the 2nd draft Ozone ISA, the CASAC augmented with additional experts had less to say about the framework itself, instead offering comments pertaining more to the explanation and application of the framework (Samet, 2012), thus indicating that the framework itself was mature and useful. CASAC called for EPA to provide a third draft of the ISA to address numerous other issues.

Likewise, in its review of the 1st draft ISA for Lead, the CASAC augmented with additional experts to form the Lead Review Panel also advised that “The framework for causal determination should be applied consistently and transparently,” thus affirming the utility of the framework itself but calling for improved explanation of its application to specific combinations of exposure duration and adverse outcome (Frey and Samet, 2011). The CASAC found that the 2nd draft ISA for Lead also had an “incomplete application of causal determination criteria outlined in the ISA’s preamble” and required further revision (Samet and Frey, 2012). In its review of the 3rd draft ISA for Lead, CASAC found that “the application of the causal framework is clearer and better documented” (Frey, 2013). One of the key issues in the lead review was to group health endpoints by major organ systems that share common modes of action.

In its review of the 3rd draft Ozone ISA, the CASAC found that the framework was well-developed and useful, leading to a recommendation to EPA staff to “consider developing the discussion of the causality framework into a manuscript for submission to a journal” (Frey and Samet, 2013).

In its review of the 1st draft of the ISA for Oxides of Nitrogen in 2014, the CASAC expressed concern that the framework was not “applied with sufficient transparency,” and advising that “there needs to be better substantiation and better documentation of the evidence and lines of reasoning for the causal determinations,” and offered specific recommendations for achieving improved transparency (Frey, 2014). CASAC found that the 2nd draft of the ISA for Oxides of Nitrogen “is a much improved document and is very responsive to the CASAC’s comments,” although offering specific suggestions for further improvements in the explanation of particular causal determinations (Diex Roux and Frey, 2015).

Given that CASAC comments pertaining to the framework for causal determination shifted over time from the formulation of the framework to its transparent application, the framework itself matured and remained unchanged in the most recent review cycle. The framework had been reviewed, improved, and endorsed by CASAC as a result of repeated review cycles, including the 2007 to 2010 review of oxides of nitrogen, 2007 to 2010 review of sulfur oxides, 2008 to 2013 review of particulate matter, 2009 to 2014 review of ozone, 2011 to 2013 review of lead, and 2013 to 2017 review of oxides of nitrogen. These review panels involved 66 different scientific experts. The review process further involved receipt of public comment at 14 public meetings for the review of each of the ISA drafts. Thus, the framework for causal determination has been extensively reviewed. Because the framework is generally applicable to reviews of each criteria pollutant, the framework is now described in a separate document, Preamble to the Integrated Science Assessments (EPA, 2015). The framework is also described in a journal publication by Owen et al. (2017).

In its review of the 1st draft ISA for oxides of sulfur, CASAC had extensive comments on specific causal determinations but did not have comments on the framework itself (Diex Roux, 2016). The CASAC review of the 2nd draft of the ISA for oxides of sulfur found that the causal determinations were appropriate (Diex Roux, 2017). The most recent sulfur oxides review panel included eight experts who had not served on previous panels that review the framework. Thus, the framework and its application has been evaluated by 74 experts over multiple panels and review cycles.

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Samet, J. and H.C. Frey, 2012, CASAC Review of the EPA's Integrated Science Assessment for Lead (Second External Review Draft – February 2012) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2012; Report No.: EPA-CASAC-12-005.

### **History of Augmented Review Panels**

**The previous four particulate matter review panels have been comprised of members of the chartered CASAC augmented with additional expert consultants.** Based on the December 1982 EPA report on Air Quality Criteria for Particulate Matter and Sulfur Oxides (EPA-600/8-82-029a), CASAC was augmented with consultants. The CASAC Subcommittee on Health Effects of Particulate Matter and Sulfur Oxides included six consultants in addition to members of the chartered CASAC. The CASAC Subcommittee on Welfare Effects of Particulate Matter and Sulfur Oxides included five consultants in addition to members of the chartered CASAC. The consultants were different for these two review activities. Thus, there were 11 consultants who augmented the chartered CASAC for this review cycle. For the 1994 to 1996 PM review, there were 6 members of the chartered CASAC and 15 additional experts on the review panel. For the 2001 to 2006 scientific review, and for the 2008 to 2010 scientific review, there were 7 members of the chartered CASAC and 15 additional experts. From 2015

to 2018, the CASAC Particulate Review Panel had 6 members of the chartered CASAC and 20 additional experts. Thus, the use of augmented ad hoc review panels for particulate matter dates back more than 35 years.

**Table 1 summarizes data regarding ad hoc review panels for review of primary standards for all six criteria, based on review of the CASAC reports to the EPA administrator for each review cycle for each pollutant.** For many of the earlier review cycles in the late 1970s and in the 1980s, the letter reports from CASAC do not list the members of the chartered CASAC or consultants who augmented CASAC. Thus, it was not possible to compile data for every CASAC review of a primary or secondary standard. However, data are available for 20 CASAC reviews of primary standards dating to as early as 1987.

**Table 1. Number of CASAC Members and Consultants for NAAQS Review Panels by Topic and Dates<sup>a</sup>**

Review	Primary or Secondary	Years	CASAC Members	Consultants	Total
CO Review	P	1999 to 2000	7	5	12
CO Review	P	1991 to 1992	6	5	11
CO Review Panel	P	2008 to 2010	3	13	16
Lead Review Committee	P,S	1986 to 1990	7	12	19
Lead Review Panel	P,S	2006 to 2008	7	17	24
Lead Review Panel	P,S	2011 to 2013	2	18	20
NOx and Sox Secondary Review Panel	S	2008 to 2011	4	12	16
NOx and Sox Secondary Review Panel	S	2013 to present	1	21	22
Oxides of Nitrogen Review Panel	P	2007 to 2009	7	17	24
Oxides of Nitrogen Review Panel	P	2013 to 2017	4	13	17
Ozone Review Committee	PS	1987 to 1992	7	12	19
Ozone Review Panel	P,S	1995 to 1996	6	10	16
Ozone Review Panel	P,S	2005 to 2008	7	18	25
Ozone Review Panel	P,S	2010 to 2014	7	13	20
PM Review Panel	PS	1994 to 1996	6	15	21
PM Review Panel	PS	2001 to 2006	7	15	22
PM Review Panel	PS	2008 to 2010	7	15	22
PM Review Panel	PS	2016 to 2018	6	20	26
Sulfur Oxides Panel	P	2007 to 2010	7	17	24
Sulfur Oxides Panel	P	2013 to 2018	6	16	22

<sup>a</sup>All of this information was obtained from [www.epa.gov/casac](http://www.epa.gov/casac) by reviewing CASAC reports posted online.

**Table 2. Summary of Primary NAAQS Review Panels By Number of Consultants<sup>a</sup>**

Description	Number
Consultants: 16 to 20	8
Consultants: 12 to 15	9
Consultants: 5 to 10	3
Total	20

<sup>a</sup>All of this information was obtained from [www.epa.gov/casac](http://www.epa.gov/casac) by reviewing CASAC reports posted online.

As shown in Table 1, although there are a few panels with only 5 to 10 additional expert consultants, it has been more typical that the chartered CASAC has been augmented with 12 or more additional experts in a given review cycle for a given criteria pollutant. **The average number of consultants for these 20 panels is 14, and the average size of the augmented ad hoc review panels is 20 members. The averages for ozone and PM review panels are 15 consulting experts and panels with a total of 21 members.**

As shown in Table 2, of 20 panels for which data could be characterized regarding the number of consultants who comprised review panels, 3 had 5 to 10 consultants, 9 had 12 to 15 consultants, and 8 had 16 to 20 consultants.

The use of augmented panels or subcommittees dates at least to the late 1970s. On October 9, 1979, the Subcommittee on Carbon Monoxide of the CASAC issued its “findings, recommendations and comments.” However, a list was not included of members of that subcommittee. Based on the December 1982 EPA report on Air Quality Criteria for Particulate Matter and Sulfur Oxides (EPA-600/8-82-029a), CASAC was augmented with consultants. There were 11 consultants who augmented the chartered CASAC for this review cycle. The dates on which these subcommittees met are not readily available, however.

Therefore, although there are not as many details available in the public record to quantify the membership or meeting dates of either subcommittees or augmented panels prior to 1987, there is evidence in the public record that **augmentation of CASAC with additional experts has been a routine practice for four decades.**

### **Integrated Science Assessment**

In our December 10, 2018 letter to CASAC and the EPA docket for the draft Integrated Science Assessment, we offered consensus advice on numerous issues related to the draft ISA. The failure of EPA to provide a second external review draft of the ISA compromises the credibility and integrity of the NAAQS review process. This is because there were many important scientific issues raised regarding the first external review draft that require revision and iteration prior to their application in risk and exposure assessment and prior to their interpretation in the policy assessment. Although we found that the draft ISA was a comprehensive scientific document, we identified numerous areas for which refinement or revision was needed as detailed in our December 10, 2018 letter to CASAC. These areas include low cost sensors, air quality, contrasts between PM<sub>2.5</sub> and UFP, coarse PM, PM components, onroad and near-road microenvironments, mixtures and copollutants, study selection, transparent application of the causal framework, more in-depth treatment of specific issues related to PM<sub>2.5</sub> and mortality,



more explanation and possible reconsideration of the causal determination for short-term exposure to coarse PM and respiratory adverse effects, more explanation and possible reconsideration of the causal determination for long-term exposure to UFP and central nervous system effects, and reconsideration of the at-risk causal finding for populations with pre-existing cardiovascular or respiratory disease. Members of the IPMRP also provided extensive individual comments that were attached to the December 10, 2018 letter from the panel.

In our March 27, 2019 letter to CASAC, we noted that “the framework for causal determination, including terminology, and the overall plan for development of the ISA, was reviewed by CASAC in 2016.” However, we strongly disagreed with statements in CASAC’s draft letter to the Administrator “that the Draft ISA lacks explicitly stated principles for drawing conclusions or lacks operational definitions.” We noted that “the various considerations in developing causal determinations are explained in the Preamble to the ISAs and have been considered already in CASAC’s review of the Draft Integrated Review Plan.” We further noted that “[w]hile there may be opportunities for EPA staff to improve the clarity and transparency of the explanations of the inferences it makes and the conclusions it draws, this is not a fundamental limitation of the underlying framework but rather a matter of routine scientific review and iteration to improve the clarity and transparency of the final document.”

The chartered CASAC developed comments that in many cases appeared to exclusively focus on doubt-raising without acknowledgment of inferences that can be supported by the scientific evidence. In our March 27, 2019 letter, the IPMRP stated that “it is inappropriate to over-emphasize or exclusively focus on discordant results and ignore the overall preponderance of the evidence when making inferences.”

The IPMRP further stated that the draft ISA “follows methods previously reviewed by CASAC, including the approach to literature review, the causal determination framework, the framework for assessing at-risk populations and life stages, and assessment of concentration-response functions, consistent with the Preamble to the ISAs and the 2016 Integrated Review Plan for the current review cycle.” Consistent with our December 10, 2018 comments, we noted on March 27, 2018 that “the ISA takes into account poverty, temperature, and season, including lags related to temperature, and makes inferences regarding whether ambient PM concentration independently causes adverse effects and whether concentration and response relationships are either confounded or modified by other variables. Some of these inferences could be explained more clearly or in more detail.”

The draft PA appears to accept the draft ISA as it was prior to external review by CASAC and the public, including the IPMRP. There is no summary in the draft PA of any changes that are being made to the draft ISA as a result of comments from CASAC and the public, including the IPMRP. Normally, in prior review cycles, there is a second external review draft of the ISA concurrent with a first review draft of the Risk and Exposure Assessment (REA). In this review cycle for PM, EPA has not produced a separate draft REA, but instead has subsumed the REA into the draft PA. Typically, in a normal review cycle, the draft PA would not be released until after EPA has finalized the ISA and completed a second draft of the REA. The typical sequence in a normal review cycle was intended to protect the science assessments from being commingled with the policy assessment, so that the scientific basis could be established irrespective of later policy interpretations. In the current review cycle, the fact that the ISA is not completed prior to external review of the draft PA provides EPA leadership with the opportunity to change the ISA to support pre-determined policy outcomes in the final PA. This is a completely unacceptable situation.

Based on the content of the draft PA, it is clear that EPA staff have elected to retain the causal determination framework for health effects attributed to exposures of varying durations to particular indicators, and to retain the causal framework for at-risk populations. This is an appropriate choice. Although the chair of CASAC has aggressively advocated that EPA adopt quantitative causal tests for individual studies based on the chair's own work, such methods have not been adequately vetted and are not ready for widespread use at this time. The merits of such proposals could be a research topic that may be informative in future review cycles. It is certainly the case that leading edge research in the field of air pollution epidemiology is concerned with potential threats to validity of making inferences as well as adoption of improved techniques that better account for confounding and modification and that help support inferences regarding causality. However, because CASAC does not have epidemiologists among its seven members, and does not have access to a sufficient number of epidemiologists with breadth, depth, and diversity of expertise and experience, this CASAC is hardly an appropriate authority on the state of epidemiological practice and science and the directions it should go.

***EPA-1. Chapter 1 – Introduction: To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for the review?***

The draft PA, Chapter 1, fails to document the ad hoc changes to the NAAQS review process and to the CASAC that have been made since the final Integrated Review Plan (IRP) was published in 2016.<sup>49</sup> Table 1-3 of the final IRP laid out the following schedule for the review of the PM NAAQS:

- Fall 2017: Release of first external review draft of the ISA  
Release Risk and Exposure Assessment (REA) planning document(s)
- Winter 2018: CASAC Review of First Draft ISA, REA Planning Documents
- Fall 2018: Release of second external review draft of the ISA  
Release of First Draft REAs  
Release of First Draft PA
- Winter 2019: CASAC Review of Second Draft ISA, First Draft REAs, and First Draft PA
- Fall 2019: Release Final ISA  
Release of Second Draft REAs  
Release of Second Draft PA
- Winter 2020: CASAC Review of Second Draft REAs, Second Draft PA
- Fall 2020: Final REAs, Final PA
- 2021 Proposed Rule
- 2022 Final Rule

Compared to the IRP, the following steps have been omitted in the current review: (a) no REA planning document(s); (b) no second external review draft of the ISA; (c) no external review drafts of the REAs; (d) no provision for a second draft of the PA; (e) no final REA as a separate document; and (e) no final ISA until after CASAC has completed its review of the draft PA.

Although the IRP is cited on page 1-1, line 7, the deviations of the current review from the IRP are complete omitted. This is inappropriate and should be corrected. The chapter should enumerate all of the changes to the NAAQS review process, the CASAC, and the PM NAAQS review since 2016. See my detailed comments above on process issues.

The schedule in the final IRP specified two drafts of each of the ISA, REA, and PA. However, the final IRP indicated that the drafts of the REA and PA would be concurrent. This differs from

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<sup>49</sup> See Reference 9.

the schedule in the external review draft of the IRP that was reviewed by CASAC earlier in 2016.<sup>50,51</sup> In the external review draft of the IRP, EPA had proposed to sequence the release of first drafts of the ISA, REAs, and PA such that CASAC would review them sequentially on a staggered schedule. Thus, under the initial proposed schedule, CASAC would have been able to provide its advice on the first draft of the REAs before receiving the first draft of the PA. The schedule in the draft IRP allowed for two drafts of each of the ISA, REA, and PA.

The final IRP sequencing of the first drafts of the REA documents such that they are released after receiving CASAC review of both the first draft of the ISA and of REA planning documents is appropriate. Since the REAs build upon information in the ISA, it is logical and appropriate that EPA consider CASAC's advice on the ISA before releasing a draft of the REAs.

Because the Policy Assessment is intended to integrate information from the ISA and the REAs, it is generally not appropriate for a first draft of the PA to be released at the same time as the first draft of the REAs. Simultaneous release of the first draft of the REAs and PA was done, for example, in the last review of the ozone NAAQS. As colleagues have pointed out (see November 26, 2016 letter to CASAC from former members of the 2009 to 2014 CASAC Ozone Review Panel), the first draft of the PA in that review was very preliminary and required substantial revision.<sup>52</sup> Transparency of the review process and clear distinction of science and policy issues is enhanced by obtaining CASAC's advice on the REAs before submitting a first draft of the PA for CASAC review.

However, in this review, there is no separate REA. The content of the REA has been incorporated into the draft PA. This is not appropriate since there are important scientific issues pertaining to the REA that should be reviewed and vetted prior to use in the PA.

Chapter 1 should clearly explain the difference between the sequence of draft documents indicated in the IRP versus the actual sequence of draft documents in this review. Rather than multiple drafts of the ISA, REA, and PA, staggered so that science issues are vetted and settled before proceeding to policy issues, this review cycle has devolved into one draft of the ISA and one draft of the PA.

The draft of the PA is being reviewed before the ISA has been finalized. Whether or how issues raised by CASAC and the public regarding the draft ISA will be resolved, if at all, are unknown. What changes, if any, are in progress for the draft ISA, and which of these changes affect content of the draft PA? For example, the draft PA argues that focus should be given to health effects causal determinations that are "causal" or "likely to be causal" in assessing the adequacy of the current primary standards with regard to protection of public health and in assessing

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<sup>50</sup> EPA, Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter, EPA-452/D-16-001, U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. <https://www3.epa.gov/ttn/naaqs/standards/pm/data/201604-draft-integrated-review-plan-casac-review.pdf>

<sup>51</sup> Diez Roux, A., "CASAC Review of the EPA's Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016)," EPA-CASAC-16-003, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, August 31, 2016. <https://yosemite.epa.gov/sab/sabproduct.nsf/9920C7E70022CCF98525802000702022/%24File/EPA-CASAC+2016-003+unsigned.pdf>

<sup>52</sup> Frey, H.C., J.M. Samet, A.V. Diez Roux, G. Allen, E.L. Avol, J. Brain, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, S.R. Kleeberger, F.J. Miller, H.S. Neufeld, A.G. Russell, H.H. Suh, J.S. Ultman, P.B. Woodbury, and R. Wyzga, "CASAC Advice on the EPA's Integrated Review Plan for the Ozone National Ambient Air Quality Standards (External Review Draft)," 24 page letter with 42 pages of attachments, submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA-HQ-OAR-2018-0279, November 26, 2018, [https://yosemite.epa.gov/sab/sabproduct.nsf/0AC9E8672B0CA54985258351005BE54F/\\$File/Ozone+Letter+181126+Submitted-rev2.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0AC9E8672B0CA54985258351005BE54F/$File/Ozone+Letter+181126+Submitted-rev2.pdf)

possible revised or new standards. The draft ISA posits a determination of “likely to be causal” for long-term exposure to UFP and central nervous system effects. Yet, it seems that this finding is not adequately addressed in the draft PA. Is this because the finding may be revised downward in the final ISA? Or, is the finding in the final ISA to later be revised downward to match a pre-determined policy outcome from the PA? The commingling of science and policy by having so much overlap in the timing between the draft PA and draft ISA, at a minimum, creates the perception that the final ISA may be tailored to match policy outcomes in the final PA that were determined before the ISA was completed.

As noted on page 1-1, line 25, the role of the PA is to “bridge the gap” between the scientific assessments, which include not just the ISA but also REAs, and judgments required of the Administrator. The fact that the science has not been appropriately vetted prior to the release of the draft PA is problematic, as noted above.

Page 1-2, lines 9-11. Should also acknowledge that CASAC is to advise on background levels and research needs.

Page 1-2, lines 12-13: There is not a separate Risk and Exposure Assessment (REA) document in this review. To be consistent with the final IRP for this review, the text should state that EPA intended to make available to CASAC and the public two drafts of the REA. The most appropriate sequence of documents is to have the first draft of the ISA reviewed and revised prior to a first draft of the REA. The first draft of an REA should be made available and reviewed before a first draft of the PA is released. This was the situation in the most recent prior review of the PM NAAQS, for which there was a separate health risk and exposure assessment (HREA) and a welfare risk and exposure assessment (WREA).<sup>5354</sup> The latter was focused on visibility. In a few cases, the REA (HREA, WREA, or both) has been combined into the PA, such as for the most recent lead NAAQS review.<sup>55</sup> However, in such cases, this is because there were no substantial updates to the REA compared to the prior review cycle. In the case of the current PM NAAQS review, there are clearly substantial updates that have led to an entirely new REA in this review. This draft PA is not based on a reinterpretation of the REA from the prior review cycle. Instead, a new REA for health effects is included in the draft PA appendices. However, the REA should have been provided separately from the draft PA. The draft REA should have been provided for review after considering CASAC and public comments on the draft ISA and before releasing a draft PA.

Page 1-3, lines 9-11: Given that CASAC has been populated with members appointed based on geographic location and government affiliation, and that CASAC has been deprived of a duly appointed CASAC PM Review Panel, CASAC is not qualified to advise the EPA in a manner

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<sup>53</sup> Samet, J.M., CASAC Review of Quantitative Health Risk Assessment for Particulate Matter – Second External Review Draft (February 2010), EPA-CASAC-10-008, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, April 15, 2010.  
[https://yosemite.epa.gov/sab/sabproduct.nsf/BC4F6E77B6385155852577070002F09F/\\$File/EPA-CASAC-10-008-unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/BC4F6E77B6385155852577070002F09F/$File/EPA-CASAC-10-008-unsigned.pdf)

<sup>54</sup> Samet, J.M., CASAC Review of Particulate Matter Urban-Focused Visibility Assessment – Second External Review Draft (January 2010), EPA-CASAC-10-009, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, April 20, 2010.  
[https://yosemite.epa.gov/sab/sabproduct.nsf/0D5CB76AFE7FA77C8525770D004EED55/\\$File/EPA-CASAC-10-009-unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0D5CB76AFE7FA77C8525770D004EED55/$File/EPA-CASAC-10-009-unsigned.pdf)

<sup>55</sup> Frey, H.C., CASAC Review of the EPA’s Policy Assessment for the Review of the Lead National Ambient Air Quality Standards (External Review Draft – January 2013), EPA-CASAC-13-005, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, June 4, 2013,  
[https://yosemite.epa.gov/sab/sabproduct.nsf/E2554E264EEF8CCB85257B80006B3014/\\$File/EPA-CASAC-13-005+unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/E2554E264EEF8CCB85257B80006B3014/$File/EPA-CASAC-13-005+unsigned.pdf)

that accurately reflects that latest scientific knowledge of the kind and extent of salient issues that must be considered.

Page 1-3, lines 23-24. The text should also cite the recent *Murray Energy v. EPA* decision of the Court of Appeals for the District of Columbia Circuit.<sup>56</sup> As stated in the court's decision, "[i]ndustry Petitioners also point to section 109(d)(2)(C) of the Act, which requires CASAC to advise EPA "of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance" of revised NAAQS. 42 U.S.C. § 7409(d)(2)(C). According to Petitioners, the fact that CASAC is required to supply information to EPA about the "social, economic, or energy effects" of the revised NAAQS implies that EPA is obliged to consider that information in setting the NAAQS." However, contrary to the petition, this decision reaffirms that "this provision was intended to "enable the [EPA] to assist the States in carrying out their statutory role as primary implementers of the NAAQS," but had "no bearing upon whether cost considerations are to be taken into account in formulating the [NAAQS].""

Page 1-4, lines 17-18: Per *Murray Energy v. EPA* (2019), background is simply irrelevant in setting the level of the NAAQS. The level of the NAAQS must be set based on health effects. Proximity to background may be an issue for implementation.

Page 1-4, lines 28-29: Given that CASAC lacks the breadth, depth, and diversity of expertise necessary for this review, which was embodied in the disbanded CASAC PM Review Panel, CASAC is poorly positioned to offer advice on "recent advanced in scientific knowledge on the effects of the pollutant on public health and welfare."

Page 1-5, lines 1-17. See also CASAC's charter with the U.S. Congress, which should be cited.

Page 1-10, lines 8-10: the text here regarding the establishment of a Federal Reference Method for measurement of ambient coarse PM sets an important precedent. EPA should establish a FRM for measurement of UFP.

Page 1-11, line 6. The NAAQS review process was revised in 2006 and then again in 2008 and again in 2009. The 2006 revision was the major revision. The revisions in 2008 and 2009 were incremental changes of the process established as a result of the 2006 revision. The text should be rewritten to more accurately convey this sequence of events, with citations.

Page 1-12, lines 15-19. Although the IRP has been followed in part, there have been substantial deviations from the IRP. The deviations from the IRP should be specifically enumerated and discussed. See my comments above on this point.

Page 1-12, lines 20-22. This memorandum contradicted EPA's own IRP for this review. See comments above.

Page 1-12, line 23. Should note that on October 10, 2018, the CASAC PM Review Panel was disbanded by Acting Administrator Wheeler. The draft ISA was released on October 15, 2018.

Page 1-12, lines 24-25. Please give the dates of the meetings.

Page 1-12, line 33. What changes are being made to the draft ISA in response to comments from CASAC and the public. How will changes in the ISA be incorporated into the draft PA? What is the rationale for depriving CASAC and the public of the opportunity to see a revised draft ISA before the PA is finalized? Related to this issue, is EPA under a court order or a consent decree to complete the PM NAAQS review by 2020?

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<sup>56</sup> <https://law.justia.com/cases/federal/appellate-courts/cadc/15-1385/15-1385-2019-08-23.html>

**EPA-2. Chapter 2 – PM Air Quality: To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for the review?**

Specific comments on Chapter 2:

Page 2-3, line 17: text should be more clear if this is specifically about primary PM emissions. Aside from stationary and mobile sources, should mention area sources and fugitive emissions. At an appropriate place, should more systematically also address sources of secondary PM precursors.

Page 2-3, line 23, should add NO<sub>x</sub> and NH<sub>3</sub> to the parenthetical note about SO<sub>2</sub>).

Page 2-7: the definitions of and distinctions between elemental carbon and black carbon should be discussed. Given that this is a topic that probably has no end, EPA could acknowledge that there are differences of opinion about the use of these terms and offer an operational definition for use here. Also related to this page, a figure that apportions PM<sub>2.5</sub> to the components of section 2.1.1.3 would be useful, such as based on a typical average for a selected year. This would help put into context information in Figure 2.5 and elsewhere... e.g., how much do EC and OC each contribute to PM<sub>2.5</sub> mass on average, and what is the variability in this contribution (e.g., inter-city? Inter-monitor? Inter-annual?) Inter-daily?).

Page 2-9, lines 9-11. To be more clear, what is meant by “or can form new particles”? Is this via condensation?

Page 2-9, lines 16-17: This text appears to be correct but may give a misleading impression. EGUs appear to be responsible for 69% of national SO<sub>2</sub> emissions in 2014, not 80%. The reader might interpret that “nearly all” of the 80% is from EGUs, which appears not to be the case. 69% is not “nearly all” of 80%.

Page 2-9, line 19: According to the emissions trend data reported by EPA,<sup>57</sup> the total NO<sub>x</sub> emitted in 2014 was 12.589 million tons, not 14.4 million tons. Please check the number and correct as appropriate.

Page 2-9, line 24: it would help to give some quantitative idea of what “significantly” means... i.e. more than X%? Between Y% and Z%?

Page 2-9: related to the content here, it would be useful to either have similar content regarding components of UFP, PM<sub>10</sub>, and PM<sub>10-2.5</sub> or some explanation of the lack of such data. This could be a paragraph on each.

Page 2-11, line 12: What is a “robust” national network? How is “robust” defined, quantified, and assessed?

Related to Page 2-11: A statement should be made that there is not a Federal Reference Method for Ultrafine Particles. Such a statement is important because a future research need is to obtain more ambient monitoring data over space and time for UFPs to support epidemiology based on UFP. Given that EPA has in the past established FRMs in anticipation of possible new indicators, it will be appropriate to provide a rationale for establishing a FRM for UFP.

Page 2-12, Figure 2-6. What are the values on the vertical axis? Are these the number of stations? Axes should be explicitly defined with axes labels.

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<sup>57</sup> <https://www.epa.gov/air-emissions-inventories/air-pollutant-emissions-trends-data>

Page 2-5, top of the page. Please add a paragraph regarding the precision and accuracy of FRM and FEM monitors for PM<sub>2.5</sub>, particularly for annual averages down to 8 µg/m<sup>3</sup> and perhaps as low as 5 µg/m<sup>3</sup>.

Page 2-18, top of page. This example of the development of an FRM for PM<sub>10-2.5</sub> is a good. An FRM should similarly be developed for UFP.

Page 2-19, line 7: I think this probably is supposed to be “country” rather than “county”.

Page 2-19: monitoring methods related to ultrafines should also be briefly summarized.

Page 2-20, top of page. What are the demonstrated uses of sensor technologies for improved spatial resolution of ambient concentration or exposure concentrations, if any, for UFP, PM<sub>2.5</sub>, PM<sub>10</sub>?

Page 2-24, 4<sup>th</sup> line from the bottom (there are no line numbers): I could not find the “design value ratio line” in Figure 2-11.

Page 2-28, bottom paragraph, continued to next page – this is very useful information. Agree that there are decreasing trends in near road PM<sub>2.5</sub> increments related to fleet turnover of heavy duty diesel trucks that is leading to increased diffusion of diesel particle filters into the onroad fleet.

Page 2-38: the text refers to the accuracy and precision of publicly available data without any quantification. It would help to say something more on this topic, earlier (see comment above about the precision and accuracy for annual average concentrations down to 5-8 µg/m<sup>3</sup>.)

Page 2-41: the discussion and treatment of this material regarding the performance of alternative hybrid modeling methods seems appropriate. The text points out that the hybrid model performance tends to be worse in parts of the western U.S and attributes this, in part to “low concentrations.” Please see Dr. Barbara J. Turpin’s comments on this issue. The performance of the modeling approaches is perhaps more related to how well the models represent spatial gradients as opposed to how well they can represent “low concentrations.” In areas with stronger spatial gradients, finer resolution models perform better, including at low concentration, whereas in areas with little to no spatial gradients, models at fine and coarse scale may have comparable performance.

Page 2-42, line 30: The text here seems a bit superficial and could be supported with more specifics.

Page 2-43, line 8: What is the interpretation/implication/significance of information given in Table 2-3? Or, if the text immediately above is in reference to this table, then the table should be cited earlier in this paragraph.

Page 2-44, line 8. What is meant by spatial “texture”? Avoid metaphors in formal technical writing. Perhaps this is referring to a spatial ‘distribution’?

Page 2-44, lines 11-14: This is a good summary of comparisons, but what is the assessment based on this information? Which of these results are more plausible?

Page 2-45, line 7: Coefficient of variation of what? And for what averaging time? In general, always indicate averaging time when reporting concentrations or concentration-derived metrics.

Page 2-49: It appears that the assessment of background PM is largely based on results from the prior review. Is there anything new that can be learned from the hybrid modeling work that could inform some of this discussion?

Page 2-49, lines 33-35: it would be useful to mention some of the dynamics of UFP that are mentioned in the draft ISA – e.g., that they are more dynamic and have spatial gradients near

sources, in part because they agglomerate to larger size ranges and thus are transformed out of the UFP size range. This has implications for the characterization of UFP background, which could be discussed.

Also, the background discussion should differentiate based on averaging times, notably daily average and annual average.

Page 2-52: what about transboundary PM precursors, such as SO<sub>2</sub>, NO<sub>x</sub>, NH<sub>3</sub>, and VOCs? Although there is some mention of a few of these, these could be treated more systematically in the text.

Minor comment: change “like” to “such as” – e.g., page 2-2, line 8.

***EPA-6. Chapters 3 to 5: What are the CASAC views regarding the areas for additional research identified in Chapters 3, 4 and 5? Are there additional areas that should be highlighted?***

This charge question should have also included reference to Chapter 2. EPA should develop a Federal Reference Method for Ultrafine Particles. There is need for ongoing comprehensive characterization of the performance of modeled ambient concentration fields estimated using hybrid modeling methods.



## Dr. Terry Gordon

SCQ-3.2 What are the Panel's views on the relative weight that the draft Policy Assessment gives to the evidence-based (i.e. draft PA, section 3.2) and risk-based (i.e. draft PA, section 3.3) approaches in reaching conclusions and recommendations regarding current and alternative PM<sub>2.5</sub> standards?

The draft PA appropriately gives the evidence-based approach the deserving amount of weight to using those studies that “demonstrate a causal or a likely to be causal relationship with PM exposures” in the risk estimates. The choice and presentation of health outcomes was logical and well written. Similarly, the risk-based approach was clearly written and well-balanced, thus permitting the logic and presentation of the conclusions and recommendations in a fair and balanced setting. In particular, the weight of the different categories of evidence was well delineated between the studies with new evidence to suggest adverse health outcomes at levels below the current standards.

SCQ 3.3 What are the Panel's views on the evidence-based approach, including:

- a) The emphasis on health outcomes for which the draft ISA causality determinations are “causal” or “likely causal”?

The emphasis on causal and likely causal health outcomes was very appropriate. The designation of nervous system effects to a likely causal level was well described. The designation of birth outcomes/reproduction as “suggestive”, however, is puzzling given the large amount of epidemiologic studies that show associations between these outcomes and ambient PM. Admittedly, this field is rapidly expanding and perhaps the ISA needs updating.

- b) The identification of potential at-risk populations?

The at-risk populations are appropriate as indentified.

- c) Reliance on key multicity epidemiology studies conducted in the US and Canada for assessing the PM<sub>2.5</sub> levels associated with health effects?

This reviewer agrees that the reliance on US and Canadian epidemiology studies is the correct approach given the potential for different PM composition and sources among continents/countries.

- d) Characterizing air quality in these key studies using two approaches: the overall mean and 25<sup>th</sup>/75<sup>th</sup> percentiles of the distribution and the “pseudo design value” reflecting a monitor with the highest levels in an area?

These approaches seemed appropriate and balanced.

- e) The preference for continuing the use of an annual PM<sub>2.5</sub> standard as the principle means of providing public health protection against the bulk of the distribution of short- and long-term PM<sub>2.5</sub> exposures?

This preference was presented in a logical fashion and is correct.

- f) The draft PA conclusions on the extent to which the current scientific information strengthens or alters conclusions reached in the last review on the health effects of PM<sub>2.5</sub>?

This reviewer agrees that the current scientific evidence strengthens the conclusions of the last review and, in particular, provides new epidemiological evidence of adverse health outcomes at or below the current standards.

- g) Whether the discussions of these and other issues in Chapter 3 accurately reflect and clearly communicate the currently available health effects evidence, including important uncertainties, as characterized in the ISA?

These issues were appropriately discussed and communicate.

SCQ-4.1 To what extent does the panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM<sub>10</sub> NAAQS review? Are there additional policy-relevant questions that should be addressed?

This chapter did an excellent job of presenting the important policy-relevant issues. This reviewer can think of no other policy-relevant questions.

SCQ-4.2 What are the Panel's views of the draft PA assessment of the currently available scientific evidence regarding the health effects associated with exposures to thoracic coarse particles, PM<sub>10-2.5</sub>?

Based upon the currently available evidence, as stated in the draft ISA, the draft PA presents a reasonable assessment.

SCQ-4.3 What are the Panel's views on the draft PA preliminary conclusion that the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM<sub>10</sub> standard and that evidence supports consideration of retaining the current standard?

This reviewer agrees that based upon the available evidence, there is not need to question the adequacy and the evidence does support that the Administer consider retaining the current PM<sub>10-2.5</sub> standard.

EPA-6 Chapters 3 to 5: What are the CASAC views regarding the areas for additional research identified in Chapters 3, 4 and 5? Are there additional areas that should be highlighted?

The designated areas are excellent although, even as an inhalation toxicologist, to be honest, it is unclear how much mechanistic studies will impact this or future PM NAAQS. It would be more impactful to emphasize research on associations of individual sources with adverse health outcomes, so states/regions could perhaps focus on the 'worst' polluters. In particular, more research is needed on traffic (i.e., pollution vs. noise/stress; environmental justice), coal emissions, and wildfire contributions to adverse health effects.

## Dr. Jack R. Harkema

### General Comments

Overall, Chapters 3 and 4 are well written and address the charge questions mandated for this PA. The authors have provided the needed policy-related assessments that are based on the key findings provided by studies identified in the ISA.

SCQ-3.3. I agree with the EPA's evidence-based approach including the emphasis on health outcomes deemed *causal* or *likely to be causal*.

SCQ-3.5. I agree with the draft PA preliminary conclusion that, *taken together, the available scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary PM<sub>2.5</sub> standards*.

SQ-3.6. *I would agree that new PM<sub>2.5</sub> alternative standards need to be developed*. First, the levels above 10 µg/m<sup>3</sup> for the annual standard are not protective of public health, and an annual standard in the range of 10 to 8 µg/m<sup>3</sup> would provide more protection, but will not eliminate substantial premature mortality effects, especially in susceptible population subgroups. Second, a 24-hour standard in the range of 30 to 25 µg/m<sup>3</sup> would provide additional protection. Third, the EPA should work towards developing a rolling 4-hour standard, instead of a midnight to midnight average interval. Fourth, based on substantial scientific evidence of the health effects of ultrafine particles near roadways, the EPA should develop Federal Reference Methods for these specific particulate pollutants.

A few specific comments and suggestions are listed below that are intended to strengthen the document for the administrator.

### Specific Comments.

#### Chapter 3.2

Table 3-1 (p 3-18). The footnote for this table is quite unusual and raises questions and concerns. I suggest deleting this footnote in the final PA. As currently written, it implies that CASAC did not provide comments and suggestions to the EPA authors in a timely manner so that they could fully refine this part of the PA. Since there will be no additional review of the ISA document there will be adequate time for the authors to thoroughly evaluate and respond to the CASAC's additional comments/suggestions on the causality determinations stated in this table. I suggest the authors continue to base their causality determinations on the weight of the scientific evidence. To this reader, all the causality determinations are appropriately defended in the text but could be better summarized in the table (see below).

Table 3-1. This table would be improved with a column for key determinates (rationale points) for each causality. This would nicely reiterate and summarize the discussion in the text.

#### Chapter 3.3 Risk Based Considerations

The initial subsections (e.g., approach) of this part of Chapter 3 contain technical risk assessment jargon that could be eliminated or carefully defined for the lay person (non-risk assessor).

A summary table for the suggested changes or no changes to the PM<sub>2.5</sub> standards (including indicator, averaging time, form, and level) this section would complement the text and help the reader understand the authors' conclusions and rationales.

#### Chapter 3.5

I would suggest adding the following future areas of research

- More state-of-the-art comparative toxicological studies (in vivo and in vitro) that are designed to determine 1) the similarities and differences in human and animal sensitivity to comparable concentrations/doses of PM exposure (species-dependent responses, the animal may have a greater or lesser response to the same dose of inhaled PM) and 2) the cellular and molecular mechanisms underlying the adverse health effect. This will enhance our ability to translate animal toxicology findings to human health concerns and provide plausible and advanced biologic mechanisms for epidemiological associations.
- Studies to better understand PM exposure-related associations with neurological, metabolic and autoimmune diseases (e.g., autism, depression, diabetes, pre-diabetic disorders, systemic lupus erythematosus).

#### Chapter 4.1-4.3

No additional comments.

## Dr. Patrick Kinney

### Section 3.2 Evidence-Based Considerations

Overall this section is well done. However, I do have a serious concern about the footnote to Table 3-1 on page 3-18. The table lists causality determinations in the 2009 PM ISA and 2018 draft ISA. These provide a central foundation for the entire chapter on primary NAAQS recommendations. The footnote says that the table does not reflect CASAC advice on the draft ISA and that “some or all of these causality determinations could differ in the final ISA.” If interpreted literally, this clause opens the door for a complete revision to the evidence on causality which then feeds into the discussions and recommendations regarding the primary NAAQS. This seems like a sort of poison pill for the entire section, which as I said is very well done.

Page 3-61, line 9, and elsewhere in this section. The statements about PM concentrations “around”, i.e., “somewhat below to somewhat above” the overall mean observed in the key long-term epidemiology studies is rather vague. I am pleased to see that this notion is made more explicit on the following page, line 7, where there is a suggestion to use the 10<sup>th</sup> or 25<sup>th</sup> percentile of the health or concentration distribution to define the lower bound of the data region in which epi results are most precise. These are then plotted in figures 3-7 and 3-8, which is very helpful.

The pseudo-design value analysis starting on page 3-70 provides a useful complement to the previous sections.

### Section 3.3 Risk-based considerations

Again, this section is well done, incorporating an appropriate set of inputs and assumptions to examine health outcomes which might occur under a range of assumptions regarding the primary NAAQS.

#### **SCQ-3.2 What are the Panel’s views on the relative weight that the draft Policy Assessment gives to the evidence-based (i.e. draft PA, section 3.2) and risk-based (i.e. draft PA, section 3.3) approaches in reaching conclusions and recommendations regarding current and alternative PM<sub>2.5</sub> standards?**

Both sets of evidence are given appropriate weight in the draft PA.

### Section 3.4 Preliminary Conclusions on the Primary PM<sub>2.5</sub> Standards

This section accurately recaps and summarizes the evidence, analyses and arguments that were presented in sections 3.2 and 3.3. The draft PA reaches the following appropriate conclusions starting at the bottom of page 3-97.

- There is a long-standing body of strong health evidence demonstrating relationships between long- or short-term PM<sub>2.5</sub> exposures and a variety of outcomes, including mortality and serious morbidity effects. Studies published since the last review have reduced key uncertainties and broadened our understanding of the health effects that can result from exposures to PM<sub>2.5</sub>.

- Recent U.S. and Canadian epidemiologic studies provide support for generally positive and statistically significant health effect associations across a broad range of ambient PM<sub>2.5</sub> concentrations, including for air quality distributions with overall mean concentrations lower than in the last review and for distributions likely to be allowed by the current primary PM<sub>2.5</sub> standards.
- Analyses of PM<sub>2.5</sub> pseudo-design values additionally support the occurrence of positive and statistically significant health effect associations based largely on air quality likely to have met the current annual and 24-hour primary standards.
- The risk assessment estimates that the current primary PM<sub>2.5</sub> standards could allow a substantial number of PM<sub>2.5</sub>-associated deaths in the U.S. The large majority of these estimated deaths are associated with the annual average PM<sub>2.5</sub> concentrations near (and above in some cases) the average concentrations in key epidemiologic studies reporting positive and statistically significant health effect associations.

When taken together, we reach the preliminary conclusion that the available scientific evidence, air quality analyses, and the risk assessment, as summarized above, can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the combination of the current annual and 24-hour primary PM<sub>2.5</sub> standards.

This material is then followed by a section that presents an alternative, more skeptical, interpretation of the evidence, highlighting uncertainties in biological pathways, potential for public health improvements below the current NAAQS (because accountability studies haven't examined those levels yet), and in risk assessment as a tool. This is a rather extreme interpretation that runs counter to most current scientific views of the available evidence. However, it does provide the administrator considerable scope in evaluating the primary PM<sub>2.5</sub> NAAQS.

**Sections 4.1-4.3 regarding the PM<sub>10</sub> standard.**  
**Sections 5.1-5.3 regarding the secondary standard.**

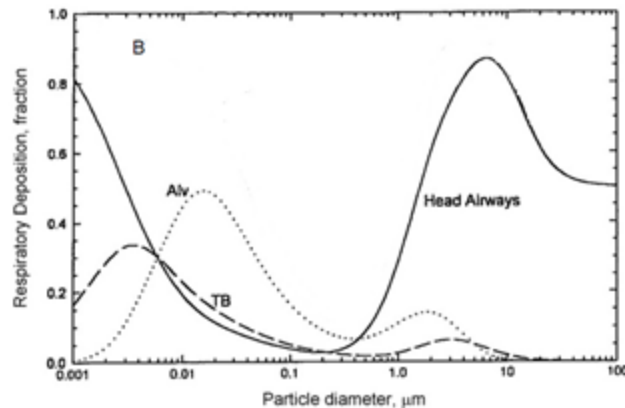
I reviewed both sections and found both to be well done and to have reached reasonable conclusions. I note that I am not an expert on this literature, so was not in a position to independently evaluate the underlying evidence.

## Dr. Michael Kleinman

### EPA-1. Chapter 1 – Introduction: To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for the review?

Chapter 1 provides a useful starting point.

The depiction of particle sizes in Figure 2-1 does not provide information with regard to why particle size might be important. A discussion of the role of particle size on lung deposition would be appropriate and would provide context for the later discussion of health effects of PM as a function of size. A diagram would be useful and could be discussed later as one talks about the differences between coarse and fine PM.



### EPA-2. Chapter 2 – PM Air Quality: To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for the review?

SCQ-2.1 *What are the Panel's views regarding whether the draft PA accurately reflects and communicates the air quality related information most relevant to its subsequent evidence-based assessment of the health and welfare effects studies, including uncertainties, as well as the development of the risk assessment for current and alternative standards? In particular, do the following sections accurately reflect and communicate current scientific understanding, including uncertainties, for: (a) relationships between annual and daily distributions of PM; (b) the review of hybrid modelling approaches used to estimate exposure in some studies and the risk assessment; and (c) information on background levels of various PM indicators?*

The discussion of the relationships between daily and annual distributions of PM would have benefitted from some integration with potential mechanisms of toxicity. Many of the disease-causing or exacerbating processes induced by PM exposures is related to formation of free radicals and the development of oxidative stress and inflammation. While in healthy individuals there are innate defenses against oxidative stress, One reason to be concerned with short term peak exposures is that normal defenses can be overwhelmed (i.e antioxidants can be consumed faster than they can be replenished) and the un-neutralized free radicals can injure tissues and organs. In the California Bay Area there were 13 occasions for which the

daily average was below the NAAQS of 35  $\mu\text{g}/\text{m}^3$  but there were 1 hr peak concentrations greater than 3 times the NAAQS, ranging from 113 TO 415  $\mu\text{g}/\text{m}^3$  (mean concentration =  $197 \pm 102$ ). These days were distributed over various stations in the Bay area and the interval was Feb to November 2018. Thus, on days when the 24hr concentration was within the NAAQS people were exposed for at least 1 hr to  $\text{PM}_{2.5}$  concentrations that were equivalent to the levels used in controlled human exposure studies, documented in Table 3-1 from the PA. Note that November 2018 was a severe fire month and there were several days above the NAAQS 24 hr standard and 1 hr concentrations exceeding 105  $\mu\text{g}/\text{m}^3$ , but the other months with high 1 hr peak exposures were most likely not fire-related.

**Table 3-2. Summary of information from  $\text{PM}_{2.5}$  controlled human exposure studies.**

Study	Population	Exposure Details (average concentration; duration)	Results
Bräuner et al., 2008	Healthy adults	10.5 $\mu\text{g}/\text{m}^3$ $\text{PM}_{2.5}$ (unfiltered) vs below detection (filtered); 24 h	No significant effect on markers of vascular function
Hemmingsen et al., 2015a, Hemmingsen et al., 2015b	Healthy, overweight older adults	24 $\mu\text{g}/\text{m}^3$ (unfiltered) vs 3.0 $\mu\text{g}/\text{m}^3$ (filtered) Copenhagen PM; 5 h	Impaired vascular function and altered heart rate variability; no significant changes in blood pressure or markers of inflammation or oxidative stress
Urch et al., 2010	Non-asthmatic and mild asthmatic adults	64 $\mu\text{g}/\text{m}^3$ CAP (lower exposure); 2 h	No significant change in blood markers of inflammation or oxidative stress
Huang et al., 2012	Healthy adults	90 $\mu\text{g}/\text{m}^3$ CAP; 2 h	No significant changes in heart rate variability
Devlin et al., 2003	Healthy older adults	99 $\mu\text{g}/\text{m}^3$ CAP <sup>28</sup> ; 2 h	Decreased heart rate variability
Hazucha et al., 2013	Adult current and former smokers	109 $\mu\text{g}/\text{m}^3$ CAP; 2 h	No significant changes in markers of inflammation or coagulation
Ghio et al., 2000	Healthy young adults	120 $\mu\text{g}/\text{m}^3$ CAP; 2 h	Increased fibrinogen (coagulation)
Ghio et al., 2003	Healthy young adults	120 $\mu\text{g}/\text{m}^3$ CAP; 2 h	Increased fibrinogen; no significant effect on markers of inflammation
Urch et al., 2010	Non-asthmatic and mild asthmatic adults	140 $\mu\text{g}/\text{m}^3$ CAP (higher exposure); 2 h	Increased blood inflammatory markers
Brook et al., 2009	Healthy adults	149 $\mu\text{g}/\text{m}^3$ CAP; 2 h	Impaired vascular function, increased blood pressure; no significant change in markers of inflammation (compared to filtered air)
Ramanathan et al., 2016	Healthy adults	149 $\mu\text{g}/\text{m}^3$ CAP; 2 h	Decreased anti-oxidant/anti-inflammatory capacity when baseline capacity was low



Sivagangabalan et al., 2011	Healthy adults	150 µg/m <sup>3</sup> CAP; 2 h	Increase in indicator of possible arrhythmia; no significant effect on heart rate
Kusha et al., 2012	Healthy adults	154 µg/m <sup>3</sup> CAP; 2 h	No significant effect on indicator of possible arrhythmia
Gong et al., 2003	Adults with and without asthma	174 µg/m <sup>3</sup> CAP; 2 h	Increased heart rate; No significant effect on indicators of arrhythmia, inflammation, coagulation; inconsistent effects on blood pressure
Gong et al., 2004	Older adults with and without COPD	200 µg/m <sup>3</sup> CAP; 2 h	Decreased heart rate variability, increase in markers of inflammation (without COPD only); inconsistent effect on arrhythmia; no significant effect on markers of blood coagulation
Liu et al., 2015	Healthy adults	238 µg/m <sup>3</sup> CAP; 130 min	Increase in urinary markers of oxidative stress and vascular dysfunction; no significant effect on blood markers of oxidative stress, vascular function, or inflammation
Bellavia et al., 2013	Healthy adults	~242 µg/m <sup>3</sup> CAP; 130 min	Increased blood pressure
Behbod et al., 2013	Healthy adults	~250 µg/m <sup>3</sup> CAP; 130 min	Increase in markers of inflammation
Tong et al., 2015	Healthy older adults	253 µg/m <sup>3</sup> CAP; 2 h	Impaired vascular function and increased blood pressure; no significant change in markers of inflammation or coagulation
Lucking et al., 2011	Healthy young men	320 µg/m <sup>3</sup> (unfiltered) vs 7.2 µg/m <sup>3</sup> (filtered); 1 h	Impaired vascular function and increased potential for coagulation; no significant effect on blood pressure, markers of inflammation, or arterial stiffness
Vieira et al., 2016a, Vieira et al., 2016b	Healthy adults; Heart failure patients	325 µg/m <sup>3</sup> (unfiltered) vs 25 µg/m <sup>3</sup> (filtered) diesel exhaust; 21-min	Increase in marker of potential impairment in heart function, impaired vascular function (heart failure patients); no significant effect on blood pressure, heart rate or heart rate variability, markers of inflammation, markers of coagulation, or arterial stiffness

**EPA-3. Chapter 3 – Review of the Primary PM<sub>2.5</sub> Standards: What are the CASAC views on the approaches described in Chapter 3 to considering the PM<sub>2.5</sub> health effects evidence and the risk assessment in order to inform preliminary conclusions on the primary PM<sub>2.5</sub> standards? What are the CASAC views regarding the rationales supporting the preliminary conclusions on the current and potential alternative primary PM<sub>2.5</sub> standards?**

*SCQ-3.1 Does the panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM<sub>2.5</sub> review? Are there additional policy-relevant questions that should be addressed?*

The question of the importance of short term standards is one that deserves additional consideration. In fact the human controlled

exposures suggest that a shorter term (1 hr ?) acute standard might have some protective value.

Based on the discussion for 2.1, the controlled human studies, which found significant cardiovascular effects should be considered as relevant to actual exposures and taken into stronger consideration with respect evaluating the adequacy of the current NAAQS levels.

SCQ 3.3 *What are the Panel's views on the evidence-based approach, including:*

*The preference for continuing the use of an annual PM<sub>2.5</sub> standard as the principle means of providing public health protection against the bulk of the distribution of short- and long-term PM<sub>2.5</sub> exposures?*

The use of the annual standard to protect against short and long term exposure health effects may not be the best approach, from the standpoint of biological mechanisms. As stated earlier, many of PM's health effects are subsequent to formation and release of free radicals leading to oxidative stress and inflammation. These are hallmarks of heart diseases, lung diseases, cancer and degenerative nerve diseases. While in healthy individuals there are innate defenses against oxidative stress, short term peak exposures can overwhelm the normal immunological defenses (i.e antioxidants can be consumed faster than they can be replenished) and the un-neutralized free radicals can injure tissues and organs. This could be especially true in people with impaired immunity, people with pre-existing diseases, the very young and the elderly.

SCQ-3.5 *What are the Panel's views on the draft PA preliminary conclusion that, taken together, the available scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary PM<sub>2.5</sub> standards?*

The evidence and discussion consistently demonstrate that the current standards do not provide an adequate margin of safety to prevent health effects. It should be noted that while the weight of evidence for PM's effects cardiovascular disease causation is stronger than that for pulmonary disease, having an impaired pulmonary system will put significant extra load on the cardiac system and could be a contributing factor to the ultimate cause of death, i.e. cardiac-related disease.

GC-1. *What scientific evidence has been developed since the last review to indicate if the current primary and/or secondary NAAQS need to be revised or if an alternative level or form of these standards is needed to protect public health and/or public welfare? Please recommend to the Administrator any new NAAQS or revisions of existing criteria and standards as may be appropriate. In providing advice, please consider a range of options for standard setting, in terms of indicators, averaging times, form, and levels for any alternative standards, along with a description of the alternative underlying interpretations of the scientific evidence and risk/exposure information that might support such alternative standards and that could be considered by the Administrator in making NAAQS decisions. Shorter averaging times (1 hr ?) to protect against acute health effects (sudden cardiac death, acute asthma attacks)*

GC-2. *Do key studies, analyses, and assessments which may inform the Administrator's decision to revise the NAAQS properly address or characterize uncertainty and*

*causality? Are there appropriate criteria to ensure transparency in the evaluation, assessment, and characterization of key scientific evidence for this review?*

There are appropriate criteria that are relevant to any scientific endeavor. Thorough documentation of methods and approaches, documentation of quality control and quality assurance, rigorous, objective analysis of the data are all necessary. The studies that were discussed in the documents were evaluated and selected because they were quality science.

*GC-3. Are there areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS? Please describe the research efforts necessary to provide the required information.*

New areas of health effects studies and new assessment methods are continuing to evolve. Evaluation and characterization of “hot spots” of high exposure, especially where those areas can be identified with impacts from local sources are needed.

*GC-4. What is the relative contribution to air pollution concentrations of natural as well as anthropogenic activity? In providing advice on any recommended NAAQS levels, please discuss relative proximity to peak background levels.*

Recent laboratory studies have demonstrated that natural organic vapors when combined with atmospheric photochemical processes and anthropomorphic combustion gases (NO<sub>x</sub>) form particles that are more toxic than secondary organic particles formed in the absences of the human pollutants. Some future attention to these could be warranted.

## Dr. Rob McConnell

**EPA-3. Chapter 3 – Review of the Primary PM<sub>2.5</sub> Standards: What are the CASAC views on the approaches described in Chapter 3 to considering the PM<sub>2.5</sub> health effects evidence and the risk assessment in order to inform preliminary conclusions on the primary PM<sub>2.5</sub> standards? What are the CASAC views regarding the rationales supporting the preliminary conclusions on the current and potential alternative primary PM<sub>2.5</sub> standards?**

*Overall, this is a very solid review and synthesis of literature and policy alternatives and implications.*

**SCQ-3.2** What are the Panel's views on the relative weight that the draft Policy Assessment gives to the evidence-based (i.e. draft PA, section 3.2) and risk-based (i.e. draft PA, section 3.3) approaches in reaching conclusions and recommendations regarding current and alternative PM<sub>2.5</sub> standards?

*There is appropriate focus on the evidence that has emerged since the last PM review for the key outcomes, including mortality and cardiovascular disease. Evidence is well summarized incl cross discipline, low level effects and accountability studies. The risk-based approach provides complementary information relevant to policy.*

*The summary of the changing conclusions regarding causality in Table 3-1 largely reflects the emerging scientific consensus based on a stronger evidence base. However, I am puzzled that there was not further consideration of likely causal relationships with premature birth and low birth weight. There is also rapidly emerging evidence from epidemiological and toxicological studies indicating that PM<sub>2.5</sub> exposure causes insulin resistance, impairs beta-cell function and causes Type 2 diabetes. The criteria for the conclusions that these were not likely causal might be explained in more detail.*

*One disturbing feature of Table 3-1 is the footnote indicating that the CASAC that reviewed the ISA found that the evidence that evidence was not sufficient to conclude that the relationship was likely causal between PM<sub>2.5</sub> exposure and nervous system effects; between long-term ultrafine particulate (UFP) exposure and nervous system effects; or between long-term PM<sub>2.5</sub> exposure and cancer". While it is within the purview of the CASAC to make such a determination, did not the CASAC itself acknowledged that it lacked the expertise to do so?*

**SCQ 3.3** What are the Panel's views on the evidence-based approach, including:

- a) The emphasis on health outcomes for which the draft ISA causality determinations are "causal" or "likely causal"?

*This is a reasonable approach. See also response to SCQ 3.2*

- b) The identification of potential at-risk populations?

*The PA acknowledges susceptibility of children, the elderly, the poor and ethnic and racial minorities based on increased exposure, people with pre-existing conditions, in short a large proportion of the population. There is voluminous data on exposure and environmental justice that was not reviewed in any detail. Also, there was little discussion of genetic susceptibility and the implications for causal inference. Where variants in*

*pathways predicted to be targeted by exposure modify effects, these results can provide a very strong argument for causality.*

- c) Reliance on key multicity epidemiology studies conducted in the US and Canada for assessing the PM<sub>2.5</sub> levels associated with health effects?

*These are the most relevant to exposures to the U.S. population. Although it might be argued that the composition of European PM<sub>2.5</sub> is different than in the U.S., PM<sub>2.5</sub> composition also differs across the U.S. and Canada, and there is strong evidence of health effects from the ESCAPE studies, for example, and other European studies (as well as elsewhere). The approach should not preclude review of selected studies from elsewhere that provide compelling evidence based on novel design or relevance to questions of interest to the PA.*

- d) Characterizing air quality in these key studies using two approaches: is the overall mean and 25<sup>th</sup>/75<sup>th</sup> percentiles of the distribution and the “pseudo design value” reflecting a monitor with the highest levels in an area?

*I look forward to the committee discussion of this question.*

- e) The preference for continuing the use of an annual PM<sub>2.5</sub> standard as the principle means of providing public health protection against the bulk of the distribution of short- and long-term PM<sub>2.5</sub> exposures?

*The PA makes a credible argument for this approach.*

- f) The draft PA conclusions on the extent to which the current scientific information strengthens or alters conclusions reached in the last review on the health effects of PM<sub>2.5</sub>?

*The PA makes a strong case that health effects are occurring at concentrations below the current long-term standard, based on studies showing effects among populations exposed at levels at or below the standard, and the supportive evidence from the design and pseudo-design values. The PA provides rationales for a lower alternative standard to levels around 10 µg/m<sup>3</sup>, levels below 10 (to as low as 8 µg/m<sup>3</sup>), and levels between 10 and 12.*

- g) Whether the discussions of these and other issues in Chapter 3 accurately reflect and clearly communicate the currently available health effects evidence, including important uncertainties, as characterized in the ISA?

*There is appropriate consideration of the uncertainties.*

**EPA-4. Chapter 4 – Review of the Primary PM<sub>10</sub> Standard: What are the CASAC views on the approach described in Chapter 4 to considering the PM<sub>10-2.5</sub> health effects evidence in order to inform preliminary conclusions on the primary PM<sub>10</sub> standard? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current primary PM<sub>10</sub> standard?**

- SCQ-4.1 To what extent does the panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM<sub>10</sub>

NAAQS review? Are there additional policy-relevant questions that should be addressed?

SCQ-4.2 What are the Panel's views of the draft PA assessment of the currently available scientific evidence regarding the health effects associated with exposures to thoracic coarse particles, PM<sub>10-2.5</sub>?

SCQ-4.3 What are the Panel's views on the draft PA preliminary conclusion that the available evidence does not call into question the adequacy of the public health protection afforded by the current primary PM<sub>10</sub> standard and that evidence supports consideration of retaining the current standard?

*The PA makes a case that, in spite of additional epidemiological studies, key uncertainties in the evidence that precluded a determination of causal role for PM<sub>10-2.5</sub> by itself or a justification for considering alternative standards for PM<sub>10</sub> in the last PM review. Additional research is needed: toxicological effects of coarse-thoracic PM; inhalation challenge studies to characterize acute effects and pathways and subclinical effects; studies of susceptible populations, especially asthmatics. Appropriate methods for exposure assessment of PM-2.5 and for analysis of exposure assigned using different methods, and of co-pollutant effects, are acutely in need of further investigation. This is not to say that current levels of exposure to PM<sub>10-2.5</sub> are safe, rather that there is not enough evidence to make a determination.*

## Mr. Richard Poirot

### Chapter 2

Overall, chapter 2 accurately reflects and clearly communicates air quality information relevant to conducting evidence-based assessments of health and welfare effects, and for conducting risk assessments for evaluating effects of current and alternative NAAQS. Relationships between recent daily and annual PM exposures are clearly presented (for example Figure 2-11). The different hybrid modeling approaches used to estimate exposures are logically derived and clearly described, and information on so-called “background” PM levels are more or less clearly explained. Some interesting results from recent near-road monitoring efforts were presented, although it wasn’t clear how/if these results were folded into the hybrid modeling analyses.

Regarding background PM, it’s not clear [how](#) this information is or will be useful in reviewing and potentially revising the NAAQS. Clearly it could be useful in the implementation phase of the NAAQS (identifying/ getting exemptions for “exceptional” and/or “natural” events). As illustrated, influence of some of these background contributions may be relatively easy to identify and quantify (especially episodes), but I assume we’re not saying these background influences don’t contribute to health effects (right?). In addition, I think there are likely complex interactions between so-called background influences and “jurisdictionally-controllable” anthropogenic sources (see p. 2-49 comment below).

An additional comment on Chapter 2 is that it would be helpful to see some graphic depictions (a few maps and perhaps a time series like Figure 2.6 but for recent years) showing the locations and numbers of the various different PM<sub>2.5</sub> monitoring techniques/networks (filter FRMs, filter CSN, IMPROVE, continuous (FEM & non-FEM), near-road, etc. A few national maps on this would be useful, as well as a few zoomed-in urban area examples - from some of the cities used in the Risk Assessment (maybe underlain by the hybrid modeling grid).

**p. 2-2, lines 20-22:** I don’t think its correct that only a small fraction of coarse mode mass occurs in particles > 10 microns. Much of the coarse mode mass is often > 10 um. See for example Brook et al. (1997), who noted that averaged across 19 long-term Canadian NAAPS sites “PM<sub>25</sub> accounted for 49% of the PM<sub>10</sub>, and PM<sub>10</sub> accounted for 44% of the TSP”. This would leave > 4 times more coarse mass in particles >10 um than in PM<sub>10-2.5</sub>. I think maybe the authors meant to say something like “small fractions of [inhalable](#) coarse mode mass can be ... greater than 10 um in diameter”.

**p. 2-7, lines 7-8:** You could also mention ammonium as an important component of PM<sub>2.5</sub>.

**p. 2-9, lines 4-8 (similar to above comment):** Why not add ammonia to your list of important precursor gasses, instead of just indicating that it “also contributes”.

**p. 2-23, Figure 2-8:** Figure 2-8 shows recent 2015-2017 average concentrations, along with some much longer-term 2000-2017 trends. I think in late 2019 that 2018 data have been available for a while and that these charts could be updated.

**p. 2-23, Figure 2.9:** As in previous comment, this could be updated through 2018. I’ve also noted from EPA’s Air quality trends website that the long-term 41% improvement you cite 2000 through 2017 decreases to 38% when carried through one more year to 2018 (U.S. EPA (2019). Zooming in to more recent 2010 to 2018 data, I note that there was steady progress each year.

Both the national mean and 90th percentile PM<sub>2.5</sub> decreased from 2010 to 2011, from 2011 to 2012, etc. all the way through 2016. After 2016, both the national mean and the 90th percentile concentrations increase from 2016 to 2017 and increase again from 2017 to 2018. It would be informative to explore this recent reversal of long-term progress, and provide explanations of possible causal factors, along with estimates of future trends.

**p. 2-49, section 2.4:** Here and/or elsewhere when you discuss “natural” vs. “anthropogenic” aerosols, you could add some discussion of PM that results from combinations of natural & manmade sources. For example, emissions from a “natural” dust storm may be enhanced by human actions such as cattle grazing, desert recreation activities, or climate change. “Wildfires” may be started by a careless match, electrical transmission lines, enhanced by historical forest & fire management practices, climate change, etc. “Natural” VOCs may be converted to SOA by reactions with manmade oxidants or through reactions catalyzed by acidic (sulfate) aerosols. Natural sea salt or dust reacts with manmade nitric or sulfuric acids, etc. Sea salt emissions are projected to increase due to climate-driven increases in surface wind speeds. Historical and continuing US emissions represent the largest contribution of any country to the cumulative buildup of global climate-forcing greenhouse gases. Thus, a fraction of transcontinental dust and smoke (considered both “natural” and “non-US”) PM reaching the US may have been enhanced by effects our own anthropogenic GHG emissions

### **Chapter 3**

#### **SCQ 3-4**

This is not my area of expertise and I defer to other panelists for their thoughts on the quantitative risk assessment. Overall, I found the choices of health outcomes and studies selected for developing long-term and short-term CR functions reasonable and clearly justified. The selection criteria for included urban areas appear to be similarly logical and clearly described. Variability and uncertainty are clearly characterized, and the results appear to be valid and robust.

I support the hybrid modeling approach as a way of estimating effects that would occur over a range of current and alternative standards (a more realistic improvement over the statistical “quadratic rollback” approach employed several NAAQS review cycles ago). I was somewhat surprised to note that the relative mortality benefits generally appeared to be somewhat greater for meeting the different annual standards for the secondary PM reductions than for the primary PM reductions (Table 3-8, for example). I might have guessed the opposite - assuming the secondary PM reduction would have been more uniform across each urban study area, while the primary PM reductions would have shown more local influence and variability (residential space heating, roadway emissions, industrial sources) within each urban area. I wonder what the reasons are for this general pattern? Could some discussion be provided? Perhaps you could provide some high resolution images of sections of a few individual urban areas contrasting spatial patterns of differences between the primary & secondary control concentrations, underlain by the hybrid model grid.

### **Chapter 5**

Welfare effects considered in Chapter 5 include those on climate, materials and visibility. Some new information is available on climate effects, and while these remain complex, mixed, and uncertain for various PM species, I think a reasonable argument could probably be developed in



support of climate-related reductions in black (& brown) carbon concentrations, although a secondary standard may not be an appropriate mechanism. Some interesting new work quantifying PM materials (soiling) effects on efficiency of solar panels is presented, but does not seem (yet) to lend itself to setting a quantitative secondary NAAQS. Relatively little new information is available on visibility effects (although I think some useful recent information on visibility preference indices has been overlooked in the ISA and PAD (more on this below).

#### **SCQ-5.1**

The policy questions raised in Chapter 5 relate primarily to visibility. These questions essentially begin with the assumptions that the indicator, level, averaging time and form of the visibility-related PM NAAQS considered (and rejected) in 2012 - are all appropriate, state of the science, and need no further justification or reconsideration. The PAD furthermore jumps immediately to the weakest end (30 DV) of the previously considered 20 to 30 dv range, combined with the weakest (90th percentile) end of the previously recommended 90th to 98th percentile range when considering possible future benefits (of which - Surprise! - there are none). Some additional modeling of reconstructed extinction using a slightly modified equation is conducted in Appendix D, and while this shows somewhat higher light extinction levels, there still appears to be minimal exceedance of the 30 dv, 90th percentile threshold. I think all 4 elements of the secondary PM NAAQS considered in the 2012 review need to be reconsidered, justified (if possible), compared to alternatives, and, if warranted, revised.

#### **SCQ-5.2 What are the Panel's views of the draft PA evaluation of the currently available scientific evidence with respect to the welfare effects of PM. Does the assessment appropriately account for any new information related to factors that influence:**

##### **Quantification of visibility impairment associated with PM<sub>2.5</sub> and examination of methods for characterizing visibility and its value to the public?**

Regarding charge question GC-1, I have concerns with all 4 elements ((indicator, averaging time, level and form) of the secondary PM NAAQS presented for consideration in the Draft PAD document (and rubber-stamped from the 2012 review), and these relate in several cases to information not considered in the ISA.

##### **Indicator (reconstructed PM light extinction from 2012 review)**

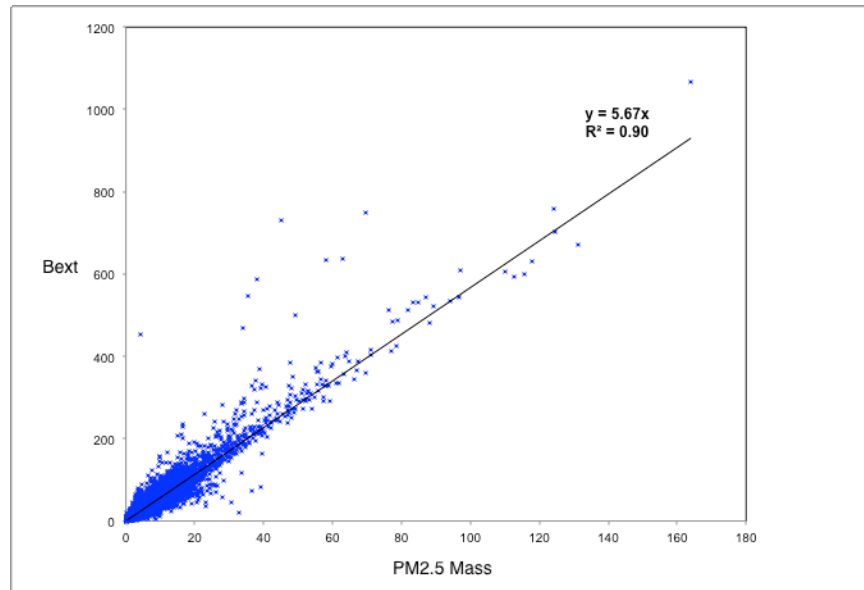
The first PM NAAQS established in 1970 included a separate secondary standard with a PM mass-based indicator (TSP). In subsequent NAAQS reviews completed in 1987, 1997 and 2006, EPA considered, with CASAC support, setting separate, visibility-related secondary PM NAAQS, in each case with a PM<sub>2.5</sub> mass indicator (although separate secondary standards were not set after those reviews). In the last review completed in 2012, EPA staff, with CASAC support, considered a different indicator: PM light extinction. During much of that recent review, it was assumed that PM light extinction (or PM<sub>2.5</sub> light extinction) could and would be directly measured by available continuous methods, such as nephelometer and Aethalometer.

Late in the review, it became clear that the Agency had no intention (resources, will, etc.) of establishing a new national monitoring network, and an inferior fallback methodology was employed to calculate PM light extinction from 1-in-3-day 24-hour filters collected in the EPA STN network and at similar state-sponsored speciation sites using the revised (II) IMPROVE algorithm. This approach takes into consideration the differential densities, size distributions,

light scattering and absorption properties and water retention characteristics of different aerosol species. This is basically the method employed to define visibility impairment and track (very) long-term progress toward improving it in remote Class I National Parks and Wilderness Areas under the Regional Haze Rule. It is not, however, necessarily any better (or as good as) a much simpler PM<sub>2.5</sub> mass indicator, [especially compared to the benefits of using the data from the existing continuous PM<sub>2.5</sub> monitors](#) in urban/suburban sites.

- The continuous PM<sub>2.5</sub> network includes 6 times as many sites as the CSN network, providing [much](#) better spatial coverage. Note that the modeled 2015-2017 reconstruction extinction in Appendix D is based on only 67 sites meeting data completeness criteria (see Figure D-1).
- The CSN network samples only every 3rd day, at best, leaving 2/3 of days unmonitored, compared to hourly sampling, every day in the continuous PM<sub>2.5</sub> network, providing 72x more temporal information - at 6x more sites.
- Filter-based CSN monitoring allows only “24-hour average extinction” estimates. This is [not](#) the averaging time over which people perceive impairment. Shorter hourly or 4 to 8-hour (daylight) averaging times would be [much](#) more appropriate, especially in urban/suburban areas where light pollution and other factors render night-time PM visibility impairment much less important. Focusing on daylight or mid-day hours would also minimize the importance of RH & speciation, leading to even tighter relationships between actual short-term visibility effects and PM<sub>2.5</sub> mass data (which are pretty good already). See CASAC recommendations on this from the 2006 review (Hopke et al., 2005, Henderson et al., 2006).
- While the IMPROVE algorithm - perhaps as enhanced by changes such as suggested by Lowenthal and Kumar (2016) - is “state of the science”, it still requires assumptions which are not always well met (the degree of sulfate ammoniation, chemical form(s) of nitrate, the varying relationships between measured OC and POM mass, etc.) See for example Hand et al., (2019); Preni et al. (2019). Use of 24-hr data also inflates the influence of higher nighttime RH (when urban visibility is least important).
- The filter-based algorithm itself has problems (which appear to be getting worse over time) in reproducing light extinction measured by nephelometry. Conversely, nephelometers have been successfully deployed as PM<sub>2.5</sub> monitors.
- A good argument can also be made that influence of (naturally) varying RH should be removed from the regulatory metric. Water influence would be minimized by focusing on the (more important) daytime hours. You could also use a fixed, long-term average RH to remove the natural variability from the regulation, or you could impose an RH screen (say eliminating hours with RH < 70%) on the PM data (as is done with urban visibility standards in Phoenix and Denver). Water effects are also decreasing over time as sulfate, nitrate and secondary semi-volatile organics decrease. I don’t think you really want the most extreme events driven by extreme uncontrollable variations in RH.
- Use of hourly data would allow eliminating hours with natural impairment (rain, snow, fog, natural dust storms, forest fires).
- Continuous PM data would allow extinction estimates or multi-hour averaged PM<sub>2.5</sub> values to be publicly reported in near-real-time, rather than waiting for months for the filter data results. (Note that the most recently available CSN data employed in Appendix D were from 2017).
- Use of the continuous PM data for secondary NAAQS regulatory purposes would lead to (needed) closer scrutiny, improved QA and better data quality.
- Light extinction from coarse particles is relatively unimportant in most regions and seasons, and when/where it is important (Southwest, spring), it’s often primarily due to natural sources. Alternatively, you could require added use of colocated continuous PM<sub>10</sub> samplers in areas like the Southwest where coarse particle scattering is important, or set a fine particle NAAQS this time and add a coarse PM component next time.

The figure below is based on [all](#) the (unscreened) IMPROVE data from all sites for the 3-year period 2015-2017, limited to sample days when both PM<sub>2.5</sub> mass and filter-based light extinction estimates are available (about 50,000 sample days).



Similar high correlations have also been observed between continuous PM<sub>2.5</sub> mass-based PM<sub>2.5</sub> monitors and nephelometers (or when the continuous nephelometer results are aggregated to 24-hr means - for comparison to filter PM<sub>2.5</sub>). See for example Chung et al. (2001), Chow et al (2006), Puget Sound (2001), Snider et al., 2015, etc. Note also that the slope of this scatterplot implies a generic extinction to mass ratio of about 6 m<sup>2</sup>/g. This is a bit higher than the expected dry PM<sub>2.5</sub> scattering efficiency (about 4 m<sup>2</sup>/g), as it includes influence from water, light absorption and coarse mass. The average scattering efficiency of coarse particles is about a factor of 10 lower (0.6 m<sup>2</sup>/g), and while this is generally a minor contributor, it can be important in certain regions and seasons (Southwest, spring). Given the above, reasonable estimates of total PM light extinction might be approximated by something like  $6 \times (PM_{2.5} + PM_{10-25}/10)$ .

The bottom line is that fine mass is a very good indicator of visibility effects, and the small amount of information gained by using speciation filter-based estimates is way more than offset by the spatial, temporal information and visibility relevance that would be gained using continuous PM<sub>2.5</sub> monitors and a sub-daily daytime averaging time. Please note the CASAC comments on secondary NAAQS from the review completed in 2006, for example: Hopke et al. (2004), page 9 and pages B9-B26, Henderson et al. (2006).

If you really want to keep the light extinction indicator, use the filter-based speciation data to calculate regional monthly or seasonal species composition + f(RH) factors to adjust the continuous PM<sub>2.5</sub> data to (slightly) better extinction estimates - which could then be considered on a sub-daily basis, much more relevant to human perception, and could be publicly reported from a much larger network in near-real time. Please note the CASAC recommendations (Samet et al., 2010) on various options for secondary PM indicators averaging times, forms, etc. in comments on the 1st draft (March, 2010) draft PM PAD. These comments came at a point

when it was still assumed PM light extinction would be continuously and directly measured, but also supported using seasonal & regional speciation and RH data to develop modifications to the hourly PM<sub>2.5</sub> data - needed to support the recommended sub-daily averaging times. I think a simple sub-daily PM<sub>2.5</sub> mass indicator which intentionally limits the influence of naturally varying RH on the regulatory metric is a better choice for an indicator. If the Agency wants to persist in advocating continued use of the every 3rd day 24-hour, filter-based reconstructed light extinction indicator, it needs to justify why it thinks it has a superior indicator. I don't think it can.

### **Averaging Time (24 Hours from 2012 PM NAAQS)**

As indicated above, once the decision was made that the PM light extinction indicator introduced in the 2012 review would not be measured directly and continuously, a fallback method was proposed to calculate PM light extinction based on every 3rd day 24-hour filter sampling. (This, in my opinion, was the point where the 2012 review ceased to represent any advancement of the science and became notably inferior to the sub-daily PM<sub>2.5</sub> secondary standard considered in the 2006 review). Filters limit the averaging time to no shorter than 24 hours, which is not the time frame over which visibility impairment is perceived. It's also especially inappropriate in urban areas where visibility during daylight hours is much more important (and is also characterized by lower RH levels - reducing the small difference between PM mass and light extinction).

EPA's Final Staff Paper (U.S. EPA, 2005) from the 2006 PM NAAQS review (which recommended a sub-daily PM<sub>2.5</sub> mass indicator in the range of 20 to 30 ug/m<sup>3</sup> for a secondary PM NAAQS) stated:

In considering appropriate averaging times for a standard to address visibility impairment, staff has considered averaging times that range from 24 to 4 hours, as discussed in section 6.2.3. Within this range, as noted above, correlations between PM<sub>2.5</sub> concentrations and RE [reconstructed extinction] are generally less influenced by relative humidity and more consistent across regions as the averaging time gets shorter. Based on the regional and national average statistics considered in this analysis, staff observes that in the 4-hour time period between 12:00 and 4:00 p.m., the slope of the correlation between PM<sub>2.5</sub> concentrations and hourly RE is lowest and most consistent across regions than for any other 4-hour or longer time period within a day (Chapter 6, Figure 6-4). Staff also recognizes that these advantages remain in looking at a somewhat wider time period, from approximately 10:00 am to 6:00 pm. Staff concludes that an averaging time from 4 to 8 hours, generally within the time period from 10:00 am to 6:00 pm, should be considered for a standard to address visibility impairment.

It can also be noted that the quality of the continuous PM<sub>2.5</sub> mass data has improved considerably over the past 20+ years, providing greater confidence in its accuracy over shorter averaging times. The Agency should consider the many benefits of using the continuous PM<sub>2.5</sub> data as the measurement basis for a sub daily 4 to 8 hour daylight averaging time. This could be combined with a continuous PM<sub>2.5</sub> mass indicator, or regional & seasonal generic species composition and f(RH) factors could be developed to convert the mass to estimated extinction (if you need to stick with a b<sub>ext</sub> indicator). Either way, the data could be reported in near-real time, and would relate more directly to the human perception of impaired visibility.

## Level (20 to 30 dv from 2012 review)

While the previous 2011 PAD recommended a range of 20 to 30 dv as an appropriate level, the Administrator (sort of) picked the upper end, before concluding that such a NAAQS wouldn't do much good. The current PAD simply starts with this upper end (30 dv) as if this were a logical, technically-supported absolute definition of "acceptable visibility" or adverse effects. It's not.

In a previous review of the draft ISA, I noted that the ISA had neglected an important recent meta-analysis of visibility preference studies by Bill Malm (Malm et al. 2011, 2019 and Malm, 2013 and 2016) which could support an alternative way of defining adversity based on geographical differences in distant landscape features. My earlier comments on this omission in the ISA are pasted below:

A second general criticism of this brief summary - as well as with the more detailed Chapter 13 discussion of visibility - is the absence of discussion of recent work on visibility preference indicators developed by William Malm over the past several years (Malm et al. 2011, 2019 and Malm, 2016). His meta analysis of multiple available visibility preference studies (in many different kinds of locations) noted that "unacceptable" levels of visibility impairment occurred at different extinction levels in different areas, but that in any area, when the more-distant visible landscape features nearly disappear - which occurs at apparent contrast levels of about 0.02–0.05 - the haze level became unacceptable to about half of the participants in each study area. This has important implications for the potential setting of PM visibility standards at nationally consistent contrast levels which are geographically variable with changing distant landscape features. It would be a relatively straightforward GIS exercise to characterize distances to prominent landscape features in population centers throughout the country and then use PM<sub>2.5</sub>-based extinction estimates to calculate contrast levels for those landscape objects to determine the extent to which visual air quality is (or is not) considered acceptable in each of those areas.

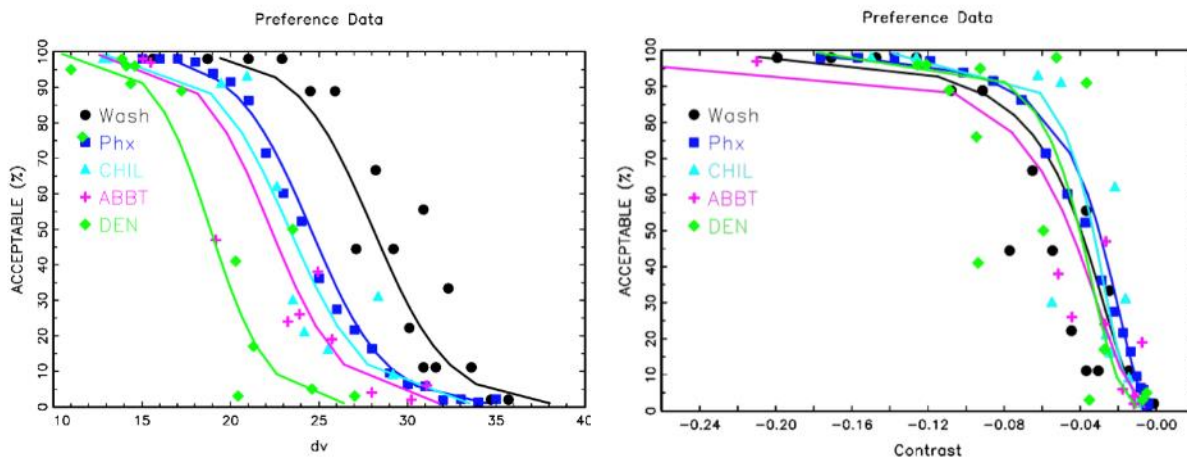
There appears to be a reference to Malm's work in the executive summary: "There have been no recent visibility preference studies; however, a recent meta-analysis demonstrates that scene-dependent haze metrics better account for preference compared to only using the deciview scale as a metric." However, any discussion of this recent work seems to be missing from the Integrated Synthesis or Chapter 13. Section 13.2.5 on "human perception of haze and landscape features" heavily emphasizes the divergent results in different visibility preference studies in areas with (or using photographs showing) different landscape features, when visual air quality is expressed as light extinction (deciviews). It concludes with:

"There is little new published information regarding preference levels in the U.S. The single new study by Smith (2013) was an investigation of "framing bias" in preference studies that can potentially occur because preference levels are chosen in part based on experimental variables such as number of photographs shown or range of the range of dv levels participants are shown when asked to state a preference about whether scenes in photographs are acceptable."

This disregards important new work in this area, which clearly shows a convergence of results across many different urban areas when the visual air quality is expressed in terms of the contrast of the most distant landscape features. Another important recent

related technological development is the ability to incorporate clouds into the Winhaze model - developed by John Molenar (Molenar and Malm, 2012). For cities in relatively flat terrain which lack distant landscape features, clouds often are the most distant scenic attribute. As they begin to disappear, viewers tend to find the degradation of visibility unacceptable, at lower levels of light extinction than they would viewing cloud-free scenes. Some discussion of this work, implications and potential future applications is warranted in chapter 13.

The figures pasted below are from a 2013 status report Malm presented on this work (Malm 2013) Please see Figures 4 and 5 from Malm et al., 2019, for updated versions of these figures and more detailed descriptions of the methods. Both figures plot percent acceptability levels from 5 urban visibility preference studies. The figure on the left (similar to Figure 5.2 in the PAD) plots percent acceptability against absolute light extinction in  $dv$ . Note that at the 50% acceptability levels in all 5 studies are bounded by a range of extinction between about 20 and 30  $dv$ . This was the basis for suggesting this range in the 2012 review, although the current PAD starts at 30, a level which is clearly unacceptable to the majority of respondents in all 5 study areas.



In the figure on the right, Malm plots percent acceptability results from the same studies against the apparent contrast of “a distant, prevalent, but not necessarily dominant, feature”, which shows a remarkable consistency at a contrast of about -0,04 across many diverse types of study areas. This contrast threshold of about -0.04 basically occurs as the visual range nears the distance of prominent distant scenic elements. People everywhere tend to find decreased visibility unacceptable as prominent, distant landscape features begin to disappear.

If this kind of approach were applied across multiple urban/suburban areas throughout the country, it would be clear that people in many diverse regions would likely find visibility impairment of 30  $dv$  to be unacceptable. The Agency should consider using this apparent contrast threshold as a basis for setting a consistent national standard which could vary geographically depending on local scene characteristics. I think it would be a relatively straightforward GIS exercise to determine regional scene characteristics across the US. This would be a similar concept to what the Agency considered in the last review of secondary SOx

+ NO<sub>x</sub> NAAQS, in which the varying biogeochemical features of local eco-regions were incorporated into the proposed standard.

### **Form (90th Percentile from the 2012 review)**

The 90th percentile is not supported in the PAD or ISA. Its just repeated from the last review cycle (where it was never justified either). It was simply a way for a secondary NAAQS - considered at the most lenient end of the staff-recommended 20 to 30 dv range - would have little to no benefit over the primary standard. The forms of the various secondary standards that have been considered/ recommended by EPA staff and/or CASAC over the years has varied widely: not to be exceeded more than 1 day/year (1971), 3-month seasonal mean averaged spatially over multiple years (1987), 98th percentile averaged over 3 years (1997), 92nd to 98th percentile, 3-year average (2006), and 90th to 98th percentile, 3 year average (2012).

With the exception of 1971, when a separate secondary PM standard was set, the secondary NAAQS considered in all subsequent reviews were rejected for various different “reasons” (see: Poirot, 2011). In the 2012 review, the Administrator selected the (most lenient) 90th percentile combined with the weakest level (30dv) before concluding that this combination really wouldn’t have much incremental benefit over the primary. The only stated justification was that the Regional Haze Rule is focused on the haziest 20% days, and that the 90th percentile - the midpoint of the haze range - would be consistent. (Although the average of haziest 20% days is closer to the 92 percentile - considered as the low bound in 2006 for that stated reason).

More importantly, this is a [false](#) equivalency. The focus in the Haze Rule is specifically on [improving](#) conditions on these worst days. The use of a similar percentile as a NAAQS form has exactly the opposite effect - of completely [ignoring](#) the worst visibility days, exculpating them from any consideration of improvement. Visibility could be worse, or much worse than 30 dv on 36 days each year, but people only find it objectionable when this happens 37 or more days per year (averaged over 3 years). This is not logical, and no other justification is provided in the PAD or ISA.

### **SCQ-5.3 What are the Panel’s views of the draft PA preliminary conclusion that the currently available scientific evidence does not call into question the protection afforded by the current secondary PM standards against PM welfare effects and that it is appropriate to consider retaining the current secondary PM standards without revision?**

As indicated above, I have criticisms of all elements of the secondary NAAQS which was considered (but ultimately rejected) by the Administrator in 2012. I also don’t think current secondary PM NAAQS provide protection against adverse visibility effects on public welfare. The combination of daily average, 90th percentile, 30 dv, filter-based reconstructed PM light extinction is a substantially weaker secondary standard than those considered by EPA staff and supported by CASAC in all previous (1987, 1997, 2006 and 2012) PM NAAQS reviews.

To illustrate the visual AQ effects of the current 24-hour NAAQS, the images below show a clear day view from Denver which has been modified by a model called WinHaze developed by John Molenaar at Air Resource Specialists and now available on-line at: <http://vista.cira.colostate.edu/Improve/winhaze/> . See Poirot (2011) for added details on visual effects of alternative NAAQS.

The figure on the right models the visual air quality effects of 35 ug/m<sup>3</sup> of PM<sub>2.5</sub> (composed of equal parts organic matter, ammonium sulfate and ammonium nitrate at 50% RH). It may be noted that this mix of pollutants at the level of the current daily PM<sub>2.5</sub> NAAQS results in light extinction of 202.71 Mm<sup>-1</sup> - or 30.09 dv - basically the upper end of the 20 to 30 dv range suggested in the final 2011 PM PAD and rubber stamped in the current PAD. So clearly, PM light extinction at 30 dv (90th percentile) offers no protection beyond that provided by the current NAAQS.

The question is does anyone really believe this is an adequate level of visibility protection?



Similarly, the current annual secondary PM<sub>2.5</sub> NAAQS at 15 ug/m<sup>3</sup> is weaker than the primary, and therefore protects nothing, since the primary standard must be attained within a fixed period of time while a secondary standard has no time requirement. Nor has any scientific justification been provided for this irrational selection. The modeled image on the left shows a similar mix of PM<sub>2.5</sub> species at 15 ug/m<sup>3</sup>. Coincidentally this results in visibility impairment of 20.15 dv - the low end of the range considered in the 2012 review. Is this acceptable annual average visibility?

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## Dr. Jeremy A. Sarnat

*General Comments:* The EPA staff who prepared the draft Policy Assessment for the PM NAAQS reviews have done a commendable job summarizing the scientific evidence presented in the PM ISA. Broadly, I find the document to be clearly written and well-justified, and presents a justifiable set of approaches for outlining the policy implications contained in the ISA. Most of the comments below address recommendation to changes in interpretation or emphasis and are not criticisms of the substantive approach for conducting this PA. In addition, I included a couple of comments that relate to the ISA, but appear not to have been addressed and could affect policy decisions within the PA.

I did find it notable, with exceptions, that much of the process and base assumptions presented in this PA, while reasonable, is largely incremental, building heavily on well-established understandings of PM exposure and health, and mainly avoiding emerging evidence, especially as it relates to susceptibility and biological mechanisms. I do appreciate this approach and recommend only that more be added, to the future directions portion of the assessment, preparing staff for what I feel are imminent larger changes to how we understand PM toxicity and regulate its presence in the environment.

The specific comments below relate to the charge questions for SCQ 3.3:

***‘What are the Panel’s views on the evidence-based approach, including:’***

- a) *The emphasis on health outcomes for which the draft ISA causality determinations are “causal” or “likely causal”?*

The practice of basing evidence-based policy exclusively on outcomes where ‘causal’ and ‘likely causal’ determination exist, is a common practice within the NAAQS Policy Assessment process and reasonable based on weight-of-evidence rationale. In some ways, however, this follows a proverbial ‘looking under the lamppost’ approach and may, for some pollutants, represent a less conservative element within the current PA (i.e., a practice being less protective of human health). With caution taken to avoid false comparisons among pollutants and the respective processes that govern their regulation, chlorpyrifos comes to mind as an example of this. With chlorpyrifos, traditional, well-established pathways and endpoints were used in regulatory decision making, when novel, perhaps slightly less established, endpoints were not adequately considered.

For PM, specifically, it is possible and even likely that the pace of discovery into molecular mechanisms and its modes of toxicity will lead to new insights into more relevant (or sensitive) outcomes that may inform the standard. This is a major current direction of the health effects work being conducted and is rightly acknowledged in section 3.5 (‘Areas for Future Research’) of Chapter 3. Of particular note are the numerous investigations using high-throughput and omics-based methods. These, and future studies should contribute towards the identification of novel modes of PM toxicity and also specific groups of individuals who may be especially susceptible to PM exposures, particularly those with metabolic syndrome. I believe this is a point that should also be mentioned earlier in the chapter when discussing the current decision to emphasize the more studied and established exposure-outcome associations.

b) *The identification of potential at-risk populations?*

The identification of 'at-risk' to include those beyond traditional definitions centering around biological susceptibility is a substantive (non-incremental) change from the previous PA. EPA staff deserve credit for thinking about elevated exposures that may arise from societal disparities, as another factor conferring risk.

c) *Reliance on key multicity epidemiology studies conducted in the US and Canada for assessing the PM<sub>2.5</sub> levels associated with health effects?*

Even though I strongly believe that single-city studies offer important insights into both acute and chronic health effects associated with PM, I support the decision to conduct the evidence-based assessment using the multicity studies.

That said, while I appreciate the rationale, the decision to exclude high-quality multicity studies from other parts of the world may be a bit restrictive. For long-term exposures, for example, it would have been reasonable to include the numerous published findings from the European ESCAPE study, specifically. Given the relatively large number of US and Canadian cities included in the analysis, however, I am generally comfortable with the current approach. From these multi-city studies, I think the PA appropriately draws attention to findings showing adverse health occurring at levels currently below the NAAQS (both with the mean and distributional data and the pseudo design values). Among the most important of these studies are three Canadian analyses (Weichenthal et al., 2016b, 2016c and Pinault et al., 2016) where significant effects following long- and short-term exposures were observed well below the current NAAQS, and > 75% of the study populations in these analyses were living in areas above the pseudo design values. As an aside, from an exposure perspective, it's worth speculating about the observed rate/odds ratios reported in these studies and whether they may actually be attenuated relative to some of the other multi-city study results presented. It could be that exposure to ambient PM in these Canadian cities is actually lower than US cities due to lower ambient PM infiltration arising from more tightly sealed homes in colder climates. This would mean that the risks from exposure to PM<sub>2.5</sub> in these studies is actually higher than reported. (It is also possible, though, that the milder warm seasons may mean that Canadians use less central AC (leading to higher exposures to ambient origin PM)).

d) *Characterizing air quality in these key studies using two approaches: the overall mean and 25<sup>th</sup>/75<sup>th</sup> percentiles of the distribution and the "pseudo design value" reflecting a monitor with the highest levels in an area?*

Characterizing exposures and corresponding health response using distributional and pseudo design values reflects a point worth reiterating and not often directly acknowledged or addressed within the regulatory community; namely, that a single PM standard likely does not reflect the same level of population exposure, nor protective of corresponding population health for all locations, or for even a single location during different times of the year. I believe the approaches used by EPA to generalize the findings from the multi-city studies is appropriate and the evidence-based conclusions drawn from these studies also seems reasonable.

- e) *The preference for continuing the use of an annual PM<sub>2.5</sub> standard as the principle means of providing public health protection against the bulk of the distribution of short- and long-term PM<sub>2.5</sub> exposures?*

While the bulk of my research frequently targets sub-daily exposure and acute response to PM, I agree with decision to use longer averaging times as a principle means of protecting health. While it may be necessary to reconsider averaging times and indicators in future assessments, I still believe the rationale used in the 2012 ISA for lowering the annual standard still makes sense.

- f) *The draft PA conclusions on the extent to which the current scientific information strengthens or alters conclusions reached in the last review on the health effects of PM<sub>2.5</sub>?*

Differentiating causal determination for both short- and long-term PM<sub>2.5</sub> exposure and corresponding cardiovascular and respiratory health effects seems arbitrary. I have noted in previous comments to the ISA that, to date, hundreds of observational and controlled results suggest casual links between PM<sub>2.5</sub> and adverse acute and chronic respiratory response. It's extremely difficult to discern meaningful differences in the weight-of-evidence collected for the PM-respiratory link, with that presented for PM-cardiovascular effects, which has been determined to be causal. Moreover, to retain this status determination, effectively places the weight-of-evidence for these health endpoints on a similar level as those presented for adverse chronic neurological effects; which I don't believe is warranted.

- g) *Whether the discussions of these and other issues in Chapter 3 accurately reflect and clearly communicate the currently available health effects evidence, including important uncertainties, as characterized in the ISA?*

I have a long-standing concern regarding the use of multi-pollutant models as a primary means of assessing confounding and robustness in the ISA and now draft PA. There are serious limitations in assessing potential confounding through this approach and I believe this discussion deserves greater attention. Briefly, there are several sources of uncertainty and potential bias in using linear multi-pollutant regressions as the sole or predominant means of assessing potential confounding. The use of linear expressions, within a co-pollutant setting, to control for confounding of non-linearly correlated co-pollutants could lead to imprecision and/or bias; an appearance of effects associated with either PM or one of its correlated co-pollutants, where they do not exist. Related to this issue is that the vast majority of the co-pollutant models focus on the issue of confounding solely (i.e., what is the effect estimate of PM, while controlling for another pollutant), rather than the potential for joint effects or effect modification. These latter scenarios appear to me to be equally plausible in characterizing PM-related health effects, and that PM, including a complex suite of particulate components and other pollutant gases, may elicit response via inflammation-mediated pathways.

## Dr. Elizabeth A. (Lianne) Sheppard

Note: I only retained in my final comments points from my preliminary comments that I do not consider fully covered in the IPMRP consensus comments. The remaining preliminary comments have been edited and additional thoughts added.

### Risk assessment comments

1. The hybrid modeling approach relies on CMAQ predictions, a Bayesian downscaler, and is restricted to year 2015. The reductions were based on emissions from either primary or secondary PM; using two methods allows better understanding of the sensitivity to the downscaling approach. There are important limitations to the approach including restriction to 2015, working at the 12 km grid level, and assuming proportionate reductions scaled by fixed percentages. Specific comments:
  - a. The air quality modeling assessment section (C.1.4.3) should make it clear what time scale the evaluation is being considered. Is it daily? Similarly the N in table C-6 is not defined. I'm guessing it is the number of observations, which is the sum of days across AQS monitors. If so, the number of monitors should also be included (e.g., in parentheses).
  - b. It is a limitation that only 2015 was used. The choice is reasonable, appropriately justified, and acceptable given the compressed timeframe EPA was working under.
  - c. The performance of the 2015 CMAQ model doesn't look particularly good to me (Table C-6). Air quality modeling experts are not concerned about this performance and I note that this concern may not be particularly important for the risk assessment.
  - d. The scientifically important features of exposure models are different when the purpose is epidemiology vs. risk assessment. Exposure predictions are often much less variable than the full range of the underlying exposure. This is OK for epidemiologic inference but a weakness in a comprehensive risk assessment. For risk assessment, it is important that the model predict the same mean and capture the full variation of the distribution represented by the underlying concentration distribution in the area under consideration. While ground truth can only be approximated due to inherently limited monitoring data, it would be helpful to see a more direct assessment of the performance of the downscaler model for the risk assessment purpose. Also it would be worth considering additional exposure models in the risk assessment as the risk assessment results may be particularly sensitive to the choice of exposure model.
  - e. The treatment of the 2015 downscaler is fairly cursory (Section C.1.4.5). I think more details are warranted. For instance, the cross-validation should be more clearly described (e.g. how were the 10% of withheld locations selected? On what time scale is Table C-8?). Also a useful assessment would be where the 47 urban areas are withheld and these are evaluated.
  - f. The linear interpolation approach to assessing additional standards represents a reasonable compromise to meaningfully reduce EPA's workload given the compressed timeframe for producing the PA. Were additional time

available I would suggest modeling at least one more level in order to understand better whether the linear assumption is reasonable.

- g. Other comments: It would be helpful to also show a version of Table C-6 restricted to the 47 urban areas. It would be helpful to include a table that documents the number of 12 km grid cells per CBSA since this will affect the estimates of spatial variability within CBSA.
2. Regarding Section C.2.2, I note that a major source of variation in numbers of individuals affected (the scale most of the risk estimates are reported on) across 12 km modeling regions is the size of the at-risk population in that region. This could come across a bit more clearly.
3. The robustness and validity of the risk estimates may be most sensitive to the use of the downscaler rather than one of the other national models presented in Chapter 2. This was not addressed at all in the risk assessment. (See also my Chapter 2 comments below.) I encourage EPA to evaluate this input in sensitivity analyses.
4. I would like EPA to carefully address whether they are able to include the entire US in their risk assessment or need to continue to rely on a subset of urban areas as they have done here.

### **Comments on the PA's preliminary conclusions regarding the PM2.5 standards**

I agree with the draft PA preliminary conclusion that the adequacy of the public health protection afforded by the current primary PM2.5 standards should be called into question.

I agree with the "...focus on the annual PM2.5 standard as the principle means of providing public health protection against the bulk of the distribution of short-and long-term PM2.5 exposures..." (p 3-13, line 7-9) Add strong statement on short-term standard

It is appropriate for the PA to discuss support for and potential implications of putting more or less weight on various aspects of the evidence. (p 3-15)

In calling into question the current standards (in favor of lower standards), EPA puts appropriate weight on the longstanding body of health evidence for serious short- and long-term effects, noting that newer evidence supports and strengthens the previous 2009 conclusions. They also note epidemiologic evidence for effects at low PM levels and that no evidence of a threshold has been identified. They highlight that the risk assessment results suggest large numbers of deaths could be avoided with a lower standard.

In considering the alternative argument that the current standard should be retained, EPA notes that substantial weight must be placed on a number of uncertainties, including the biologic pathways, public health impacts of air quality improvements, and the risk assessment results. As was solidified during our meeting discussion and developed fully in our consensus comments, these arguments for retaining the current standard are not scientifically justified.

In discussing potential alternative standards, the arguments for the indicator, averaging time, and form are straightforward and indicate no change is needed. In discussing the level, I agree with EPA's appropriate focus on "the annual PM.25 standard as the principle means of providing increased public health protection." Their consideration is

informed by existing concentrations and their relationship with design and pseudo-design values, as well as effects in controlled human exposure studies and their risk estimates. Together these justify a lower alternative standard. Furthermore, as became apparent during our meeting discussion, the standards will be less protective if only the annual standard is lowered without lowering the 24-hour standard. Thus I do not concur with EPA's recommendation to retain the 24-hour standard. There are locations where the 24-hour standard is the controlling standard and in order to protect public health in those locations the 24-hour standard also should be lowered.

#### **EPA-6: Future research areas**

A few topics to add to the research agenda:

- Better understanding of exposure models and their features, comparing and contrasting their utility for epidemiology vs. risk assessment. (Builds on comment on p 2-48, lines 24-27)
- There is ongoing need for characterization of the performance of modeled ambient concentration fields estimated using hybrid modeling methods. We need to better understand the different implications of the hybrid models.
- Methods for mixtures and effect modification.
- Causal inference methods. See for instance the commentary by Carone, Dominici, and Sheppard, *Epidemiology*, in press.

#### **Chapter 2 comments**

- P 3-37 | 3-4: Please add the size bins
- P 2-38 figure 2-22: The legend of this figure is confusing since the x axis is year for both y-axis measures. Also I suggest a time series plot is clearer if plotted using connected lines rather than points as shown. The best fit lines can still be included. Also, please clarify whether there are data missing in the plot, or whether some values are overplotted. (A line plot would be less confusing w.r.t. this point.)
- It seems to me that the key goal of Section 2.3.3 Predicted Ambient PM<sub>2.5</sub> Based on Hybrid Modeling Approaches is to present results from several models and provide context for the one selected for use in the risk assessment.
  - I suggest reframing this section and eliminating extra detail. As part of this reframing I suggest presenting the link of the models discussed to the health studies to the models used in the risk assessment. (However, priorities in choosing exposure models useful for risk assessment are distinct from those for epidemiologic inference. For risk assessment (and in contrast to epidemiology), it is essential to capture the full variation of the population exposure distribution. For epidemiology it is the quality of the predicted mean and the spatial alignment of the data used in the model with the target health study population that are important for inference.)
  - P 2-39: I find EPA's use of "hybrid" terminology confusing. Its first use on line 3 seems clear enough to me and consistent with my understanding of the common usage for air pollution prediction models. This brief mention acknowledges the reference to "hybrid" is to capture the explicit combination of data from multiple sources. It does not refer to weighting of all the same kind of data (e.g. as in inverse distance weighting), or using some air quality



data as predictors in a regression model. Section 2.3.3.1.1, Overview of hybrid methods, goes on to include interpolation and machine learning methods, which I would not consider “hybrid”. Regarding interpolation methods, perhaps it is the reference to including weighting by a CTM (line 23), that makes this description “hybrid”? I encourage EPA to revisit this section. One solution may be to simplify the presentation and eliminate some of the detail.

- Section 2.3.3.1.2 seems to be too much detail for the PA. Also there are many details in how R<sup>2</sup>'s are calculated that may mean the estimates reported on p. 2-41 are not comparable. One hint that this may be the case is that the Di and Hu study estimates have opposite ordering for their R<sup>2</sup> and RMSEs. Also generally the RMSEs are more interpretable scientifically and the RMSE value for the downscaler results should be reported. Finally, cross-validated results ought to appropriately capture overfitting so this should be reflected in any cross-validated model performance statistics.
- Since maps inherently smooth over large spatial scales, it is hard to interpret the effect of showing the predictions “at their native resolution”. I suggest one set of zoomed in maps in a region with sufficient PM<sub>2.5</sub> variation with a total of 16 or 64 12-km grid cells to allow better understanding of the impact of the native resolution.
- P 2-46 Figure 2-26: It is probably worth spelling out coefficient of variation here since the CV abbreviation is easily confused with cross-validation. Also provide an explicit definition of its use here, which I believe is the standard deviation of the estimates across the 4 models divided by the mean across these four.
- Figure 2-28 is particularly informative and suggests to me that there are some structural features in the data and its use in the downscaler model that provide such strong bands of similar concentrations in the middle section of the US. This feature suggests to me that it would be worth considering additional exposure models in the risk assessment as the risk assessment results may be particularly sensitive to the choice of exposure model.
- Given human contributions and causes, is it fair to classify all wildland fires as “background”? See references included in the consensus comments that suggest this is an incorrect classification.
- We should clarify the difference in emphasis in model- vs monitor-based methods for urban areas and the relevance of this focus for the PA. p 2-48 10-13

### **Comments on CASAC and my reaction to consultant comments**

- I agree completely with Duncan Thomas' comments, a CASAC consultant. Of particular note he provides important overall perspective about the state of causal inference in epidemiology. This is a perspective CASAC hasn't heard under Dr. Cox's leadership and it is an important one. Dr. Thomas' perspective is completely consistent with my recently published commentary, available online (Carone, Dominici, Sheppard, *Epidemiology*, in press). (I also submitted this paper to the CASAC docket.)

- EPA should leverage Dr. Thomas' replies, particularly to Dr. Cox's questions, in its revisions to the PA. Particularly given the outsize attention CASAC is paying to causal inference, I think it is important for the PA to address these considerations directly.
- I want to express concern about the CASAC Chair providing references to his own research to CASAC. Given his leadership position and federal rules about conflict of interest, this self-promotion is of concern.
- I want to express concern about the apparent outsized role of the CASAC Chair in the upcoming Panel deliberations. As per the October 24-25 draft agenda, Tony Cox has been assigned to respond to charge questions for four of the five chapters and is the lead discussant for two of these. I do not think it is appropriate for CASAC perspective to be dominated by one person's views and the optics suggest CASAC's opinion will be dominated by Tony Cox. Furthermore, a more appropriate role of the Chair is to navigate consensus among all Panelists, rather than to dominate the discussion. Based on previous CASAC meetings, I am concerned that he will attempt to push the Committee to an extreme perspective without attention to consensus.

### **Causal inference, epidemiologic studies, and evidence**

Regarding application of causal inference methods, under appropriate conditions, i.e., reasonable causal assumptions, causal inference tools allow us to draw causal conclusions from epidemiologic studies, much as we would if we could experimentally manipulate the exposures in the populations under study. Causal inference relies on framing a causal question of interest in terms of counterfactual or potential outcomes, and then ensuring that the causal question can be estimated from the observed data by mapping onto these observed data the unobservable causal contrast obtained from the potential outcomes. Essential to this mapping is the validity of the required causal assumptions. These assumptions are challenging to meet in their entirety in many studies, and particularly observational studies, although as CASAC consultant Duncan Thomas notes, "these may be reasonable depending on the context." Furthermore, even when the causal assumptions cannot be met completely, a causal framework can still be useful for informing policy-relevant decision-making. I also wish to note that there are many challenges to conducting valid causal inference analyses of observational data, from the most basic framing of causal questions and ensuring the validity of the causal conditions, to actually estimating causal effects. Specific to air pollution epidemiology, some more difficult aspects of these challenges include defining a causal effect due to the complex time-varying nature of air pollution exposures, including their multi-pollutant nature; the inherent limitations of relying on observational data, particularly with regard to estimating the relatively small effects typical in air pollution studies; the challenge of accurately quantifying the exposure used in the inference; and the current emerging state of methodological research in the field of causal inference.

Given the important policy implications of the PM<sub>2.5</sub> health effect evidence from observational studies, I emphasize that the epidemiologic study evidence is credible for advancing air pollution policy. While it would be ideal if the PA could rely on recently developed causal inference methods for these policy inferences, most of the current

body of evidence was developed under conventional inferential analyses that aren't explicitly framed in a causal inference framework. Nonetheless, these existing studies give us important insights, and when taken together, combine to give a weight of evidence that is substantially stronger than any single study can provide alone. As noted by CASAC consultant Duncan Thomas, "it would be inappropriate to dismiss them [i.e., epidemiologic studies] as not addressing causation, given their concordance and the general conformity with the criteria used by epidemiologists for decades to qualitatively evaluate causation." Carone et al (in press) state that, "causal inference methods should not be used as another opportunity to weaponize science against itself." The Clean Air Act requires EPA to act to protect public health with an adequate margin of safety, even in the presence of uncertainty. Just because most air pollution epidemiology studies do not explicitly apply causal inference methods, this is not an appropriate justification for discounting or discrediting the evidence they provide.

Carone M, Dominici F, Sheppard L. In pursuit of evidence in air pollution epidemiology: The role of causally driven data science. *Epidemiology*, 2019, in press. NIHMSID 1535952

### **A few insights based on the Panel (IPMRP) discussion**

- The risk assessment in the context of acceptable risk: The risk assessment implies that the risk at the current standard is greater than 1 in 10,000 (using ~50,000 excess deaths and a US population of 330 million). This is MUCH higher than what would be considered acceptable for increased risk in the general population for cancer risk assessments. While these are not directly comparable, this is helpful perspective.
- I concur with arguments about the importance of a sub-daily standard, particularly to capture traffic-related PM in the morning and wood smoke exposures in the evening.
- There is a need for a Federal Reference method for UFP.

### **Specific details to consider in revising the PA**

- C-30 lines 16-17: Revise the wording of this section to clarify that the measured concentrations are the basis of the projection vs. the current wording, which implies that the measured concentrations are the result of the projection.
- Figures C-26 and C-28: Please use a different color scheme from the maps and define the color scale. The current presentation invites confusion.
- Add RRF – relative response factors – to the list of abbreviations.
- P 3-19 line 13 "cohorts"
- P 3-23 l 28: I agree with the judgment that the heterogeneity is multifactorial.
- A few places with discussion of the width of CIs relative to the mean PM: As I understand the text, the feature being described is a property of CIs for regression model estimates ( $\hat{Y}$ ). (e.g., p 3-51, p 3-10)
- Figure 3-11 p 3-83: It would be helpful to add some clarification in the text or as a footnote regarding the values reported on the graph that correspond to the various standards.
- P 3-85 table 3-5: Add a footnote to define the ranges reported in the table.
- P 3-87 observations about potential alternative standards should note that the study used to develop the risk estimates had more impact

- P 3-90: Fix the Figure 3-12 title to be more stand-alone, adding that it is IHD mortality and that the risk estimates come from Jerrett.
- P 3-90 footnote 68: I think the explanation should be reworded to say the risk estimates were truncated. Or perhaps the intended meaning is that what is reported are the risk estimates for a range of concentrations depicted at the integer concentration level. Clarify.
- P 3-91: It appears that the graphic is a table, not a figure. Also refine the caption.
- Figures 3-3 to 3-6, it would be helpful to add a column for the pseudo-design values and to order the studies (perhaps within country) by PM means.

## Dr. Barbara J. Turpin

**SCQ 2.1** *Regarding whether the draft PA accurately reflects and communicates the air quality related information most relevant to its subsequent evidence-based assessment of the health and welfare effects of studies, including uncertainties, as well as the development of the risk assessment for current and alternative standards?*

*In particular, do the following sections accurately reflect and communicate current scientific understanding, including uncertainties for:*

- a) relationships between annual and daily distributions of PM;*
- b) the review of hybrid modelling approaches used to estimate exposure in some studies and the risk assessment; and*
- c) information on background levels of various PM indicators?*

- a) Annual and daily:** The document notes that, in the Northwestern US, daily and sub-daily (2-hr) concentrations (and the relationship between annual and daily) are heavily influenced by wildfire emissions in the summer/fall and stagnation in the winter. ***Not reflected adequately here are the impacts of controllable emissions, including seasonal or episodic emissions on these features nor do they reflect impacts from controlled burns, which are*** a major risk reduction approach for forestry. The text implies that these high concentrations are beyond our control. It does not acknowledge that stagnation events concentrate *anthropogenic emissions* near the surface in the winter, sometimes leading to high ground-level concentrations. Local heat emissions in urban settings (the Urban Heat Dome) can contribute to local stagnation as well. The episodic but substantial contribution of residential wood combustion for home heating is one of these anthropogenic sources. It does not acknowledge that anthropogenic activities impact climate, which contributes to drought and fire in the west. Currently, the inaccurate impression that is created regarding 24 h and sub-daily concentrations is used to discount and exclude measurements in the Northwest and California from the risk assessment and the consideration of whether the annual standard can adequately control for health effects associated with short term exposures (Chapter 3).

The text in question is here:

Page 2-26 “Northwest U.S. has very high daily design values relative to the annual design values. This is due to episodically high PM<sub>2.5</sub> concentrations that affect the region, both from wintertime stagnation events and summer/fall wildfire smoke events”

2-30 Wildfires are having an important and substantial impact on Apr-Sept exposure in the western US. Only says “Most of the sites measuring these very high concentrations are in the northwestern U.S. and California, where wildfires have been relatively common in recent years”

- b) Hybrid modelling:** Performance of Methods (2.3.3.1.2) -- The most important points that should be made in this section do not come through clearly. Impressively, some of the more sophisticated methods have n-fold cross validation R<sup>2</sup> better than 80% and root-mean-square error (RMSE) of 2-3 µg/m<sup>3</sup> for daily PM<sub>2.5</sub> predictions. These methods clearly lead to improved exposure estimates in locations without samplers. The second paragraph tells where performance is worse but not where it is better. Approaches including land-use features, rather than straight Bayesian downscaling, are better at

capturing concentration gradients close to sources. The consistency of the regional concentration estimates across methods is remarkably good (Table 2-3).

Rather than focus on variability among the methods, this text should be explaining why some methods work better than others. The Bayesian downscaler does not incorporate information about locations of primary  $PM_{2.5}$  sources (i.e., surrogates such as land use variables), whereas several other methods, including the neural network, do. All these methods are designed to predict broad spatial  $PM_{2.5}$  features, but the neural network and other methods including land use variables do a better job of capturing spatial gradients near sources. Ideally, the concentrations predicted across the US from the *best* performing methods should be used to conduct risk assessment for the entire country, rather than conducting the risk assessment for only a modest number of sites. The Bayesian downscaler is the worst of these methods (especially for the Northwest and California), and yet it was the one selected for further analysis. The selection of the Bayesian downscaler likely leads to an underestimation of exposure and risk in the Northwest and California, assuming higher populations are spatially collocated with sources.

Importantly, the text is wrong as to the reason that there is worse agreement between these methods in the west. The reason is not because concentrations are low in the west, it is because spatial concentration gradients are substantially greater in the west than in the east, where  $PM_{2.5}$  is more influenced by secondary formation and more therefore regionally homogeneous.

In some cases, variations between methods are discussed with no explanation given as to why they make sense. For example:

“Predictions span a wider range of concentrations for the western regions centered on California and Arizona (Figure 2-25, panels a and c) than the eastern region centered on New Jersey (Figure 2-25, panel b).”

This makes sense – in the eastern US, a larger fraction of  $PM_{2.5}$  is secondary, formed regionally, and thus concentrations can be expected to be more spatially homogeneous. This is not explained.

“Despite general agreement among predictions for the California and the eastern U.S. areas, the spatial texture of the concentration fields differs among methods. For instance, the 12-km Bayesian downscaler produces the smoothest  $PM_{2.5}$  concentration field, and the 1-km neural network (DI2016) produces the field with the greatest variance.”

This also makes sense, since the Bayesian downscaler does not incorporate information pertaining to the locations of primary  $PM_{2.5}$  sources, whereas the neural network does. Thus, both are designed to predict broad spatial  $PM_{2.5}$  features, but the neural network will do a better job of capturing spatial gradients near sources. This is not explained, and may leave the reader without this important context.

“In Figure 2-26, the coefficient of variation (CV; i.e., the standard deviation divided by the mean) among methods is shown in percentage units based on predictions that were averaged to a common 12-km grid. The largest values occur in the western U.S. (Figure 2-26, panel a), where terrain is complex, wildfire is prevalent, monitoring is relatively

sparse, and PM<sub>2.5</sub> concentrations tend to be low. The distance from the grid-cell center to the nearest monitor is greater than 100 km for broad areas of the west (Figure 2-27).”

Yes, distance to monitors is large in many parts of the West, but the reason the simpler method (Bayesian downscaler) does not perform as well in the west is because of the larger concentration gradients, not the low concentrations. The methods that make use of land use variables (e.g. neural network) have an advantage in situation. The spatial gradients are more extreme in the west, whereas in the east regional secondary formation leads to more spatially uniform concentrations. The differences between methods make sense.

- c) **Background:** As an upperbound, background was estimated by assuming all biogenic SOA is natural. For the record, I would like to remind the authors that even though it is made from biogenic hydrocarbons, **biogenic SOA is not necessarily natural.**

There is substantial evidence that anthropogenic emissions impact the formation of SOA from biogenic VOCs. This was raised in my comments on the first draft of the Integrated Science Assessment. One important example is isoprene. Oxidation of isoprene leads to several gas phase products. A major SOA precursor is isoprene epoxydiol (IEPOX), which forms SOA when it reacts with wet acidic sulfate (anthropogenic). Thus, IEPOX SOA is formed as a result of reactions with anthropogenic emissions, and thus are controllable. Field studies measuring tracers of IEPOX SOA suggest that it is a major source of aerosol (roughly one-third of organic PM<sub>2.5</sub>) in the southeastern US in both rural and urban locations (see reference below and in the ISA).

Budisulistiorini, S., Li, X., Bairai, S.T., Renfro, J., Liu, Y., Liu, Y.J., McKinney, K.A., Martin, S.T., McNeill, V.F., Pye, H.O.T. and Nenes, A., 2015. Examining the effects of anthropogenic emissions on isoprene-derived secondary organic aerosol formation during the 2013 Southern Oxidant and Aerosol Study (SOAS) at the Look Rock, Tennessee ground site. *Atmospheric Chemistry and Physics*, 15(15), pp.8871-8888.

Budisulistiorini, S.H., Canagaratna, M.R., Croteau, P.L., Marth, W.J., Baumann, K., Edgerton, E.S., Shaw, S.L., Knipping, E.M., Worsnop, D.R., Jayne, J.T. and Gold, A., 2013. Real-time continuous characterization of secondary organic aerosol derived from isoprene epoxydiols in downtown Atlanta, Georgia, using the Aerodyne Aerosol Chemical Speciation Monitor. *Environmental science & technology*, 47(11), pp.5686-5694.

As another example, model predictions by Carlton et al, suggest that more than 50% of biogenic SOA in the Eastern U.S. could be controlled by reducing anthropogenic NO<sub>x</sub> emissions.

Carlton, A.G., Pinder, R.W., Bhave, P.V. and Pouliot, G.A., 2010. To what extent can biogenic SOA be controlled?. *Environmental Science & Technology*, 44(9), pp.3376-3380.

The following text does not recognize that SOA from biogenic VOCs is, in part, controllable:

Page 2-3 “Natural sources of PM include...oxidation of biogenic hydrocarbons such as isoprene and terpenes to produce secondary organic aerosol (SOA),”

Page 2-50: “sources that contribute to natural background PM.... oxidation of biogenic hydrocarbons such as isoprene and terpenes to produce SOA”

Page 2-55: “As a region, the Southeast has the highest levels of biogenic aerosol production in the country, so the organic matter contribution at these three sites likely represents an upper bound for the country of what natural biogenic organic aerosol production could be under present atmospheric conditions.”

**Additionally:** Please note that water-soluble gases also contribute via multiphase reactions in clouds and aerosols. Not reflected in the following text:

Page 2-9 “In addition, atmospheric oxidation of VOCs, both anthropogenic and biogenic, is an important source of organic aerosols, particularly in summer. The semi-volatile and non-volatile products of VOC oxidation reactions can condense onto existing particles or can form new particles (U.S. EPA, 2009, section 3.3.2; U.S. EPA, 2018, section 2.3.2).”

**SCQ 3.3** *Regarding approaches described in Chapter 3 of the PA considering the PM<sub>2.5</sub> health effects evidence and the risk assessment in order to inform preliminary conclusions on the primary PM<sub>2.5</sub> standards? Regarding rationales supporting the preliminary conclusion on the current and potential alternative primary PM<sub>2.5</sub> standards? Regarding the evidence-based approach, including:*

- e) *The preference for continuing the use of an annual PM<sub>2.5</sub> standard as the principle means of providing public health protection against the bulk of the distribution of short- and long-term PM<sub>2.5</sub> exposures?*

The PA presents a substantial case, using multiple lines of evidence, that the current PM<sub>2.5</sub> standards are not adequate to protect public health with a requisite margin of safety. ***It will be necessary to reduce both the annual and 24 h standard.*** The annual standard may be used as the principle means to provide public health protection against health effects associated with short- and long-term exposures, but cannot be used as the only means of protecting public health. It is clear from Figure 2-11 that lowering the annual standard vs the 24 h standard will protect different people. Lowering the annual standard alone will result in reduced short- and long-term exposures for people predominantly in the east and industrial Midwest, but will not provide protection from short term and peak exposures for people in the Northwest and California. The health of people in the Northwest and California must still be protected whether or not wildfires and stagnation events occur during summer, fall and winter seasons.

**SCQ 3.4** *Regarding the quantitative risk assessment for PM<sub>2.5</sub>, including:*

- c) *The hybrid modeling approach used...*

See response to SCQ 2.1 (b) above.

- d) *The characterization of variability and uncertainty in the risk assessment?*

Page 3-70: As stated above (comments on Chapter 2) the performance of the hybrid models (most particularly the Bayesian downscaling) is not hampered by low



concentrations. It is hampered by strong spatial concentration gradients. Hybrid methods that include land use factors related to primary sources are better able to address this. Regional secondary formation in the east means that spatial gradients are much smaller and the models perform better. It makes sense that the neural network hybrid model would perform better than the Bayesian downscaling in the west for this reason. Thus, I disagree with the following statement:

“factors likely contributing to poorer model performance often coincide with relatively low ambient PM<sub>2.5</sub> concentrations, potentially accounting for the observations that model performance for hybrid models weaken by some metrics with decreasing PM<sub>2.5</sub> concentration and that the normalized variability between predictions based on different hybrid modeling approaches increases with decreasing concentrations. Thus, uncertainty in hybrid model predictions becomes an increasingly important consideration as lower predicted concentrations are considered.”

Uncertainty is larger for Bayesian downscaling models specifically, in locations with large concentration gradients. In the west, more weight should be placed on the other hybrid models.

**SCQ 3.5** *Regarding the draft PA preliminary conclusion that, taken together, the available scientific evidence can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary PM<sub>2.5</sub> standards.*

I agree that the evidence is strong. Specifically, ***I agree with the following statement, which is well documented in the evidence base and supported by the risk assessment.***

**(page 3-98)**

“When taken together, we reach the preliminary conclusion that the available scientific evidence, air quality analyses, and the risk assessment, as summarized above, can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the combination of the current annual and 24-hour primary PM<sub>2.5</sub> standards.”

Regarding the subsequent paragraph:

“In contrast to this preliminary conclusion, a conclusion that the current primary PM<sub>2.5</sub> standards do provide adequate public health protection would place little weight on the broad body of epidemiologic evidence reporting generally positive and statistically significant health effect associations, particularly for PM<sub>2.5</sub> air quality distributions likely to have been allowed by the current primary standards, or on the PM<sub>2.5</sub> risk assessment. Rather, such a conclusion would place greater weight on uncertainties and limitations in the evidence and analyses”

A conclusion that the current primary PM<sub>2.5</sub> standards do provide adequate public health protection cannot be justified based on the weight of the evidence from multiple kinds of data and analyses clearly documented in the ISA and PA. No scientific rationale is offered for affording any uncertainties and limitations greater weight than that given to the scientific results.

## Dr. Ronald Wyzga

### **Chapter 1 – Introduction: To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for the review?**

The Chapter is clearly written, but it omits key factors that set the context for this review. First of all, it does not indicate the differences in the overall review process for PM in this review as opposed to previous reviews. Secondly, there was limited review of the ISA with only one draft reviewed despite the comments made on the first draft. Thirdly, there is no formal risk and exposure assessment as has been included in previous reviews. Finally, the content of this chapter is dependent upon the science and conclusions of the ISA. Only a draft version is available; the final version is planned for release in December 2019. Given the uncertainty about the content of this document, it makes it difficult to make this document at best provisional and subject to change given changes in the ISA. This Chapter needs to recognize these factors and indicate how the overall process will accommodate them.

### **Chapter 3 – Review of the Primary PM<sub>2.5</sub> Standards: What are the CASAC views on the approaches described in Chapter 3 to considering the PM<sub>2.5</sub> health effects evidence and the risk assessment in order to inform preliminary conclusions on the primary PM<sub>2.5</sub> standards? What are the CASAC views regarding the rationales supporting the preliminary conclusions on the current and potential PM<sub>2.5</sub> standards?**

#### **SCQ-3.1 Does the panel find that the questions posed in this chapter appropriately reflect the important policy-relevant issues for the PM<sub>2.5</sub> review? Are there additional policy-relevant questions that should be addressed?**

The content is based upon a draft ISA; it is unclear whether a final ISA would influence the discussions and conclusions of this chapter. By and large the questions addressed are reasonable. I would have like to have seen more discussion of PM components other than ultrafine particles. Although virtually all PM components have been shown to have some adverse health impacts, there are some differences among major components for both respiratory and cardiovascular endpoints. Although these differences would not change the PM indicator, they are noteworthy and could help inform risk managers about the need to consider all major PM components in achieving compliance, I base my conclusions on two relatively recent reviews in which I was involved. A comprehensive review of the literature for both short-term and long-term studies found that different components were associated with respiratory and cardiovascular endpoints; moreover, although no major components of PM were exonerated, there appeared to be greater and more associations with organic particles than with other components. See A. C. Rohr and R. Wyzga, *Attributing health effects to individual particulate matter constituents. Atmospheric Environment* 62 130-152 2012 and R.E. Wyzga and A. C. Rohr. *Long-term Particulate Matter Exposure: Attributing Health Effects to Individual PM Components. J of the Air and Waste Manage. Assoc.* 2014.

#### **SCQ 3.2 What are the Panel's views on the relative weight that the draft Policy Assessment gives to the evidence-based (i.e., draft PA Section 3.2) and risk-based (i.e. draft PA, section 3.3) approaches in reaching conclusions and recommendations regarding current and alternative PM 2.5 standards?**

I like the fact that two approaches were considered; the conclusions for each were similar which adds strength to an overall conclusion. Both approaches clearly indicate

that the current standard is not protective. These sections do not consider all studies covered in the ISA. Greater justification of the studies considered need be incorporated into the PA.

**SCQ 3.3 What are the Panel's views on the evidence-based approach, including:**

**a) The emphasis on health outcomes for which the draft ISA causality determinations are "causal" or "likely causal"?**

I have no problem with considering the adverse health effects in two categories. It should be noted that consideration of the "causal" and "likely causal" categories will most likely result in standards that are protective of other categories. To the extent that this may not be true, some indication could be useful.

**b) The identification of potential at-risk populations?**

The draft PA rightly indicates that very large subpopulations are at-risk. Greater specificity is not necessary.

**c) Reliance on key multicity epidemiology studies conducted in the US and Canada for assessing the PM 2.5 levels associated with health effects?**

There should be greater discussion about how the results might change if a broader set of studies considered in the ISA were included here.

**d) Characterizing air quality in these key studies using two approaches: the overall mean and 25 th /75 th percentiles of the distribution and the "pseudo design value" reflecting a monitor with the highest levels in an area?**

The approach is reasonable although there should be some discussion about the nature of the overall statistical distribution; this may be covered in Chapter 2, which I have not yet reviewed.

**e) The preference for continuing the use of an annual PM 2.5 standard as the principle means of providing public health protection against the bulk of the distribution of short- and long-term PM 2.5 exposures?**

If the analysis were the other way around, would it be as useful? My concern is that some extreme events could possibly alter some of the assumptions between long-term and short-term air quality measures.

**f) The draft PA conclusions on the extent to which the current scientific information strengthens or alters conclusions reached on the last review on the health effects of on the health effects of PM<sub>2.5</sub>?**

I agree with the conclusions.

**g) Whether the discussions of these and other issues in Chapter 3 accurately reflect and clearly communicate the currently available health effects evidence, including important uncertainties as characterized in the ISA?**

Without seeing the final ISA, it is difficult to evaluate this question. This chapter considers a subset of studies covered in the current iSA; it would be helpful to explain further how the subset was chosen and what would be the impact of considering a wider set of studies.

**SCQ 3.4 What are the Panel's views on the quantitative risk assessment for PM<sub>2.5</sub> including:**

- a. The choice of health outcomes and studies selected for developing concentration-response functions for long and short-term effects?

I would like to see greater explanation of how the selected studies were chosen, and what the likely impact would be if additional studies were chosen as well. I was struck by the fact that the studies that used modeling as opposed to monitoring to estimate PM exposures appeared to give slightly different results. I would like to see some discussion of this. Is it because different geographic regions were considered or some other reason?

- b. The selection criteria for the 47 urban areas and PM<sub>2.5</sub> air quality scenarios analyzed?

No problems here.

- c. The hybrid modeling approach used for quantifying exposure surrogates across an area and adjusting air quality for alternative standard levels, as supplemented by interpolation/extrapolation?

It seems reasonable

- d. The characterization of variability and uncertainty in the risk assessment?

Again if additional studies were considered, would the results and their variability change much?

- e. The robustness and validity of the risk estimates?

I would like to see more discussion of the differences seen in those studies that considered modeling as opposed to monitoring to estimate PM levels.

**SCQ-3.5 What are the Panel's views on the draft PA preliminary conclusion that, taken together, the available scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the current primary PM<sub>2.5</sub> standards?**

I agree.

**SCQ-3.6 What are the Panel's views on the conclusions in the draft PA regarding developing potential PM<sub>2.5</sub> alternative standards with respect to:**

- a. The preliminary conclusion that the available information continues to support the PM<sub>2.5</sub> mass-based indicator, remains too limited to support a distinct standard for any specific PM<sub>2.5</sub> component or group of components, and remains too limited to support a distinct standard for the ultrafine fraction?

The issue here remains tied to the ISA. I agree that no major constituent of PM is exonerated, but the draft ISA, in my opinion, does not fully discuss the relative roles of major constituent categories. See my comments with regard to charge question 3.1.

- b. The preliminary conclusion to retain the annual and 24-hour averaging times?

Reasonable, but it should be pointed out that most studies make use of commonly reported air quality measures. Further research to indicate whether other averaging times would be preferred is lacking.

- c. The preliminary conclusion that it is appropriate to consider retaining the forms of the current annual and 24-hour PM<sub>2.5</sub> standards, in conjunction with revised levels?

- d. The preliminary conclusion that the range for alternative levels for the annual PM<sub>2.5</sub> standard should begin below 12 µg/m<sup>3</sup> and extend as low as 8 µg/m<sup>3</sup>?  
Reasonable

- e. The possible rationales for alternative annual PM<sub>2.5</sub> levels of 12, 10, and 8 µg/m<sup>3</sup>?

Reasonable, but I would like to see further discussion of why the Canadian studies and those studies which used modeled air quality data appear to give different results.

- f. The preliminary conclusion that, in conjunction with a lower annual standard intended to protect against both short- and long-term exposures, the evidence does not support the need for a revised level for the PM<sub>2.5</sub> 24-hour standard?

I worry about this. The arguments supporting this position are not crystal clear to me and all of the assumptions therein need be clearly articulated.

- g. The discussion of an alternative approach to lower the level of the 24 hour standard to 30 µg/m<sup>3</sup> to provide increased protection for both short- and long term exposures?

I liked this.

**Chapters 3 to 5: What are the CASAC views regarding the areas for additional research identified in Chapters 3, 4 and 5? Are there additional areas that should be highlighted?**

The current review must be based upon existing information; however, there are several areas that could inform future reviews of the standard and help reduce some of the uncertainties associated with this process.

I believe that future research should include the following:

- More detailed measurement of PM components; in particular, more detailed measurements of organic components. Several studies have suggested that some organic components may be of greater health concern than others. EC and OC are catchall categories defined by a measurement technique. Availability of such measurements would facilitate their use in future epidemiological studies.
- Research should also continue to define in more detail the physiological bases for adverse health responses to PM and its components. It may be that different components are associated with different components. If so, consideration of

components may provide a more precise understanding of the biological basis for observed responses in epidemiological studies.

- Alternative exposure metrics need to be explored. How important are peak exposures as opposed to average exposures in explaining observed health responses? What is the appropriate time average for peak exposures? Do current average measures adequately limit exposures to peak levels? Is the relative change in exposure important; research needs to consider the issue of delta exposure. How important are past exposures in explaining responses to current levels; indeed the correct question to ask is what are the impacts of current exposures given past exposures? This is particularly important when health outcomes, e.g., cancer, develop over an extended period of time and when cross-sectional designs are considered. These designs compare exposures and health responses across geographic entities. Although there are changes in air quality over time, the relative ordering of air quality across geographic entities changes minimally. What is the latency of response? Tied to this is the issue of cumulative exposure, which should be examined.
- Consideration of the NAAQS for the coarse fraction of PM is limited because measurement of the coarse fraction per se is limited. There are studies, especially considering asthmatic response, that report significant associations with PM<sub>10</sub> but not PM<sub>2.5</sub>. Statistical and other phenomena could explain these results, but they could also suggest that coarse PM, independent of fine PM, may be of health concern. More research on the relationship between asthmatic and other respiratory responses and coarse PM is needed.
- Health research tends to be focused on one pollutant at a time even when several pollutants are measured, but they are most often considered independently. How important is joint exposure to more than one pollutant in influencing health response? Is sequencing of exposures important?

People spend more of their time in indoor environments. Indoor PM levels can be high in these environments? How important are these? If they are not as important, why? What is the health impact of joint indoor and outdoor exposures? Are health responses to outdoor PM levels greater when indoor levels are high?

## Attachment D

### History, Membership Criteria, and Administrative Procedures of the Independent Particulate Matter Review Panel

#### A.1 History of the Independent Particulate Matter Review Panel

The core statutory obligation of the EPA Clean Air Scientific Advisory Committee (CASAC) is incorporated into CASAC's charter with Congress.<sup>58</sup> Under that charter, CASAC may be augmented with experts. Specifically, the charter states:

“EPA, or CASAC with the Agency's approval, may form subcommittees or workgroups for any purpose consistent with this charter. Such 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.”

Augmentation of CASAC with additional experts for the review of criteria and standards has been a routine practice for four decades. Additional experts have been appointed to review panels that interact with members of the chartered CASAC for all reviews since the late 1970s.<sup>59</sup> 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.

The previous four particulate matter review panels have been comprised of members of the chartered CASAC augmented with additional experts. CASAC was augmented with additional experts for the joint review of the criteria and standards for particulate matter and sulfur oxides in the early 1980s.<sup>60</sup> The CASAC Subcommittee on Health Effects of Particulate Matter and Sulfur Oxides included six experts in addition to members of the chartered CASAC. The CASAC Subcommittee on Welfare Effects of Particulate Matter and Sulfur Oxides included five additional experts in addition to members of the chartered CASAC. In total, there were 11 additional experts who augmented the chartered CASAC for this review cycle. For the 1994 to 1996 PM review, there were 6 members of the chartered CASAC and 15 additional experts on

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<sup>58</sup> United States Environmental Protection Agency Charter, Clean Air Scientific Advisory Committee, Filed with Congress, June 5, 2019, [https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/\\$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf)

<sup>59</sup> Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, “CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018),” 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014-0859, December 10, 2018. Pages E-37 to E-39, [https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/\\$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf)

<sup>60</sup> EPA, Air Quality Criteria for Particulate Matter and Sulfur Oxides, Volume 1, EPA-600/8-82-029a, U.S. Environmental Protection Agency, Research Triangle Park, NC, December 1982. [http://ofmpub.epa.gov/eims/eimscomm.getfile?p\\_download\\_id=459608](http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=459608)

the review panel.<sup>61</sup> For the 2001 to 2006 scientific review, and for the 2008 to 2010 scientific review, there were 7 members of the chartered CASAC and 15 additional experts.<sup>62,63</sup> From 2015 to 2018, the CASAC Particulate Review Panel had 6 members of the chartered CASAC and 20 additional experts.<sup>64</sup> Thus, the use of augmented review panels specifically for particulate matter dates back 37 years.

The 7-member chartered CASAC does not have the breadth, depth, and diversity of expertise required for a review of the particulate matter criteria and standards that meets the requirements of the Clean Air Act for a “thorough review” that “shall accurately reflect the latest scientific knowledge” of the “extent and kind of ... effects.”<sup>65</sup> The only credible way to provide a “thorough review” that “shall accurately reflect the latest scientific knowledge” is to engage scientists who are active at the leading edge of scientific work in disciplines and areas related to the subject matter of a review, as described in the February 4, 2015 Federal Register request for nominations, and as illustrated by the history of CASAC Review Panels.

On February 4, 2015, the EPA Science Advisory Board (SAB) office issued a “Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel.”<sup>66</sup> In this notice, EPA stated that it will “form a CASAC ad hoc panel to provide advice through the chartered CASAC on the scientific and technical aspects of air quality criteria and the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM).” The notice further stated:

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<sup>61</sup> Wolff, G.T., “Closure by the Clean Air Scientific Advisory Committee (CASAC) on the Staff Paper for Particulate Matter,” Letter to Carol M. Browner, EPA-SAB-CASAC-LTR-96-008, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, June 13, 1996.  
[https://yosemite.epa.gov/sab/sabproduct.nsf/C146C65BA26865A2852571AA00530007/\\$File/casl9608.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/C146C65BA26865A2852571AA00530007/$File/casl9608.pdf)

<sup>62</sup> Henderson, R. “Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter,” EPA-CASAC-LTR-06-002, Letter to Stephen L. Johnson, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, March 21, 2006, [https://yosemite.epa.gov/sab/sabproduct.nsf/CD706C976DAC62B3852571390081CC21/\\$File/casac-ltr-06-002.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/CD706C976DAC62B3852571390081CC21/$File/casac-ltr-06-002.pdf)

<sup>63</sup> Samet, J.M., “CASAC Review of Policy Assessment for the Review of the PM NAAQS – Second External Review Draft (June 2010),” EPA-CASAC-10-015, Letter to Lisa P. Jackson, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, September 10, 2010, [https://yosemite.epa.gov/sab/sabproduct.nsf/CCF9F4C0500C500F8525779D0073C593/\\$File/EPA-CASAC-10-015-unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/CCF9F4C0500C500F8525779D0073C593/$File/EPA-CASAC-10-015-unsigned.pdf)

<sup>64</sup> Diez Roux, A., “CASAC Review of the EPA’s Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016),” EPA-CASAC-16-003, Letter to Gina McCarthy, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, August 31, 2016.  
[https://yosemite.epa.gov/sab/sabproduct.nsf/9920C7E70022CCF98525802000702022/\\$File/EPA-CASAC+2016-003+unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/9920C7E70022CCF98525802000702022/$File/EPA-CASAC+2016-003+unsigned.pdf)

<sup>65</sup> Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, “CASAC Review of EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018),” 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014-0859, December 10, 2018. Page E-39.  
[https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/\\$File/PMRP+Letter+to+CA+SAC+181210+Final+181210.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CA+SAC+181210+Final+181210.pdf)

<sup>66</sup> 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>



“The SAB Staff Office is seeking nominations of nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to PM. Experts are sought in: 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.”

The notice also stated:

“Selection criteria to be used for panel membership include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; (e) skills working in committees, subcommittees and advisory panels; and, (f) for the panel as a whole, diversity of expertise and viewpoints.”

On November 17, 2015, a memorandum from Aaron Yeow to Chris Zarba in the EPA Science Advisory Board office established the CASAC PM Review Panel.<sup>67</sup> The panel was formed for the following purpose:

“An ad hoc expert panel of the CASAC will provide independent advice through the chartered CASAC on EPA’s technical and policy assessments that support the Agency’s review of the National Ambient Air Quality Standard (NAAQS) for PM, including drafts of the Integrated Review Plan, Integrated Science Assessment, Risk/Exposure Assessment, and Policy Assessment.”

In the case of particulate matter, for which there are health effects data from multiple scientific disciplines, including epidemiology, toxicology, and controlled human studies, it has been common practice to have multiple experts in each of these disciplines to assure breadth and depth of expertise. The CASAC PM Review Panel was comprised of leading scientists recognized nationally and internationally for their expertise in multiple scientific disciplines, including air quality, exposure assessment, dosimetry, toxicology, epidemiology, medicine, risk assessment methodology, uncertainty analysis, and related fields.

The CASAC Particulate Matter Panel held teleconference meetings on May 23, 2016, and August 9, 2016, to peer review the EPA’s Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016).<sup>68</sup>

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<sup>67</sup> Yeow, A., Formation of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel, Memorandum to C. Zarba, Science Advisory Board Staff Office, U.S. Environmental Protection Agency, Washington, DC, November 17, 2015, [https://yosemite.epa.gov/sab/sabproduct.nsf/0/EB862B233FBD0CDE85257DDA004FCB8C/\\$File/Determination%20memo-CASAC%20PM.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/EB862B233FBD0CDE85257DDA004FCB8C/$File/Determination%20memo-CASAC%20PM.pdf)

<sup>68</sup> Diez Roux, A., “CASAC Review of the EPA’s Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016),” EPA-CASAC-16-003, Letter to Gina McCarthy, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, August 31, 2016. <https://yosemite.epa.gov/sab/sabproduct.nsf/9920C7E70022CCF98525802000702022/%24File/EPA-CASAC+2016-003+unsigned.pdf>

On October 10, 2018, then acting EPA Administrator Wheeler eliminated the CASAC PM Review Panel by press release,<sup>69</sup> with a follow-up email from the SAB office on October 11, 2018. This was done without advance notice and without prior consultation with the panel or the CASAC. There is no precedent for disbanding a review panel in the middle of a review cycle.

The EPA released the external review draft of the Integrated Science Assessment (ISA) on October 15, 2018, five days after disbanding the CASAC PM Review Panel.<sup>70</sup> The Federal Register notice announcing that the draft ISA was available for public review was dated October 16, 2018 and published on October 23, 2018.<sup>71</sup>

Compared to the chartered CASAC, the PM review panel has more experts, covers more scientific disciplines, and has multiple experts who provide diversity of perspectives in many key disciplines, such as epidemiology, toxicology, and human clinical studies, among others.

Since that time, members of the disbanded CASAC PM Review Panel have formed this Independent Particulate Matter Review Panel (IPMRP). Like the disbanded CASAC PM Review Panel, the IPMRP is committed to providing “public service” “in protecting public health and safeguarding our nation’s air,” as described in the Nov 20, 2015 appointment letters from the EPA SAB office to panelists. The panel does not require affiliation with EPA to carry on its mission. Although no longer affiliated with the U.S. EPA, the IPMRP continues as a group of independent science advisors recognized for their national leadership in policy-relevant science pertaining to the particulate matter NAAQS.

The mission of this Panel is three-fold: (1) to provide independent advice regarding technical and policy assessments pertaining to the EPA’s review of the National Ambient Air Quality Standard (NAAQS); (2) objectively observe and assess modifications to the NAAQS Review Process and their implications; and (3) educate the public about the public health and public welfare objectives of the NAAQS, the NAAQS review process, and scientific issues pertaining to the NAAQS. Given the process under which this group was originally formed as the CASAC PM Review Panel, we are recognized for our expertise and our independence.

On December 10, 2018, the IPMRP submitted public comments to the CASAC pertaining to the EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018).<sup>72</sup> The IPMRP subsequently submitted comments to the CASAC on March 27,

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<sup>69</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-act-committee>

<sup>70</sup> EPA, “Integrated Science Assessment for Particulate Matter (External Review Draft),” EPA/600/R-18/179, U.S. Environmental Protection Agency, Research Triangle Park, NC, October 2018. [https://yosemite.epa.gov/sab/sabproduct.nsf/0/932D1DF8C2A9043F852581000048170D/\\$File/PM-1STERD-OCT2018.PDF](https://yosemite.epa.gov/sab/sabproduct.nsf/0/932D1DF8C2A9043F852581000048170D/$File/PM-1STERD-OCT2018.PDF)

<sup>71</sup> EPA, “Integrated Science Assessment for Particulate Matter (External Review Draft),” *Federal Register*, 83(205):53471-53472 (October 23, 2019). <https://www.govinfo.gov/content/pkg/FR-2018-10-23/pdf/2018-23125.pdf>

<sup>72</sup> Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Samat, E.A. Sheppard, B. Turpin, and S. Vedal, “CASAC Review of EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018),” 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014–0859, December 10, 2018.

2019 with additional comments on the draft ISA.<sup>73</sup> These letters contain detail on the statutory requirements for the review of the NAAQS, history of the CASAC PM Review Panel and the IPMRP, and specific findings and recommendations related to the CASAC, NAAQS review process, and draft ISA.

In early September of 2019, EPA released an external review draft of the Policy Assessment (PA) for the PM NAAQS review.<sup>74</sup> A Federal Register notice published on September 11, 2019 indicated availability of the draft PA for public comment through November 12, 2019.<sup>75</sup> The chartered CASAC will hold a public teleconference on October 22, 2019 to receive public comments to consider in their peer review of the EPA's Policy Assessment for Particulate Matter on October 24-25, 2019.<sup>76</sup> The chartered CASAC will hold a public meeting at a location to be determined in North Carolina on October 24-25, 2019 for the purpose of conducting a peer review of EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019).<sup>77</sup>

The CASAC stated in its April 11, 2019 letter to the EPA Administrator that “the breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals.”<sup>78</sup> Furthermore, the CASAC recommended that “the EPA reappoint the previous CASAC PM panel or appoint a panel with similar expertise.” The disbanding of the PM Review Panel on October 10, 2017 deprived CASAC of the needed expertise. The EPA Administrator responded in a letter dated July 25, 2019 that disregarded CASAC's advice to reappoint the disbanded panel or form a new panel. Specifically, the

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[https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/\\$File/PMRP+Letter+to+CA+SAC+181210+Final+181210.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CA+SAC+181210+Final+181210.pdf)

<sup>73</sup> Frey, H.C., A.V. Diez Roux, P. Adams, G. Allen, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R. McConnell, R.L. Poirot, J.A. Samat, E.A. Sheppard, B. Turpin, and S. Vedal, “03-07-19 Draft CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018),” 19 page letter submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, March 27, 2019.

[https://yosemite.epa.gov/sab/sabproduct.nsf/A491FD482BB83BEE852583CA006A2548/\\$File/Written+Comments+from+17+Members+of+the+CASAC+PM+Review+Panel+that+was+Disbanded+on+October+11+2018+rev.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/A491FD482BB83BEE852583CA006A2548/$File/Written+Comments+from+17+Members+of+the+CASAC+PM+Review+Panel+that+was+Disbanded+on+October+11+2018+rev.pdf)

<sup>74</sup> EPA (2019), Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft, EPA-452/P-19-001, U.S. Environmental Protection Agency, Research Triangle Park, NC, September 2019. [https://www.epa.gov/sites/production/files/2019-09/documents/draft\\_policy\\_assessment\\_for\\_pm\\_anaqs\\_09-05-2019.pdf](https://www.epa.gov/sites/production/files/2019-09/documents/draft_policy_assessment_for_pm_anaqs_09-05-2019.pdf)

<sup>75</sup> EPA, “Release of a Draft Document Related to the Review of the National Ambient Air Quality Standards for Particulate Matter,” *Federal Register*, 84(176):47944-47945 (September 11, 2019). <https://www.govinfo.gov/content/pkg/FR-2019-09-11/pdf/2019-19627.pdf>

<sup>76</sup> Public Teleconference of the Chartered Clean Air Scientific Advisory Committee (CASAC) on Particulate Matter, 10/22/2019, 12:00 PM - 04:00 PM. <https://yosemite.epa.gov/sab/sabproduct.nsf//MeetingCalCASAC/A2DF51609E3DFC9C85258473006CF120?OpenDocument>

<sup>77</sup> Public Meeting of the Chartered Clean Air Scientific Advisory Committee (CASAC) on Particulate Matter, 10/24/2019 to 10/25/2019. <https://yosemite.epa.gov/sab/sabproduct.nsf//MeetingCalCASAC/49FAF8892AD2D38285258473006D1F4A?OpenDocument>

<sup>78</sup> Cox, L.A. (2019), “CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018),” EPA-CASAC-19-002, Letter to A. Wheeler, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, April 2019. [https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf)

Administrator stated that he would instead “create a pool of subject matter experts.”<sup>79</sup> In addition, he rejected the CASAC request for the augmented committee to review a revised draft of the ISA. On August 7, 2019, EPA issued a Federal Register notice to request nominations for consultants to support CASAC reviews of particulate matter and ozone.<sup>80</sup>

The use of a “pool of subject matter experts” rather than a review panel to augment the chartered CASAC is unprecedented. Review Panels augment and report through the chartered CASAC, working in parallel and in collaboration with the members of the chartered CASAC. Members of review panels are nominated by the public and the nominations are subject to public comment. The SAB staff office reviews, vets, and appoints members of review panels. Members of review panels participate in meetings with members of the chartered CASAC, and deliberate interactively with members of the chartered CASAC on complex subject matter. The chartered CASAC is ultimately responsible for the content of advice sent to the Administrator, but the formulation of that advice is informed based on deliberations with panelists who provide the breadth, depth, and diversity of needed scientific expertise.

In contrast, there has been no opportunity for public comment on the nominees for the pool of subject matter experts, who were named in an EPA press release on September 13, 2019.<sup>81</sup> The decision regarding appointments of ad hoc consultants to serve as subject matter experts was made by the Administrator, not by the SAB Staff Office. All interactions between CASAC and the subject matter experts will be done solely through the Designated Federal Official (DFO) for CASAC and the CASAC chair, in writing. Subject matter experts will not be allowed to participate in deliberative meetings with CASAC. For example, subject matter experts are not allowed to, unless invited in writing by the chair, respond to all charge questions that might be of interest to the consultant. Subject matter experts will not be allowed to deliberate or interact with the CASAC other than in writing. The appointment of subject matter experts by the Administrator is not correcting the deficiencies in CASAC’s ability to conduct a thorough review that have resulted from disbanding the PM Review Panel.

Therefore, the IPMRP will continue to provide its expert advice, based on the breadth, depth, and diversity of its expertise, and based on interactive deliberation among its members. The IPMRP will submit its review and advice as a public comment to the CASAC and as a public comment to docket EPA-HQ-OAR-2015-0072 for the PM NAAQS review.

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<sup>79</sup> Wheeler, A.R. (2019), Letter to L.A. Cox, EPA Clean Air Scientific Advisory Committee, from Administrator, U.S. Environmental Protection Agency, Washington, DC, July 25, 2019, [https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002\\_Response.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf)

<sup>80</sup> EPA, “Request for Nominations of Consultants To Support the Clean Air Scientific Advisory Committee (CASAC) for the Particulate Matter and Ozone Reviews,” *Federal Register*, 84(152):38625 (August 7, 2019). <https://www.govinfo.gov/content/pkg/FR-2019-08-07/pdf/2019-16913.pdf>

<sup>81</sup> EPA, “Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts,” News Release, U.S. Environmental Protection Agency, Washington, DC, September 13, 2019. <https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts>.

## A.2 Membership Criteria for the Independent Particulate Matter Review Panel

The criteria for membership on the IPMRP are that any member of the CASAC PM Review Panel from any time during the CASAC PM Review Panel existence from 2015 until being disbanded on October 10, 2018, and any member of the chartered CASAC from any time during the CASAC PM Review Panel's existence, is eligible, with the exception of any such persons currently serving as members of the chartered CASAC. All of the members of the IPMRP were originally appointed by EPA as Special Government Employees (SGEs) and were subject to disclosure requirements and ethics review. Members of the IPMRP have submitted updates of these disclosures for review by a former EPA Deputy Ethics official in a good faith effort to meet or exceed peer review process and ethics requirements.

On October 31, 2017, EPA Administrator Scott Pruitt signed a memorandum that changed membership criteria for EPA advisory committees.<sup>82</sup> The memorandum states that “no member of an EPA federal advisory committee currently receive EPA grants,” but that this “principle should not apply to state, tribal, or local government agency recipients of EPA grants.” This is inconsistent with the Federal Advisory Committee Act and inappropriate for four reasons. One is the obvious inconsistency of implying that receiving a grant creates a conflict of interest for one but not another class of persons. The second is the longstanding recognition that receipt of a peer-reviewed scientific research grant, for which the Agency does not manage the work nor control the output, is not a conflict of interest. Per the Office of Management and Budget (OMB): “When an agency awards grants through a competitive process that includes peer review, the agency’s potential to influence the scientist’s research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist’s ability to offer independent scientific advice to the agency on other projects.”<sup>83</sup> A 2013 report by the EPA Office of Inspector General reaffirmed that receipt of an EPA research grant is not a conflict of interest.<sup>84</sup> However, there can be situations in which a member of an advisory committee should recuse themselves from discussions that might pertain to their own work. Thus, third, the CASAC has had recusal policies in place for dealing with this issue and situations in which a member’s work may come up for deliberation. Fourth, the memorandum does not acknowledge that persons with financial or professional ties to regulated industries have, at the very least, the appearance of conflict of interest. With respect to members who currently hold or have recently held EPA STAR research grants, we reject Administrator Pruitt’s restrictions.

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<sup>82</sup> Pruitt, E.S., “Strengthening and Improving Membership on EPA Federal Advisory Committees,” Memorandum, U.S. Environmental Protection Agency, October 31, 2017. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>.

<sup>83</sup> Office of Management and Budget, “Final Information Quality Bulletin for Peer Review,” *Federal Register*, 70(10):2664-2677 (January 14, 2005), <https://www.govinfo.gov/content/pkg/FR-2005-01-14/pdf/05-769.pdf>

<sup>84</sup> EPA, “EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees,” Report No. 13-P-0387, Office of Inspector General, U.S. Environmental Protection Agency, Washington, DC, September 11, 2013. <https://www.epa.gov/sites/production/files/2015-09/documents/20130911-13-p-0387.pdf>

### **A.3 Administrative Procedures for the October 10-11, 2019 and October 18, 2019 Meetings of the Integrated Particulate Matter Review Panel**

The meeting was opened with remarks from a person filling the role of a designated official who described the ethics review procedure and the status of the members with respect to ethics compliance. We had a period for public comments. Following that, the panel deliberated on charge questions or groups of charge questions in a sequential order. A former EPA lawyer and a former EPA air science/policy expert were available as a resource for IPMRP questions.

The goal of the deliberations was to develop “consensus” panel responses to charge questions relating to the review of the draft Policy Assessment and elicit the Panel’s recommendation on the criteria and standards, as well as to consider other statements that the panel may wish to make. “Consensus” does not mean that all members of the panel must share or agree to the same viewpoints. “Consensus” means that all members of the panel agree that the written responses to charge questions and other written statements from the panel accurately reflect the views of the panel. If there are topics for which there are a diversity of viewpoints among members of the panel, the “consensus” response should accurately reflect such diversity of viewpoints. If a consensus response could not be achieved then it is acceptable for one or several panel members to express a dissenting opinion on all or part of the final report. The dissenting opinions, if any, should be captured in writing and included in the final report or the appendices.

The role of the chair is to facilitate the work of the panel. Examples of responsibilities of the chair are to monitor and guide progress on the agenda, enable panelists to have an opportunity to provide input and deliberate, assist the panel in identifying areas of consensus, and assist the panel in focusing on issues that require deliberation. The chair can also address issues regarding the scope of the Panel’s work and recommend approaches to formulating and communicating advice.

The following are the most common procedural considerations for this type of meeting:

- The deliverable from the panel meeting is a written report. The written report includes the following key elements: (1) a summary letter; (2) consensus responses to charge questions; and (3) individual member comments. The letter may additionally include consensus responses on other issues identified by the panel. The purpose of the letter is to concisely communicate the high level key findings and advice of the panel. The purpose of the consensus responses to charge questions is to provide more detail regarding the Panel’s findings and advice.
- All panelists were invited and encouraged to prepare written pre-meeting comments that address charge questions relevant to each panelist’s expertise, as well as any other issues that the panelist may want to address that generally relate to the scope of issues for review of the draft Policy Assessment and of the PM NAAQS.
- The panel is in deliberation if more than half of its members are interacting in formulating a written or oral statement on an issue. Panel deliberations must occur in public. Small groups of panelists, representing up to less than one-half of the panel members, may interact offline to refine draft materials.
- For each charge question or related group of charge questions, discussants and lead discussants were assigned. Discussants prepare draft responses to the charge questions. During deliberations at the public meeting, the lead discussant, with assistance from the

other discussants, formulated draft consensus written responses to the charge questions. Drafts of consensus responses were circulated among discussants for editing and revision, as long as the discussant group had fewer than 50% of panel members.

- During the course of the meeting, the lead discussant for each charge question identified the top “bullet points” that might be included in the Panel’s letter. This enabled the full panel to deliberate on key points for inclusion in the Panel’s letter.
- All key points for the main letter from the panel to the Administrator and the docket, and for the consensus responses to charge questions, were deliberated in a public meeting. No information not deliberated in a public meeting was included in the letter or consensus responses to charge questions.
- Comments from individual members that were reported only as individual comments did not have to be deliberated in the public meeting. However, any individual comments that might inform the formulation of panel consensus on an issue were deliberated with the panel.
- Individual panelists did not engage in deliberations on studies that they authored or co-authored, or research for which they are or were a principal investigator or co-principal investigator, other than to respond to clarifying questions.
- After the October 10-11, 2019 meeting and prior to the follow-up teleconference on October 18, 2019, a draft letter was prepared by the chair and drafts of consensus responses to charge questions was prepared by the charge question discussant groups. The panel deliberated during the follow-up teleconference to revise, as needed, the draft letter and consensus responses to charge questions and approve the final letter and consensus responses to charge questions.
- Individual members of the panel submitted a final version of their individual comments for attachment to the final letter.