

December 10, 2018

Louis Anthony (Tony) Cox, Jr., Ph.D.
President, Cox Associates
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and
Chair, Clean Air Scientific Advisory Committee
U.S. Environmental Protection Agency
Washington, DC 20460

and

Docket EPA–HQ–ORD–2014–0859
U.S. Environmental Protection Agency
Washington, DC 20460

Subject: CASAC Review of EPA’s Integrated Science Assessment (ISA) for Particulate Matter
(External Review Draft – October 2018).

Dear Dr. Cox:

We were members of the U.S. Environmental Protection Agency (EPA) Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel. Our panel was formed in November 2015 during the current review cycle for the primary and secondary National Ambient Air Quality Standards (NAAQS) for particulate matter (PM). Our panel was dismissed without notice by press release on October 10, 2018 with a follow-up email from the EPA Science Advisory Board (SAB) office on October 11, 2018. We include 15 members of the disbanded PM review panel, of which 8 are former members of the chartered CASAC, and 2 are former chairs of CASAC. This letter represents our consensus.

In this letter: (1) we review the statutory requirements for scientific review of NAAQS; (2) we describe our role and experience in the current NAAQS review and the disbanding of our panel; (3) we discuss the impacts of recent changes to the criteria for membership on the CASAC and to the NAAQS review process; and (4) we provide our partial review regarding the external review draft of the Integrated Science Assessment for PM. The recent changes in criteria for CASAC membership and for the NAAQS review process are given in memoranda of October 31, 2017 and May 9, 2018, respectively, by former EPA Administrator Scott Pruitt. Based on our review of the statutory requirements, history of the PM review in the current review cycle, recent changes by EPA to CASAC and the NAAQS review process, and of the draft ISA, we formulate advice for the CASAC and EPA.

Our advice is summarized in the form of **8 findings** and **44 recommendations** for the CASAC and EPA. The **8 findings** are summarized in **Table 1**. The **44 recommendations** are summarized in **Table 2**. The main points in this letter, including the findings and recommendations, are supported by details in this letter and attached individual comments from 12 members.

Table 1. Major Findings

MAJOR FINDING 1:	The myriad of changes to the National Ambient Air Quality Standard (NAAQS) review process are collectively harmful to the quality, credibility, and integrity of the scientific review process and to the Clean Air Scientific Advisory Committee (CASAC) as an advisory body.
MAJOR FINDING 2:	The current 7-member CASAC does not have the depth or breadth of expertise needed for the particulate matter review, nor could any group of this size cover the needed scientific disciplines.
MAJOR FINDING 3:	The late 2020 deadline for completing the particulate matter (PM) review does not provide sufficient time to complete the “thorough review” of the “latest scientific information” of the “kind and extent” of “all identifiable effects” mandated by the Clean Air Act for the review of NAAQS, even if the committee were supported by a robust panel of experts in the multiple disciplines involved.
MAJOR FINDING 4:	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. The statute requires only “one person representing State air pollution control agencies.”
MAJOR FINDING 5:	An underlying principle is to maintain distinction between science and policy issues. The Pruitt May 9, 2018 memorandum violates this principle by commingling science and policy considerations.
MAJOR FINDING 6:	In 2014, the CASAC provided advice to the Administrator regarding how CASAC’s role in reviewing adverse effects of NAAQS implementation should be structured. This advice has been ignored by the U.S. Environmental Protection Agency (EPA).
MAJOR FINDING 7:	The current framework for causal determinations used in the Integrated Science Assessment (ISA) has been well-vetted by CASAC and has stabilized over multiple reviews. However, there is room for more transparent communication of specific causal determinations in the ISA.
MAJOR FINDING 8:	There are numerous scientific issues in the external review draft of the Integrated Science Assessment for Particulate Matter that require revision.

Table 2. Recommendations

With regard to **MAJOR FINDING 1**: Changes to the National Ambient Air Quality Standard (NAAQS) review process are harmful.

Recommendation 1: The Clean Air Scientific Advisory Committee (CASAC) should recommend, and we recommend, that the U.S. Environmental Protection Agency (EPA) rescind the October 31, 2017 and May 9, 2018 memoranda by former EPA Administrator Scott Pruitt.

Recommendation 2: CASAC should recommend, and we recommend, wider consideration of approaches to streamlining the NAAQS review process, including opportunity for input from EPA staff in the Office of Research and Development (ORD) and Office of Air Quality Planning and Standards (OAQPS), CASAC, and other stakeholders including the public.

Recommendation 3: CASAC should advise EPA, and we advise EPA, that, if it wishes to change the criteria for appointments to EPA advisory committees including CASAC, it should provide opportunity for input on such criteria from EPA staff in ORD and OAQPS, the EPA Science and Technology Policy Council, CASAC, and other stakeholders including the public.

Recommendation 4: CASAC should not agree to changes to the review process or to the schedule proposed by EPA.

With regard to **MAJOR FINDING 2**: Lack of breadth and depth of expertise.

Recommendation 5: We advise, and CASAC should advise, the current Acting Administrator that CASAC does not have adequate breadth and depth of scientific expertise 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.

Recommendation 6: We remind CASAC and EPA, and CASAC should remind the current Acting Administrator, that it has been long-standing practice, for four decades, to augment the 7-member CASAC with additional independent expert consultants, and this augmentation is essential to a high-quality review.

Recommendation 7: We remind the current Acting Administrator, as should CASAC, that in all past reviews conducted by CASAC, it has always been the 7-member chartered CASAC that approves the content of letter reports and attachments transmitted from CASAC to the Administrator. This is clearly indicated in CASAC's charter with Congress.

Recommendation 8: We call for, and CASAC should call for, the immediate formation of an Ozone Review Panel and for the reinstatement of the CASAC Particulate Matter (PM) Review Panel.

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Table 2. Recommendations, Continued

With regard to **MAJOR FINDING 3**: Inadequate review time.

Recommendation 9: CASAC should reject EPA's proposed accelerated schedule. EPA should allow time for an adequate review by relaxing its fall 2020 deadlines for final rules for both ozone and PM.

Recommendation 10: CASAC should reject EPA proposals for only one review draft of an Integrated Science Assessment (ISA), and a Policy Assessment (PA) with embedded Risk and Exposure Assessments (REAs). EPA should allow for multiple drafts as needed, including separate drafts of the health and welfare REAs prior to a draft of the PA.

Recommendation 11: We advise the current Acting Administrator, as should CASAC, that the CASAC, supported by an augmented panel of scientific experts, requires typically two years to finish this review, contingent on timing and quality of EPA assessment documents.

Recommendation 12: We remind CASAC and EPA, and CASAC should remind EPA, that the courts have recognized the importance of CASAC's role and the need for adequate scientific review time.

Recommendation 13: Delays in initiation of the review cycle by EPA should not infringe on the adequacy of the time frame needed by CASAC to properly do its job with adequate quality and integrity. CASAC should affirm this recommendation.

Recommendation 14: We affirm, and CASAC should affirm, the important role of public comments.

Recommendation 15: EPA should immediately begin the review cycle for carbon monoxide. CASAC should form and EPA should approve a Carbon Monoxide Review Panel augmented with additional experts. EPA should allow adequate time for this review.

Recommendation 16: EPA should immediately begin the review cycle for lead. CASAC should form and EPA should approve a Lead Review Panel augmented with additional experts. EPA should allow adequate time for this review.

Recommendation 17: EPA should immediately begin the review cycle for oxides of nitrogen. CASAC should form and EPA should approve an Oxides of Nitrogen Review Panel augmented with additional experts. EPA should allow adequate time for this review.

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Table 2. Recommendations, Continued

With regard to **MAJOR FINDING 4**: Committee composition is based on non-scientific criteria.

Recommendation 18: Scientific expertise for panels should be relevant to the particular review. Different NAAQS reviews require different expertise. We recommend, and CASAC should recommend, that membership criteria for the chartered CASAC and for its augmented panels should emphasize scientific expertise, not geographic diversity nor affiliation with state, local, and tribal agencies, other than to meet the Clean Air Act requirement for “one person representing State air pollution control agencies.”

Recommendation 19: We recommend, and CASAC should recommend, that receipt of an EPA research grant should not disqualify membership on the CASAC or CASAC review panels.

Recommendation 20: We recommend, and CASAC should recommend, that CASAC members should not be dismissed *en masse* or appointed *en masse*, and turnover in a given year should be limited to a minority fraction of the total panel. Members should be eligible for reappointment to a second term especially if such appointments would provide continuity, key scientific expertise, and institutional memory. CASAC should include members with prior experience with the review process from prior service on CASAC or CASAC review panels.

With regard to **MAJOR FINDING 5**: Science and policy are commingled.

Recommendation 21: CASAC should reject EPA’s proposal to combine documents such as the ISA, REA, and PA in NAAQS review as a matter of routine procedure. Further, the CASAC review of the REA should not be concurrent with the PA. EPA should not commingle the first draft of REAs with the first draft of the PA. EPA should revise the review schedule such that CASAC is provided with a staggered sequence of first draft documents for the ISA, REAs, and PA, with time allowed for CASAC and public input on the first draft of a document to be addressed prior to issuing the first draft of the successive document.

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Table 2. Recommendations, Continued

With regard to **MAJOR FINDING 6**: Inappropriate strategy to review implementation effects.

Recommendation 22: CASAC should not commingle deliberations regarding potential adverse effects of implementation with scientific issues regarding review and revision of NAAQS pertaining to public health and welfare.

Recommendation 23: CASAC and EPA should consider both adverse and beneficial effects of NAAQS implementation.

Recommendation 24: To develop advice on implementation effects, CASAC should be augmented with a panel of appropriately selected national and international experts. Such a panel may be able to address more than one NAAQS.

Recommendation 25: To avoid illegally commingling implementation issues when formulating a NAAQS, review of implementation effects should be done on a separate schedule than review regarding science pertaining to retaining or setting standards.

Recommendation 26: EPA and CASAC must take a scientific approach to providing advice regarding implementation effects, and such a review should be done with the same scientific rigor as the CASAC review of other aspects of the process.

Recommendation 27: EPA should develop one or more appropriate and relevant implementation assessment documents, which could build upon existing documents such as retrospective and prospective studies of the benefits and costs of the Clean Air Act. Such documents from EPA should be developed with the same level of scientific rigor and analysis as the other assessment documents, with similar requirements in regard to the supporting literature.

Recommendation 28: EPA and CASAC should recognize that the first attempt at doing this will involve the development of new data, methods, and analyses of adequate scientific validity and policy-relevance, which will take time.

With regard to **MAJOR FINDING 7**: Causal Framework

Recommendation 29: The state of the science of causal inference methodology is insufficient to recommend replacing the ISA's approach to causal determinations or for differently weighting studies used in the causal determinations based on a new criterion of how they apply causal inference methods. Therefore, the causal framework as stated in the Preamble to the ISAs should be retained in this review cycle.

Recommendation 30: The causal framework is not consistently and transparently applied in the external review draft of the PM ISA. Therefore, the framework should be consistently and transparently applied.

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Table 2. Recommendations, Continued

With regard to **MAJOR FINDING 8**: The external review draft of the PM ISA requires extensive revisions.

Recommendation 31: A second draft of the ISA is needed and should be subject to a proper review by an appropriately constituted CASAC PM Review Panel.

Recommendation 32: Material on low cost sensors should be added to the ISA, per CASAC's advice on the PM Integrated Review Plan.

Recommendation 33: Numerous revisions are needed for Chapter 2 to more accurately reflect the current status of measurement methods, data, and interpretation of data.

Recommendation 34: The relationship between fine particles (PM_{2.5}) and ultrafine particles (UFP) requires more detailed characterization and assessment.

Recommendation 35: A more thorough treatment of PM components is needed in the context of air quality measurement and exposure assessment.

Recommendation 36: More attention is needed to exposure microenvironments that are associated with the potential for high exposure to PM, including (for example) in-vehicle, on-road, and near-road (including schools near roads).

Recommendation 37: Study selection should be done more consistently or exceptions should be more clearly justified.

Recommendation 38: There should be more consistency and transparency in the application of the causal framework, including identification and explanation of studies or factors that led to up or down weighing of determinations, and more critical assessment of issues such as mixtures, copollutant models, and exposure error.

Recommendation 39: The ISA does a very good job of describing and synthesizing new evidence pertaining to exposure to PM_{2.5} and premature mortality. The assumption that the C-R relationship is linear, with no threshold, is reasonable and consistent with available scientific evidence.

Recommendation 40: The causal determination for short term exposure to coarse PM and respiratory effects should be informed by a more detailed critical evaluation of the supporting science so that the basis of the finding is more complete and transparent.

Recommendation 41: The causal determination for long term exposure to UFP and nervous system effects should be informed by a more detailed critical evaluation of the supporting science so that the basis of the finding is more complete and transparent.

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Table 2. Recommendations, Continued

Recommendation 42: With regard to populations with pre-existing cardiovascular or respiratory disease, a more thorough critical evaluation is recommended to support or possibly revise the ‘suggestive’ findings with respect to being at-risk populations.

Recommendation 43: Recent work regarding alternative scene-dependent haze metrics as visibility preference indicators is not mentioned and should be cited and evaluated.

Recommendation 44: As noted in individual member comments, and more generally, additional literature should be cited and incorporated. The end date for the literature review should be specified. Literature published up to the end date should be reviewed.

Statutory Requirements

Section 108 of the Clean Air Act requires that the Administrator periodically review and update the air quality criteria for an air pollutant so that they “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities.” Section 109 requires the Administrator to adopt NAAQS that are “requisite to protect public health” with an “adequate margin of safety” and to “protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air” based on the scientific knowledge embodied in the air quality criteria. Section 109 requires EPA to conduct a “thorough review” of the air quality criteria and the NAAQS at five-year intervals. As part of this review, Section 109 also requires that the Administrator “appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.” This scientific review committee must review the air quality criteria and the NAAQS, and recommend any “appropriate” revisions to the criteria and the NAAQS, consistent with the obligations of Sections 108 and 109. The scope of scientific issues involved in satisfying Section 108’s requirements means that a broad range of scientific expertise is needed to conduct the comprehensive scientific assessments needed for the periodic NAAQS reviews.

For this review to be “thorough”, “accurate”, and reflect “the latest scientific knowledge ... of all identifiable effects”, a broad range of scientific expertise is needed. The CASAC charter reflects the need for this breadth of expertise. Thus, the charter states that “[m]embers will be persons who have demonstrated high levels of competence, knowledge, and expertise in scientific/technical fields relevant to air pollution and air quality issues.” Moreover, for the past four decades, comprising well over 20 reviews, CASAC has recognized that the chartered CASAC requires participation of additional experts, acting as consultants, in order that its review be “accurate” and “thorough.” This augmentation of chartered CASAC expertise again is reflected in the CASAC charter, which 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.”

The combined implications of Sections 108 and 109 of the Clean Air Act, as well as the CASAC charter and historic practice, are that the role of the scientific review committee (i.e. CASAC) requires that scientists who are at the leading edge of research in their respective fields be involved, either directly as members of CASAC or through CASAC involving consultation with these experts. The Act clearly requires that EPA appoint a committee comprised of scientific experts, and that EPA obtain the advice of scientists with breadth and depth of expertise appropriate to the required scope of “accurate” and “thorough review,” “latest scientific knowledge” and “kind and extent” of “all identifiable effects” required by law.

From a scientific perspective, scientific experts who are qualified to conduct a “thorough review” based on the “latest scientific knowledge” are those who are engaged in peer-reviewed scientific research in pertinent scientific disciplines and areas of study. This is why the SAB Staff Office sought “nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to PM” in its February 4, 2015 Federal Register notice on “Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel.”

The 2015 to 2018 CASAC Particulate Matter Review Panel

Review panels are comprised of additional scientific experts appointed as special governmental employees to supplement the chartered CASAC. As noted in attached individual comments, CASAC has a long history of being augmented with additional experts to support its review activities. At the time that the CASAC PM Review Panel reviewed the Integrated Review Plan external review draft on August 31, 2016, the panel was comprised of six members of the chartered CASAC and 20 consultants, for a total of 26 panel members. The augmentation of CASAC with panels has been well-established for four decades, as detailed in attached member comments. This has ensured a multidisciplinary, comprehensive, integrated and thorough review of massive amounts of scientific literature encompassing wide-ranging and complex scientific studies.

Augmentation of the expertise of the chartered CASAC with that of the panel members was critical to the quality, credibility, and integrity of our scientific review process. The panel members provided needed breadth and depth of expertise beyond that of the chartered CASAC (See quote on page 9 from CASAC’s charter).

The final rule for the PM primary and secondary NAAQS from the last review cycle was published in the Federal Register on January 15, 2013. The review process for the PM standards started with a Federal Register notice on December 3, 2014 that was a “Notice of Workshop and Call for Information on Integrated Science Assessment for Particulate Matter.” Thus, the current review cycle started approximately 23 months after the conclusion of the prior review cycle.

On February 4, 2015, the EPA Science Advisory Board (SAB) office announced in a Federal Register notice (Volume 80, Number 23, pages 6086-6089) a “Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel.” 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:

“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.” [emphasis added]

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.” [emphasis added]

On November 17, 2015, a memorandum from Aaron Yeow to Chris Zarba in the EPA Science Advisory Board office established the “Formation of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel.” 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.”

The November 17, 2015 memorandum is known as a “determination” memorandum because it determines the formation and membership of the panel. The determinations in the memorandum included the type of review body, the nature of the review, types of expertise needed, financial conflict of interest considerations, applicability of “lack of impartiality” regulations, other considerations, how individuals were selected, and the selected members of the CASAC PM Review Panel. Thus, the CASAC PM Review Panel was duly appointed.

On March 14, 2016, EPA issued a Federal Register Notice for “Notification of a Public Teleconference of the Clean Air Scientific Advisory Committee Particulate Matter Panel” for the purpose of conducting a “peer review” of “the EPA’s Draft Integrated Review Plan (IRP) for the National Ambient Air Quality Standards (NAAQS) for Particulate Matter.”

On April 19, 2016, EPA issued a Federal Register Notice for “Release of the Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter.” The panel met and deliberated regarding the external review draft of the IRP in public teleconferences on May 23, 2016 and August 9, 2016. On August 9, 2016, the chartered CASAC approved a draft letter to the Administrator with attached responses to charge questions. The chartered CASAC

issued a letter to the EPA Administrator on August 31, 2016 (EPA-CASAC-16-003) regarding the result of its review.

The chartered CASAC stated in its letter that more attention was needed to summarize the list of “future research” items identified in the Policy Assessment from the prior review cycle and to discuss what EPA has done to address them. The CASAC encouraged EPA to seek scientific input early in the review process from the CASAC Air Monitoring and Methods Subcommittee (AMMS), including “policy-relevant PM monitoring issues for both the primary (PM_{2.5} and other particle indicators) and the secondary (e.g., visibility) NAAQS, as well as the performance of PM ‘sensors’.” The CASAC advised EPA to include “specific information about the study quality evaluation process and evaluation criteria that will be used in the ISA, acknowledging the limitations and difficulties involved.” The CASAC further encouraged the EPA to emphasize in the ISA “new evidence relevant to standards that has become available since the prior review.” The CASAC also encouraged EPA to include in the ISA discussions of the following:

- “Evaluation and summary of health effects across temporal windows of exposure”
- “The potential importance of exposures during critical windows of susceptibility”
- “Discussion of cancer risk”
- “The modification of PM-associated health effects by PM composition”
- “Uncertainties in emission profiles”

With regard to the Health Risk and Exposure Assessment (HREA) document, the CASAC recommended that:

“the EPA specify the criteria that will be used in the HREA Planning Document to determine whether development of a new HREA is justified, particularly for the exposure assessment. The CASAC encourages the EPA to consider expansion of the geographic scope of the HREA to the entire continental United States, which can be facilitated by use of high-quality modeled estimates of PM_{2.5} at all census tract centroids in its assessments. The CASAC encourages the EPA to consider more representative exposure metrics, including use of modeled PM at the census tract-level and exposure estimates from stochastic population-based models rather than relying only on data from fixed site monitors.”

With regard to the Welfare Risk and Exposure Assessment (WREA) document, the CASAC found that the draft IRP did “not adequately address welfare effects,” particularly related to impacts beyond visibility acceptance, processes to identify potentially affected populations, measurement of impacts for these affected populations, additional forms of PM deposition, and indicators aside from light extinction.

In response to a public comment urging development of impacts of possible revisions of standards, the CASAC reiterated its letter of June 26, 2014 (EPA-CASAC-14-004) on this point. The CASAC stated that:

“cost and implementation issues are not relevant or allowable considerations in setting or revising a NAAQS (Whitman vs. American Trucking Association, Inc., 2001). Therefore, these issues will not be taken into consideration during the

CASAC's review of the scientific and technical documents (IRP, ISA, HREA, WREA, and PA) that will support the setting or revision of the PM NAAQS. The CASAC reiterates that, separate from the standard-setting process, it would be receptive to providing advice on possible adverse effects associated with implementation of existing NAAQS, upon request by the EPA. In response to such a request, the SAB Staff Office would form an ad hoc CASAC panel to obtain the full expertise necessary to conduct a review of EPA documents or analyses of any "adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards" (42 U.S. Code § 7409)."

EPA released the final Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (EPA-452/R-16-005) in December 2016. 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

This schedule differed from that in the external review draft of the IRP. 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 schedule in the final IRP also allows for 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 schedule was not reviewed by CASAC. 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. 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.

On October 10, 2018, EPA issued a press release that: (a) "tasked" the chartered CASAC with "leading the review of science for any necessary changes to the NAAQS for ozone or particulate matter"; and (b) stated that such changes "would be finalized by late 2020." On October 11, 2018, an email from Khanna Johnston to Aaron Yeow of the EPA SAB office was forwarded to members of the CASAC PM Review Panel that stated "the CASAC PM Review Panel will no longer be involved with the Agency's PM NAAQS review and your service on the panel has concluded." Four days later, on October 15, 2018, the first external review draft of the Integrated Science Assessment for Particulate Matter (EPA/600/R-18/179) was released. The draft ISA document has 1,881 pages.

On November 7, 2018, a new determination memorandum was issued from Aaron Yeow to Thomas H. Brennon in the EPA SAB office. The memorandum states that the "the seven-member Chartered CASAC will serve as the body to review the remaining key science assessments for the agency's PM NAAQS review" but offers no explanation for reason(s) why the CASAC PM Review Panel would no longer be involved. The memorandum states that the chartered CASAC has "expertise in toxicology, engineering, medicine, ecology, and atmospheric science."

Compared to the November 17, 2015 determination memorandum, the following scientific areas are not specifically mentioned: air quality and climate responses, atmospheric chemistry, dosimetry, 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. Engineering was not mentioned in the November 17, 2015 determination memorandum and it is not clear why engineering was added in the November 7, 2018 determination memorandum. The scientific areas of "medicine, ecology, and atmospheric science" in the November 7, 2018 determination memorandum are stated broadly and not with the specificity (e.g., controlled clinical exposure, light extinction, visibility impairment, related welfare effects, climate response, atmospheric chemistry) as in the November 17, 2015 determination memorandum.

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, controlled clinical studies, and others.

At its November 29, 2018 teleconference on consultation regarding the draft Integrated Review Plan for ozone, some members of CASAC discussed issues pertaining to the methodology for making causal determinations regarding adverse outcomes from exposure to air pollutants. CASAC Chair Dr. Tony Cox indicated that there is now 'substantial' literature pertaining to air pollution and health effects that draws distinctions between different types of causality, citing work done by the Health Effects Institute on accountability as an example. CASAC member Dr. Mark Frampton indicated that trying to restructure the causality framework would generate a lot of controversy and a lot of discussion. Newer literature could be acknowledged without insisting that the framework be changed. In response, Dr. Cox indicated a desire to "point out" and "suggest" but that there is a "need to go further" while also stating that he expected CASAC to "not insist" that the causal determination framework be revised. Any significant revisions to the causal determination framework would necessitate additional drafts of the ISA and changes to the Preamble to the ISAs, which would require adequate time, public notice, opportunities for public meetings at which the public may provide comments, and adequate time for CASAC deliberations. As currently constituted, CASAC does not have the right depth, mix and diversity of expertise to take on revision to the causal determination framework.

As Dr. John Vandenberg of EPA's National Center for Environmental Assessment pointed out during the November 29, 2018 teleconference, and as pointed out in EPA's presentation on review of the draft PM ISA released on December 7, 2018, the causal determination framework has been reviewed by CASAC over the years and has been revised and improved based on CASAC advice. As detailed in attached individual comments, the causal determination framework has been reviewed by CASAC review panels for all six criteria pollutants and by the chartered CASAC on numerous occasions, with at least 14 public meetings on ISAs for which the causal framework was a key factor. The framework and its application has been evaluated by 74 experts over multiple panels and review cycles.

To the extent that this CASAC seeks to review and possibly revise the causal determination framework in the context of the current reviews of ozone and particulate matter, CASAC should be augmented with multiple experts with different perspectives in causal determination and causal inference for both the ozone and PM reviews.

The December 7, 2018 presentation released by EPA regarding the review of the draft PM ISA contains a revised schedule for completing the review of the PM NAAQS. EPA proposes that CASAC will review only the current external review draft of the ISA and that, irrespective of comments from CASAC and the public that may call for a second external review draft, the ISA will be finalized without further review by "2019-2020." EPA is not proposing that CASAC will be provided with planning documents for the health and welfare REAs. EPA proposes that there will not be separate documents for the health or welfare REAs but that "quantitative risk and air quality analyses" will be incorporated into an external review draft of the PA. Furthermore, EPA proposes that CASAC will review only one draft of the PA. Thus, EPA proposes that CASAC will not review the scientific basis of the health or welfare REAs prior to their use in the PA, thereby commingling science and policy issues and leading to a less transparent

treatment of these issues. EPA proposes that, irrespective of comments from CASAC and the public that may call for a second external review draft, the PA will be finalized without further review by “2019-2020.” The proposed schedule reduces the number of public meetings of CASAC, thereby leading to fewer opportunities for public comment.

A similar schedule was proposed by EPA for the review of the NAAQS for ozone at the November 29, 2018 meeting of the chartered CASAC regarding the external review draft of the ozone Integrated Review Plan.

EPA has disbanded the CASAC PM Review Panel that was formed for the current review of the PM NAAQS, and has refused to form a CASAC Ozone Review Panel even though it had called for nominations for such a panel on July 27, 2018. Such panels typically have 15-20 additional experts. The chartered CASAC, comprised of only 7 members, is being tasked with review of both the ozone and PM NAAQS simultaneously, without augmentation by combined additional 30-40 experts in ozone and PM review panels, as would be typical practice based on precedent and need. CASAC review activities, which would typically take an average of two or more years to finish the PM review and three years to conduct the ozone review, are being compressed into a year. The 7 members are being overloaded with too much work in too short a time. The 7 members of CASAC do not have the breadth, depth, and diversity of expertise and experience to conduct either the ozone or PM reviews without augmentation, much less both reviews simultaneously. A review process with only one draft ISA, no REA planning documents, and only one draft of a combined REA/PA is substantially curtailed.

The combined effect of the recent announcements and recent deliberations of CASAC is:

1. A duly appointed and properly constituted panel of two dozen experts in the breadth and depth of needed scientific disciplines for the PM review, including representation of multiple perspectives, was disbanded.
2. The panel was disbanded during a review cycle, with no advance notice, discussion, opportunity for input, or reasonable explanation. This is arbitrary and unprecedented.
3. The review was placed solely with the chartered CASAC.
4. The 7 members of CASAC do not have the breadth and depth of expertise, or multiple perspectives, needed for this review. For example, CASAC lacks an epidemiologist.
5. In announcing on December 7, 2018 a new schedule and sequence of documents for the remaining of the PM review, EPA is substantially deviating from the Integrated Review Plan for PM.
6. The remaining time frame for this review is to be highly expedited, from an end date of 2022 given in the final IRP to 2020 per the October 10, 2018 press release and EPA’s December 7, 2018 presentation.
7. To meet the highly expedited schedule, EPA proposes to skip key and necessary steps such as reviewing revised drafts of EPA staff documents, and reviewing a staggered sequence of documents including the ISA, REA planning documents, REAs, and PA in which there is sufficient time for EPA staff to incorporate CASAC advice from one document before proceeding to the next document.
8. EPA is proposing to provide the REAs and PA simultaneously as one document.

9. The CASAC does not have sufficient diversity of scientific perspectives to undertake review and possible revisions to the causal determination framework.

Based on these findings, the following should be done:

1. CASAC and EPA should, as soon as possible, reappoint the PM Review Panel.
2. If CASAC seeks to revisit the causal determination framework, the PM Review Panel should include new members with expertise in causal determination and causal inference.
3. Since a PM Review Panel was not engaged in the review of the first external review draft of the ISA, CASAC and its reinstated PM Review Panel should be provided with a second external review draft of the ISA for review.
4. EPA should allow enough time between drafts for EPA staff to incorporate advice from CASAC, and enough sequencing between the ISA, REA planning documents, REAs, and PA to allow content of a preceding document to be revised based on CASAC input before releasing the first draft of a successive document. Furthermore, to promote separation between, and transparency regarding, science and policy issues, the first draft of the PA should not be released until after receiving and incorporating CASAC advice regarding the first draft of the REAs.

Changes to Criteria for Appointments to CASAC

Over the decades, CASAC members have been appointed based on their scientific expertise. As stated in CASAC's charter, "[m]embers shall be persons who have demonstrated high levels of competence, knowledge, and expertise in the scientific/technical fields relevant to air pollution and air quality issues." As noted in the November 17, 2015 determination memorandum for the CASAC PM Review Panel, EPA sought "nationally and internationally recognized scientists in the science of air pollution related to PM" and further elaborated that "[e]xperts were 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."

In contrast, an October 31, 2017 memo from former EPA Administrator Scott Pruitt requires that members of EPA federal advisory committees should "reflect prominent participation from state, tribal, and local governments," and that priority should be given to "geographic diversity." There is no mention of the importance of having experts of high stature that represent the wide range of scientific disciplines, and the depth of knowledge and experience, necessary to the work of committees such as CASAC or the EPA Scientific Advisory Board (SAB).

On October 10, 2018, EPA announced that Acting Administrator Wheeler appointed five new members to the 7-member chartered CASAC. The current CASAC is comprised of representatives from four state agencies, one federal agency, a consulting firm, and one academic researcher. For the most part, these members were selected for their geographic location or affiliation, rather than primarily based on depth of expertise.

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 illogical 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 Peer Review Bulletin of 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.” A 2013 report (Report No. 13-P-0387) by the EPA Office of Inspector General reaffirmed that receipt of an EPA research grant is not a conflict of interest. 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 same appearance of conflict of interest.

The October 31, 2017 memo calls for greater turnover in membership of EPA advisory committees but 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 subject matter expertise and without prior experience on CASAC or CASAC review panels, selected instead for their affiliation or geographic location.

To be clear, we laud anyone who is willing to serve on CASAC, and these comments are not directed toward any particular individual. CASAC should be constituted based primarily on scientific expertise, should include active researchers, should not exclude research grant recipients, and should include a sufficient number of members with previous experience on CASAC or its review panels to ensure continuity and to avoid inefficiencies related to lack of experience. The October 31, 2017 memorandum should be rescinded.

NAAQS Review Process

Here, we provide our analysis and advice regarding the time frame for this review and regarding the appropriate approach for developing advice on effects of implementation of a NAAQS.

NAAQS Review Timeframe

We understand from the historical record and from the last PM review that the timeframe for NAAQS review cycles usually has taken longer than the statutory mandate for reviews “at five-

year intervals.” Concern about the length of review cycles was a clear motivating factor for the May 9, 2018 memorandum by Administrator Scott Pruitt regarding “Back to Basics Process for Reviewing National Ambient Air Quality Standards.” It is a matter of public record that the review cycle for PM in the last review was completed on January 15, 2013, which was 6.25 years after completion of the prior review cycle on October 17, 2006. However, CASAC’s role in the last PM review spanned only 2.8 years, from its first meeting to discuss in the IRP on November 30, 2007 to its last meeting regarding its advice on the policy assessment and regarding the standards on September 10, 2010. It is a matter of public record that nearly all of the NAAQS review cycles for various combinations of criteria pollutants and standards (primary, secondary) since the inception of the NAAQS have taken more than five years.

As noted in attached individual comments, the NAAQS review process was revised in 2006 in large part to shorten the duration of NAAQS review while maintaining or enhancing its scientific rigor and credibility, taking into account key factors such as the need to promote separation between science and policy issues. The duration of NAAQS review has generally decreased in the last decade compared to prior decades. However, challenges clearly remain in achieving the statutory mandate for a five year review. Prior to making substantial changes to the NAAQS review process, EPA should properly diagnose the causes of schedule delays and slippage, and should also recognize the need to maintain the scientific quality and scope of the review process consistent with the requirements of the Clean Air Act.

The May 9, 2018 memorandum implies that delays in review cycles beyond the five year statutory requirement are significantly related to the scientific aspects of the review process, including aspects involving CASAC. The memorandum fails to acknowledge the following key points:

- (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 take specifically into account the first five listed EPA-driven factors that lead to delays in review cycles. Based on incomplete 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.

Although the 2006 to 2013 review of the primary and secondary PM NAAQS took longer than five years, these delays are mainly attributable to actions of the EPA. CASAC and its PM Review Panel for that review cycle reacted in an appropriate and reasonable time frame to all draft reports submitted for review in terms of developing comments from individual members, conducting public meetings, deliberating in public, and providing consultations or advice.

In the current review of the primary and secondary PM NAAQS, the review started on December 3, 2014, 23 months after the conclusion of the prior review on January 15, 2013, with a call for information on the ISA. The first CASAC meeting of the PM review cycle took place nearly 18 months later on May 23, 2016, because the IRP was not available until April 2016. The time from CASAC's advice to EPA of its review of the IRP until the first draft of the ISA in October 2018 was 25 months. In the 4.0 years since the current review cycle started, which corresponds to 5.9 years since the conclusion of the last review cycle, EPA has provided CASAC with only one document to review until now, which was the IRP.

Thus, we reject the implication that delays in the NAAQS review process are in any substantial way due to CASAC's role. Delays in the current NAAQS review for PM cannot be attributed to CASAC. Moreover, in the final IRP, EPA planned to complete the PM review in 2022, not 2020 as per the May 9, 2018 memorandum. However, as noted below, 2022 is no longer a realistic end date. It is unreasonable for EPA to ask its staff in ORD and OAQPS, and CASAC, to sacrifice a reasonable schedule for the scientific aspects of the NAAQS review to compensate for EPA's delay in starting and conducting the review.

Based on analysis of the most recently completed review cycles for primary NAAQS for each of the six criteria pollutants, the average amount of time it has taken from CASAC's first public review meeting on the first external review draft of an ISA to CASAC's final public review meeting on the policy assessment is 2.1 years. Additional time is needed by EPA after receiving 'closure' on CASAC's advice to formulate and publish its proposed rule, obtain and respond to public comment, and formulate and publish its final rule. For the most recently completed review cycles of the criteria pollutants, it has taken EPA an average of 1.9 years to finalize a rule after receiving CASAC's advice. Thus, it is unrealistic that this review can be completed within two years. Realistically, the remainder of the current review for PM will take four years, conditional on the timing and quality of EPA assessment reports. The quality and credibility of the review will also depend on whether CASAC is augmented with an appropriately constituted PM Review Panel.

To reduce delays in the NAAQS review process, CASAC should advise EPA, and we advise EPA, to do the following:

- (1) Begin a new review cycle in a timely manner after ending the prior review cycle;
- (2) Develop assessment documents for CASAC review in a timely manner; and
- (3) As needed, provide revised documents for CASAC review in a timely manner.

We note also that the duration of time from closure of CASAC's role to promulgation of a final rule is at least in part at the discretion of EPA.

Furthermore, we note, as mentioned in attached individual member comments, that the courts have recognized the important role of CASAC in the NAAQS review process. Even for reviews for which EPA has been under a court order or a consent decree for a NAAQS review schedule, the courts have allowed adequate time for CASAC's review. Thus, EPA should not abridge CASAC's review time, nor truncate the process, to achieve a self-imposed schedule. As further noted in attached individual member comments, this schedule is self-imposed because EPA is selectively choosing when it will or will not comply with the statutory requirement for a 5-year review. For example, EPA has not started review cycles for carbon monoxide, lead, or oxides of nitrogen.

If EPA seeks to go "back to basics" in meeting the Clean Air Act requirement for five year reviews of NAAQS, it is puzzling that EPA has been silent on the time that has elapsed since the last final rule for the carbon monoxide NAAQS, which was more than seven years ago, on August 31, 2011. It has been more than two years since the last lead NAAQS was finalized on October 18, 2016. Thus, if EPA is to meet its statutory mandate for a five year review, it should immediately begin reviews for CO and lead. The most recent review for oxides of nitrogen recently completed on April 6, 2018, and it is not too soon to start the next review cycle. As soon as the final decision is promulgated for the current review of sulfur oxides, the next review cycle for sulfur oxides should commence. EPA delays in starting review cycles should not lead to curtailing the amount of time needed for scientific review of quality and scope consistent with requirements of the Clean Air Act.

CASAC's Role in Advising on Implementation Effects

The CAA states that CASAC shall advise the Administrator EPA regarding "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance" of NAAQS. However, past EPA administrations have typically not asked CASAC for this advice, nor have EPA staff prepared scientific assessment documents for CASAC review that would be relevant to developing such advice. The May 9, 2018 memorandum indicates that EPA will include a charge question to CASAC seeking such advice. The October 29, 2018 memorandum from John Vandenberg of EPA/NCEA to CASAC regarding CASAC review of the draft ISA includes the "standardized set of charge questions" from the May 9, 2018 memorandum, including: "[p]lease advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS."

In a June 26, 2014 letter (EPA-CASAC-14-004) to the Administrator, CASAC outlined how such advice would need to be developed, taking into account that it is illegal to consider cost or technological feasibility when setting a NAAQS. CASAC stated that it would not commingle deliberations regarding potential adverse effects of implementation with scientific issues regarding review and revision of NAAQS. CASAC noted that not all implementation effects are adverse; therefore, "any comprehensive assessment would include both adverse and beneficial effects." For example, there are economic benefits from avoided morbidity and premature mortality. CASAC further advised that "the SAB Staff Office would form an ad hoc CASAC panel to obtain the full expertise necessary to conduct such a review." CASAC reaffirmed its advice on

how to review implementation effects in its August 31, 2016 letter to EPA regarding the draft IRP for PM (EPA-CASAC-16-003).

The expertise to address social, economic, and energy effects differs from that needed to address other aspects of CASAC's mandate. Review of implementation effects should be done on a separate schedule than review regarding science pertaining to retaining or setting standards. Furthermore, EPA should recognize that as a scientific advisory committee, it would be CASAC's responsibility to take a scientific approach to providing advice regarding implementation effects based on valid methods and data, and that such advice cannot be based merely on anecdotes or stakeholder opinions.

CASAC historically relies on EPA staff to prepare draft assessment documents and does not have the resources to commission its own studies. The May 2018 memorandum indirectly acknowledges that CASAC needs to be provided with relevant documents. To clearly separate its advice on implementation versus advice on the standards themselves, an appropriately formulated separate CASAC NAAQS implementation review panel should be provided with a separate draft implementation assessment document. Such a panel may be able to provide advice regarding more than one NAAQS. It is likely that there will be a significant learning curve for the both the agency and CASAC in dealing with assessment of implementation issues, which should be recognized in setting schedules. The timing of CASAC advice regarding implementation logically would not be the same as that regarding whether to revise a standard, to avoid conflating implementation issues with the development of advice regarding the setting of NAAQS.

The External Review Draft of the Integrated Science Assessment

We provide our consensus analysis, evaluation, and advice regarding particular elements of the first external review draft of the ISA. Because our panel was disbanded days before the ISA was released, we were not able to conduct our work in the same manner as would have otherwise occurred. For example, we were not able to convene a two day meeting for deliberations among members of the former panel. Therefore, we have not attempted to cover the full scope of the ISA or to develop the thoughtful consensus understanding that unfolds over a multi-day meeting. Instead, we focus on selected issues. Thus, these comments should not be interpreted as being a substitute for those that would come from a CASAC PM Review Panel.

Preamble to the ISAs

The Preamble to the ISAs (EPA/600/R-15/067) explains general methodologies pertaining to literature review, causal determination, and determination of at risk populations and life stages that apply to all ISAs. We note in particular that the causal determination framework has been reviewed by at least 11 review panels and by the chartered CASAC on numerous occasions from 2008 to the present. At least 74 experts, including members of the chartered CASAC and members of CASAC review panels, have been on panels that have provided advice regarding the causal determination framework. The causal framework is well established. In recent years,

comments by CASAC have transitioned from less about the framework itself toward ensuring transparent application of the framework to particular determinations. Examples of issues considered in formulating the framework include but are not limited to publication bias, model selection bias, concentrations relevant to ambient levels, common-causes, specificity of criteria, coherence of evidence, robustness of conclusions, improved representation of effect modification and confounding, and uniform descriptive language. Over time, CASAC advised EPA of the need for consistency across documents in the application of the framework. In 2011, in its review of the first draft of the ISA for Ozone, CASAC stated (EPA-CASAC-11-009):

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.

In 2015, EPA published the Preamble for the ISAs (EPA/600/R-15/067) to help ensure that the same framework would be applied consistently in subsequent ISAs.

As the framework itself has stabilized, the typical challenges in causal determination have been to ensure that it is “applied with sufficient transparency,” with “substantiation and better documentation of the evidence and lines of reasoning for the causal determinations,” as illustrated by CASAC’s advice on the first draft of the ISA for Oxides of Nitrogen in 2014 (EPA-CASAC-14-002).

Recent studies sponsored by the Health Effects Institute on accountability and causal inference methodology would be appropriate to include in literature review for the revised ISA. The ISA is based on existing studies and information. Given the absence of a demonstrated quantitative framework that has been evaluated in the context of air pollution and that serves the same purpose as the current causal determination framework (including evaluating multiple lines of evidence and taking into account factors such as biological plausibility and mode of action), it would be premature to make substantial changes to the current causal determination framework. However, emerging trends in causal determination and inference should be identified, and their potential implications could be discussed.

The current framework for causal determinations used in the ISA has been well-vetted by CASAC and has stabilized over multiple reviews. However, there is room for more transparent

communication of specific causal determinations in the ISA. The state of the science of causal inference methodology is insufficient to recommend replacing the ISA's approach to causal determinations or for differently weighting studies used in the causal determinations based on a new criterion of how they apply causal inference methods.

Comments on the ISA

In addition to preparing individual written statements (attached), members of our group held two teleconferences to identify and briefly discuss key issues related to the ISA. These teleconferences were 90 minutes each and were each attended by approximately 10 of us, such that between the two teleconferences nearly all of us participated. However, these teleconferences do not substitute for the originally planned two days of face-to-face meeting that we expected to have as the CASAC PM Review Panel to review the draft ISA. We identify key issues from our discussions.

Lack of Proper Review: As noted in detail in preceding portions of this letter and in attached member comments, the chartered CASAC lacks adequate breadth and depth of scientific expertise to review the ISA. The ISA should be reviewed by a reinstated PM review panel to assure that the ISA receives a thorough review based on the latest scientific knowledge pertaining to the kind and extent of issues relevant to this review. Furthermore, as we note in our comments elsewhere in this letter, there are scientific issues in the draft ISA, and that have been raised by the chartered CASAC, which should be represented with additional relevant scientific disciplines on the PM review panel, specifically neuroscience, metabolic science, and science related to causal determination and causal inference. Thus, a second draft of the ISA is needed and should be subject to a proper review by an appropriately constituted CASAC PM Review Panel.

Low Cost Sensors: In comments on the IRP, the former CASAC PM Review Panel (see letter EPA-CASAC-16-003) asked EPA to include a review of PM measurement methods in the ISA, and particularly mentioned low cost sensors, which may have value in helping to quantify spatial variability at higher resolution than can be done with conventional reference or equivalent methods at fixed sites. This material should be added to the ISA.

Air Quality: Major PM_{2.5} and PM_{10-2.5} (coarse particles) source categories need to be better resolved and estimated. Ambient PM_{2.5}, PM_{10-2.5}, and PM₁₀ mass concentrations should incorporate the most recent (e.g., 2015-2017) measurements. Inconsistent periods (ranging between 2001-2016) are used in different sections of the ISA that do not enable comparisons. Although national average PM_{2.5} and PM₁₀ concentrations have declined over the past decade, discussions on areas that still exceed PM_{2.5} and PM₁₀ NAAQSs are needed. PM_{10-2.5} composition needs additional examination with respect to bioaerosol speciation that is relevant to adverse effects. Characterization of ultrafine particles needs to be updated. There needs to be discussion of the loss of semi-volatile mass (SVM) from Federal Reference Method (FRM) PM_{2.5} samples, even though it is recognized that the FRM, when used in routine monitoring networks, can routinely under-measure PM_{2.5} by 10% or more. The relative paucity of epidemiological

data re: UFP health effects is due to the lack of an UFP monitoring network. Trends in UFP monitoring should be assessed.

More Characterization of Contrast Between PM_{2.5} and UFP: Just as PM_{2.5} is part of PM₁₀, UFPs are part of PM_{2.5}. Further discussion of distinctions between UFP compared to PM_{2.5} is needed. For example, PM mass is arguably not a good indicator of particle number concentration. UFP measurements are often in terms of particle count, with less focus on mass concentration, whereas PM_{2.5} measurements are generally mass-based. The total particle count for PM_{2.5} is mostly attributable to UFP, whereas the total mass of PM_{2.5} is typically mostly attributable to particles larger than the UFP size range. A policy-relevant question is whether UFP and PM_{2.5} are usefully used concurrently, or should consideration be given to UFP and PM_{2.5-UFP} to more clearly draw distinctions between UFP and particles larger than UFP that are in the PM_{2.5} size range?

Coarse PM: The general treatment of coarse PM (PM_{10-2.5}) is uneven in the draft ISA. Although coarse PM is reasonably well covered in the health effects chapters, its coverage in the Executive Summary and the Integrative Summary borders on cursory. Furthermore, the composition/speciation of coarse PM is not adequately addressed. It would also be helpful if the preface would more clearly articulate the rationale for PM₁₀ as an indicator in the current NAAQS, given that PM_{2.5} is part of PM₁₀. More attention is needed regarding the data quality and coverage of coarse PM monitoring to help with policy-relevant inferences later in the review cycle regarding possible alternative indicators. The ISA gives the impression in some places of lack of monitoring data regarding coarse PM, but this information is not accurately presented with proper context. In general, the scientific evidence pertaining to causality regarding coarse PM and adverse effects is increasing but this is not well-reflected in the executive summary or the integrative summary.

Background Concentration: The ISA appears to be providing reasonable coverage and treatment of background concentration for PM. A challenge for continental-scale PM_{2.5} measurements is the separation of manmade from natural emission contributions at continental-scale and global-scale PM monitoring sites.

PM components: Members of our group find that the ISA does not give adequate treatment of PM components particularly with regard to advances in measurement methods, quantification of ambient concentration, and quantification of exposure. More specifics should be covered on these topics. For example, the Executive Summary does not adequately acknowledge the substantial contributions of anthropogenic emissions to the formation of SOA from biogenic VOCs. This should be rectified in the Executive Summary and other parts of the document where this topic is addressed, including Chapters 1 and 2. Some of the examples given in the ISA pertaining to components focus on correlation between PM species and PM mass, but a balanced treatment will also recognize that PM component composition may vary over space and time differently from variation in PM mass. Nonetheless, the treatment of PM components in the context of health effects appears to be reasonable. For example, in Chapters 5 and 6, PM components are acknowledged but are shown not to explain association of effects better than

does PM mass. In Chapter 11, evidence with regard to health effects attributable to PM components is appropriately characterized and is weak.

Onroad and Near-Road Microenvironments: PM exposure concentrations can be very high in in-vehicle, on-road (e.g., bicyclist) and near-road microenvironments. Yet, the ISA devotes scant attention to these key microenvironments. These transport-related microenvironments, as well as schools (and their playgrounds) located near major roads, and other such microenvironments, merit more explicit attention.

Mixtures and Co-Pollutants: Although acknowledged in various places in the document, more critical attention is needed to the reality that particulate matter of various size ranges is part of an overall mixture of pollutants and other stressors to which humans are exposed. More clarity is needed regarding which studies address PM-dominated mixtures/stressors. Additionally, there appears to be an over-reliance on copollutant models in assessing the potential for confounding throughout the draft ISA. While this approach may be valid and informative in specific settings, a more critical assessment of the potential biases and limitations of copollutant models, and explicit and transparent consideration of such potential biases and limitations, within a measurement error framework, should be addressed when interpreting results from such models

Study Selection: Although in most parts of the ISA that we were able to review study selection appears to be reasonable, there are examples for which study selection criteria appear to be inconsistently applied. For example, the selection of lung function studies in Asia for which PM_{2.5} exposures were higher than U.S. levels should be reassessed or better justified.

Transparent Application of Causal Framework: A general concern, which is fairly typical for a first draft of an ISA, is that the causal framework is not consistently and transparently applied. This alone merits a second draft of the ISA for review again by the chartered CASAC and an appropriately constituted CASAC PM Review Panel. One example of the need for more transparency is that the EPA staff should more clearly indicate which studies or factors led to 'upweighting' or 'downweighting' of causal determination categories. As noted in individual member comments, the ISA should include tables that address/identify critical pieces of evidence that were factors in causal determinations, with due consideration for pollutant mixtures and critical evaluation of copollutant models. In making causal determinations, EPA should pay careful and critical attention to issues related to exposure error more so than appears to be the case in the current draft.

PM_{2.5} and Mortality (Chapter 11): There have been very substantial additions to the body of scientific literature regarding the mortality effects of PM exposures since the 2009 PM ISA. Overall, Chapter 11 does a very good job of describing and synthesizing this new evidence. Effectively all of the evidence presented is from epidemiology. Given the large number of new epidemiologic studies, particularly the very large number of published short-term time-series mortality studies, the focus of the synthesis and evaluation on the most informative studies,

that is the multi-city studies and those with PM concentrations within the range of exposures experienced within the United States, is appropriate.

As noted in Chapter 3, major advances in PM_{2.5} exposure assessment have come from hybrid approaches incorporating multiple sources of data, including not only ambient monitors, but also dispersion and chemical transformation models, land use regression, and remote sensing satellite data. These approaches have allowed estimation of PM_{2.5} exposures in populations not included in previous epidemiologic studies. This chapter includes limited discussion comparing exposure assessment techniques (sections 11.1.7, 11.2.5.1, and 11.3.5.2). Indeed, for short-term PM_{2.5} exposures, this discussion is limited to urban versus rural exposure assessment (section 11.1.7.2). It would be informative to include a more in-depth evaluation of the epidemiologic results stratified by these alternative exposure assessment methods. This would help understand PM_{2.5} associations, but also provide direction in addressing the weaknesses in the PM_{10-2.5} and UFP exposure assessments for epidemiologic studies.

These new exposure assessment approaches have meant that populations in communities far from the traditional monitoring network are now included in the epidemiologic studies. In turn this means much better representation of populations with low exposures. A major objective for this ISA was to assess concentration-response functions and the evidence for a threshold at these lower ambient PM exposures. While the number of studies examining alternative CR functions and cut points is limited, we would recommend attempting to provide a more structured or quantitative synthesis of this evidence.

As noted, the evidence presented is overwhelmingly from epidemiology. Understanding that epidemiology does not show causality, it is important to also document the evidence for biological plausibility. This is done through reference to Chapter 5 on respiratory effects and Chapter 6 on cardiovascular effects. These sections should be expanded to give a deeper summary of the findings from these earlier chapters, and also a more explicit link to the total mortality evidence.

A key science question is whether there is evidence of adverse effects at low exposure/dose and the strength of such evidence. The ISA should include specific and separate reporting of studies that address low exposures at or below the level of the current NAAQS, to clearly indicate the evidence for these adverse effects at levels at or below the current standard.

With regard to the shape of the concentration-response (C-R) relationship for PM_{2.5} and premature mortality, although some studies have attempted to look at the potential for superlinearity, the evidence for this is weak. The ISA treatment of this topic could more deeply synthesize studies. The assumption that the C-R relationship is linear, with no threshold, is reasonable and consistent with available scientific evidence.

Coarse PM and Health Effects: Another example of a topic which requires more deliberation by a review panel is the scientific evidence regarding the causal determination for short-term exposure to coarse PM and respiratory adverse effects. This is a topic which merits attention by

a reinstated PM review panel. Short-term exposure to coarse PM was found by EPA staff to be “suggestive of, but not sufficient to infer, a causal relationship” for respiratory effects. This finding may be too weak, or it may be appropriate. This causal determination should be informed by a more detailed critical evaluation of the supporting science so that the basis of the finding is more complete and transparent.

Long-term exposure to Ultrafine Particles and Central Nervous System Effects: This topic illustrates precisely why CASAC must be augmented with an appropriately constituted PM Review Panel. In our discussions of this topic, we agreed that this is an example of a topic for which we would have engaged in deep and extensive deliberations at a face-to-face meeting if our panel had not been disbanded. Our group includes experts with varying perspectives. We are open to hearing perspectives of our colleagues, and the public, and to revising our own individual opinions based on scientific data, information, and inferences offered by our colleagues or the public. Although we were able to engage in some interactive discussion on this topic, we were not able to convene the entire panel nor deliberate for the length of time needed to reach closure on this issue. Furthermore, in the course of our discussions, we identified that our panel does not include an expert in neuroscience, which is a scientific discipline relevant and necessary to evaluation of central nervous system effects.

EPA presents a reasonably balanced review of the data, communicating its strengths and uncertainties. In particular, it is very helpful and important to document the apical endpoints even if the full mechanism/mode of action is not certain. Here, we offer neither a statement of support of EPA’s proposed finding of “likely to be causal” nor do we offer a recommendation to change the finding: instead, we point out that given the circumstances, we were not able to adequately deliberate on this topic, with the full range of needed expertise, to make a recommendation either way. Thus, our main recommendation is that this issue needs to be deliberated by an appropriately constituted PM Review Panel.

We do, however, offer some suggestions for issues that should be considered. EPA staff have followed the causal determination framework by noting that there is consistency in toxicological studies and some support from an epidemiological study. On the other hand, there are differences in biology between humans, rodents, and other animal models and such differences might need further consideration in interpreting the relevance of the toxicological studies with regard to implications for humans. EPA’s proposed causal determination is broadly reasonable, but there is room for more detailed critical review. Another line of reasoning not explored in the draft ISA is to synthesize information from PM_{2.5} epidemiologic and toxicological studies in the consideration of health implications of UFP. UFP is part of PM_{2.5}. Depending on exposure and dosimetry, UFP may be a key influential factor for some PM_{2.5} studies. This is illustrative of a topic that could be part of a deeper deliberative exploration of the link between UFP and CNS effects.

In Chapter 8, it would be helpful to connect the biological pathways for the three exposures considered (PM_{2.5}, PM coarse, UFP) for short-term and long-term exposures, respectively. The summary tables (Tables 8-7, 8-20, 8-23, 8-26, 8-31, 8-38) appear to be missing a distinguishing

marker on whether the components in the table up-weigh or down-weigh the association. There are some additional references we suggest incorporating. The summary sections are a good synthesis of the emerging data.

Metabolic Effects: We are not aware that the CASAC has any experts on metabolic effects. The reinstated PM review panel should be augmented to include expertise relevant to the assessment of metabolic effects.

At-Risk Populations and Life Stages: Children and race are appropriately identified and characterized. With regard to populations with pre-existing cardiovascular or respiratory disease, EPA staff indicate that the evidence is “suggestive.” However, the reviewed studies might support a stronger finding. Therefore, a more thorough critical evaluation is recommended. The finding of inadequate evidence for “older lifestage” is appropriate.

Welfare Effects: With regard to Chapter 13 and welfare effects, the ISA should incorporate additional recent studies as detailed in individual member comments. The Chapter 13 discussion and identification of causal effects of PM on visibility, climate and materials is clear, concise and comprehensive. However, we note that our review focused only on visibility impairment and that we did not have multiple experts review visibility impairment. Although the review of visibility impairment is well done, it omits important recent work by William Malm and others evaluating alternative scene-dependent haze metrics as visibility preference indicators. This work could provide an improved basis for determining unacceptable levels of impairment across a wide range of urban areas, and should be presented and discussed in this chapter. See individual comments for more details.

Need for a Second Draft of the ISA: A second draft of the ISA is needed. A key and highly compelling reason is that the 7-member chartered CASAC does not have the breadth and depth of expertise needed to review the first external review draft of the ISA, as detailed earlier in this letter. Secondly, there are many scientific issues for which the ISA should be revised. It would not be reasonable for CASAC to provide ‘closure’ on the ISA without a second review, nor is the chartered CASAC an adequate body for conducting a second review. CASAC should recommend and EPA should approve the re-instatement of the CASAC PM Review Panel in time for the second draft of the ISA to be reviewed by a CASAC PM Review Panel. The CASAC PM Review Panel should be augmented with experts in neuroscience, metabolic science, and causal determination and causal inference.

Findings and Recommendations

Based on statutory requirements, our review of the recent changes to membership criteria for CASAC and the NAAQS review process, the review process for particulate matter, and the draft ISA, we state the 8 major findings given in Table 1. Based on the 8 major findings in Table 1, we make 44 recommendations as given in Table 2.

Both EPA and CASAC are required to conduct the scientific review in a manner that meets the statutory requirements of the Clean Air Act. Furthermore, CASAC should conduct the review in a manner that is consistent with the level of quality of prior CASAC reviews.

Sincerely,

/signed/

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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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Attachments

Attachment A: Written Statement from George Allen (2 pages)

Attachment B: Written Statement from John Balmes (3 pages)

Attachment C: Written Statement from Judith Chow (12 pages)

Attachment D: Written Statement from Douglas Dockery (6 pages)

Attachment E: Written Statement from H. Christopher Frey (42 pages)

Attachment F: Written Statement from Jack R. Harkema (2 pages)

Attachment G: Written Statement from Donna Kenski (3 pages)

Attachment H: Written Statement from Richard Poirot (9 pages)

Attachment I: Written Statement from Jeremy Sarnat (3 pages)

Attachment J: Written Statement from Lianne Sheppard (10 pages)

Attachment K: Written Statement from Barbara Turpin (3 pages)

Attachment L: Written Statement from Sverre Vedal (4 pages)

**WRITTEN STATEMENTS FROM
INDIVIDUAL FORMER MEMBERS OF THE
2015-2018 CASAC PARTICULATE MATTER REVIEW PANEL**

**Public Comment on the
Integrated Science Assessment for the Review of the
Particulate Matter National Ambient Air Quality Standards**

SUBMITTED TO
**Docket ID No. EPA-HQ-OAR-2018-0279
U.S. Environmental Protection Agency
Washington, DC**

DATE
December 10, 2018

- Attachment A: Written Statement from George Allen (2 pages)
- Attachment B: Written Statement from John Balmes (3 pages)
- Attachment C: Written Statement from Judith Chow (12 pages)
- Attachment D: Written Statement from Douglas Dockery (6 pages)
- Attachment E: Written Statement from H. Christopher Frey (42 pages)
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WRITTEN STATEMENT
**Public Comment on the
CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter
(External Review Draft – October 2018)**

PREPARED BY:
George Allen

SUBMITTED TO
**Docket ID No. EPA-HQ-OAR-2018-0279
U.S. Environmental Protection Agency
Washington, DC**

DATE
December 10, 2018

With regard to Chapter 2:

Measurement issues with the PM2.5 FRM.

PM2.5 in many areas has continued to trend downward since the last PM NAAQS review, driven by reductions in power plant SO₂ emissions and thus lower levels of sulfate, especially in the central and eastern US. Nitrate and organic carbon have not had similar downward trends, and thus are now larger fractions of PM2.5. These components of PM2.5 are more difficult to measure since they can be semi-volatile and lost in part during and after sampling, resulting in more under-measurement of PM2.5 relative to measurements where sulfate is a large fraction of the total PM2.5. There is no discussion of the loss of semi-volatile mass (SVM) from Federal Reference Method (FRM) PM2.5 samples, even though it is recognized that the FRM, when used in routine monitoring networks, can routinely under-measure PM2.5 by 10% or more. This loss is a function of composition and post-sample filter handling, and can vary substantially over sampling time and location from minimal loss to substantially more than 20% on a single sample. These SVM losses will get more pronounced as the PM composition shifts from stable transported species to more local and fresher (and thus more volatile) PM sources.

Limitations of current national monitoring networks for PM parameters other than PM2.5 and PM10.

Data for PM measurement metrics other than PM2.5 and PM10 continue to be relatively sparse. While particle number concentration (an indicator of ultrafine particles or UFP), particle surface area, PM-coarse (PM10 - PM2.5), bulk composition (EC, OC, SO₄, NO₃), or elemental composition may be responsible for some of the observed PM health effects, measurements of these particle metrics is usually insufficient to support epidemiological studies. This chapter points out that UFP and PM-coarse concentrations are much more spatially variable than PM2.5, especially in urban areas, making it difficult to use a central monitor to represent exposure to a large population, further complicating attempts to assess health effects of these components of PM with traditional epidemiological study methods.

Ability of the current PM_{2.5} monitoring network to measure low annual average PM_{2.5} concentrations.

Clint Woods, Deputy Assistant Administrator, OAR, said at the Texas Environmental Superconference on August 2, 2018 that 5 ug/m³ "is well below what any current monitor can measure." (InsideEPA, August 3, 2018) This statement is not consistent with the measurement capabilities of existing instruments. The standard that Mr. Woods is referring to is the annual PM NAAQS, which has a form of a 3-year average of 24-hour PM measurements on at least every third-day. Thus, the 3-year average is composed of at least ~ 300 individual daily (24 hour) measurements over this 3-year interval. While it is true that some continuous PM measurement methods have substantial uncertainty at 5 ug/m³ for 1-hour measurements, the Federal Reference Method for PM_{2.5} is capable of measuring a 3-year average concentration of 5 ug/m³ with sufficient accuracy and precision for use in comparison to an annual PM_{2.5} NAAQS. In the last few years, continuous Federal Equivalent Methods for PM_{2.5} using optical measurement techniques have become more common, and these methods produce data that are very stable at low PM concentrations, even for hourly average concentrations.

WRITTEN STATEMENT
**Public Comment on the
CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter
(External Review Draft – October 2018)**

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SUBMITTED TO
Docket ID No. EPA-HQ-OAR-2018-0279
U.S. Environmental Protection Agency
Washington, DC

DATE
December 10, 2018

GENERAL COMMENTS

I am a physician-scientist with particular expertise in the effects of air pollution on respiratory health outcomes. That said, I also have conducted research on air pollution effects on cardiovascular and metabolic outcomes. I have been on previous CASAC review panels for Ozone, SO_x, and NO_x. Since 2008, I have been the Physician Member of the California Air Resources Board.

I have read the Executive Summary and Chapters 1, 5, 6, and 8.

Overall, the EPA has compiled a well-written document that has presented, reviewed, and evaluated the available scientific literature on the potential health effects of PM in an appropriately thorough and reasonable way. In general, I agree with the causal determinations that have been made based on the established framework for evaluating the weight of evidence regarding associations between PM and health outcomes, but I have two specific concerns that I describe below.

MAJOR COMMENTS

1) The relative paucity of epidemiological data re: UFP health effects is due to the lack of an UFP monitoring network. Given the robust toxicological evidence of UFP toxicity, there needs to be a push to develop a monitoring network. The 2008-2009 CASAC NO_x review panel of which I

was a member recommended that EPA mandate near-roadway monitoring regarding implementation of the NO_x NAAQS. Given the increasing concern about UFP toxicity, as exemplified by the classification in the draft ISA of the association between long-term exposure to UFP and neurological effects, there is a need to start building UFP monitoring capability. The draft ISA recognizes this need, but it should be emphasized more strongly in the document.

2) While EPA has reached reasonable causality conclusions based on the established framework for evaluating the weight of the evidence, the decision to classify UFP and central nervous system effects as likely causal is based almost entirely on the toxicological literature (and one controlled human exposure study). The need to support the toxicological evidence with epidemiological studies should be more strongly emphasized in the chapter.

3) Based on some of my own work (see references below), I find staff's assessment of the association of short-term exposure to PM_{10-2.5} (coarse fraction) and respiratory effects as "suggestive of, but not sufficient to infer, a causal relationship" a bit too weak. I think the epidemiological evidence re: coarse fraction exposure and asthma exacerbations is strong enough to merit "likely to be a causal relationship."

4) While overall Chapter 5 is well-written and the causal determinations are appropriate given the weight of the evidence, multiple non-significant associations that could be due to chance are treated as if they were "true" associations. Specific examples are given below.

SPECIFIC COMMENTS

1) p. 1-61, line 9 Bradford Hill never used the term "criteria" for his seminal thinking about causal inference from observational epidemiological studies. In the reference cited, he called them "viewpoints."

2) p. 5-5, lines 32-35 These two sentences are poorly worded and need to be revised.

3) p. 5-6, lines 26-28 "Using knock-out mice lacking the β 2 adrenergic receptor specifically in alveolar macrophage, it was demonstrated that inhalation of PM_{2.5} *enhanced* cytokine release from alveolar macrophages." This sentence is incorrect – the paper cited reports that in the mice lacking the β 2 adrenergic receptor inhalation of PM_{2.5} *ATTENUATED* cytokine release from macrophages.

4) p. 6-7, line 3 ST segment is not a specific marker for myocardial infarction (MI). It can also be a marker of myocardial ischemia without MI.

5) p. 6-12, line 9 The "positive association at short lag period" in the cited Ostro et al. 2016 study was not significant.

6) p. 6-12, line 14 None of the "positive associations" observed in the Talbott et al. 2014 study were significant.

7) p. 6-14, line 7 The text here re: the Gardner et al. 2014 study and Fig. 2 are in conflict about whether PM_{2.5} exposure is associated with increased risk of STEMI vs. NSTEMI. The text is correct while the figure shows a reduced risk of STEMI and an increased risk of NSTEMI.

8) p. 8-5, lines 24-25 “Evidence for perturbation of the blood brain barrier is provided by a controlled human exposure study (Liu et al., 2017).” In the paper cited the only statistically significant findings were for coarse CAPS, not PM_{2.5}. The citation is used to support PM_{2.5} effects on blood-brain barrier integrity, but is inappropriately used here.

p. 8-81, lines 7-9 “Evidence for changes in the HPA stress axis is provided by a controlled human exposure study that demonstrated an increase in a marker of the HPA stress axis in association with UFP exposure (Liu et al., 2017).” Again, the cited study does not support this statement. The authors state the following: “Ultrafine CAP was not significantly associated with changes in any blood and urinary neural biomarkers examined.”

p. 8-82, section 8.5.2.1 This entire section should be deleted because there was only a non-significant effect on one biomarker.

References

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Qiu H, Yu IT, Tian L, Wang X, Tse LA, Tam W, Wong TW. Effects of coarse particulate matter on emergency hospital admissions for respiratory diseases: a time-series analysis in Hong Kong. *Environ Health Perspect* 2012;120(4):572-576.

WRITTEN STATEMENT
**Public Comment on the
CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter
(External Review Draft – October 2018)**

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U.S. Environmental Protection Agency
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December 10, 2018

Chapter 2 intends to document suspended particulate matter (PM) sources, atmospheric chemistry, and ambient concentrations, especially with respect to their adverse effects on health, visibility, climate, and ecosystems. It provides some comparisons of recent PM_{2.5} and PM₁₀ measurements with those in the 2009 PM ISA (U.S. EPA, 2009) and highlights changes over time. Although this is a good first attempt, several key areas need additional discussion/clarification: 1) major PM_{2.5} and PM_{10-2.5} (coarse particles) source categories need to be better resolved and estimated; 2) ambient PM_{2.5}, PM_{10-2.5}, and PM₁₀ mass concentrations should incorporate the most recent (e.g., 2015-2017) measurements -- inconsistent periods (2001-2016) are used in different sections of the ISA that do not provide comparable comparisons; 3) although national average PM_{2.5} and PM₁₀ concentrations have declined over the past decade, discussions on areas that still exceed PM_{2.5} and PM₁₀ NAAQSs are needed; 4) PM_{10-2.5} composition calls for additional examination with bioaerosol speciation that is relevant to adverse effects; 5) characterization of ultrafine particles needs to be updated; and 6) recent development and performance of low-cost “air sensors” and their pros and cons in community exposure as well as air quality management needs to be elaborated. The following sections recommend specific revisions.

Source Emissions (Section 2.3)

The discussion of PM emissions needs elaboration. The 2014 National Emissions Inventory (NEI, U.S.EPA, 2018) is compared with the 2002 NEI described in the 2009 PM ISA. Figure 2-2a (Page 2-8) shows PM_{2.5} reductions from ~5,800 Ktons/year in 2002 to <5,400 Ktons/year in 2014. Details on emission reductions of major source categories would be helpful to highlight the decade-long emission changes. Relative annual average PM_{2.5} emissions in Figure 2-2b for 2014 should be compared with 2002. Mobile source emissions do not appear in the 2014

emissions; this should be separated from the “Other” category that accounts for 26% of $PM_{2.5}$. It is important to distinguish gasoline-engine versus on-road/non-road diesel-engine contributions to $PM_{2.5}$. Annual emission inventory limitations and uncertainties need to be discussed (Miller et al., 2006; Mobley et al., 2005)

Fuel combustion other than residential-wood (6% of $PM_{2.5}$) is not noted, neither are industrial process emissions. These commonly applied source categories should be listed to provide an overview of source emissions. The ISA states that “Dust and fire each account for approximately 36% of total $PM_{2.5}$ emissions included in the 2014 NEI” (Page 2-7, Lines 21-22), but Figure 2-2b shows dust and fires each accounting for only 32% of total $PM_{2.5}$ emissions. These emission estimates are high compared to emissions from the five counties shown in Figure 2-3 (Pages 2-9 to 2-11) with an estimated 11-18% from dust and 0-3% from fires. $PM_{2.5}$ emissions with more detailed source categories from the selected five counties (i.e., one each in NY, PA, AZ, and two counties in CA) do not cover the Midwest or Central Great Plain regions. Examples by region may be more appropriate. Fugitive dust emissions are always overestimated for well-known reasons (Watson and Chow, 2000; Watson et al., 2000). Both major dust storms and wildfires are episodic and regional, making their inclusion of “annual” and “national” averages misleading.

For PM precursor emissions of VOC, SO_2 , NO_x , and NH_3 , the ISA notes that “Figure 2-5 shows the difference in NEI national emission estimates for SO_2 , NO_x , and NH_3 between the 2006 NEI and the 2014 NEI, showing SO_2 decreasing...” (Page 2-14, Lines 1-2), but Figure 2-5 (Page 2-16, which repeated the Figure shown on Page 2-13) notes the comparison for 2002, but not 2006. The “Summary” box (Page 2-1) and text on Page 2-14 (Lines 2-3) also indicate SO_2 emission reductions from 13.9 million metric tons (MMT) in 2006 to 4.8 MMT in 2014. To be consistent with $PM_{2.5}$ emissions, the same 2002 NEI should be used for comparison. Emission units are KTon/year in Figures 2-2 and 2-5, but are stated as MMT in the text. Consistent terminology should be used throughout the ISA.

Total $PM_{10-2.5}$ emissions should be given to provide some perspective on changes from 2002 to 2014. The ISA notes that “Mineral dust, organic debris, and sea spray have also been identified as mainly in the coarse fraction” (Page 2-20, Lines 3-4), but Figure 2-6 (Page 2-21) shows fires account for ~11% of total $PM_{10-2.5}$ emissions, with nothing on “organic debris” or “sea spray”. (The Figure 2-6 caption indicates PM_{10} , not $PM_{10-2.5}$, emissions). Major sources in the “Other” category that account for 15% of $PM_{10-2.5}$ should be discussed.

Measurements, Monitoring, and Modeling (Section 2.4)

Aside from the $PM_{10-2.5}$ FRM that is specified in 40 CFR, Part 50, Appendix O, no reference is given for IMPROVE samplers or continuous FEMs (Page 2-29) such as the optical particle counters or BAMs. Development of other alternative $PM_{10-2.5}$ samplers should be acknowledged and discussed (e.g., Leith et al., 2007; Liu et al., 2011; Sardar et al., 2006). The statement that “Automated dichotomous FEMs also rely on two measurement devices, but instead of having separate inlets...” (Page 2-29, Lines 8-9) would be better stated as “-- having a $PM_{2.5}$ separator in series with a PM_{10} inlet rather than parallel PM_{10} and $PM_{2.5}$ inlets.” Note that the virtual impactor (Conner, 1966; Loo and Jaklevic, 1974) divides the air stream into two separate channels. Approximately 10% of the fine particles are collected in the coarse channel that needs to be corrected.

Light scattering devices as indicators of PM concentrations have long been used in exposure studies (e.g. Smargiassi et al., 2012; Wallace et al., 2011), but the relation of their outputs

for different designs and filter-based measurements are variable (Chow et al., 2006; Zhang et al., 2018). These measurements are proliferating owing to the availability of low-cost light-scattering PM sensors (AcrobaticIndustries, 2017; Aoki, 2018; Citi-Sense, 2017; PurpleAir, 2018). Some discussion is needed on the appropriate acquisition and use of these data, with special emphasis on the current limitations in data quality and interpretation.

Chemical Composition (Section 2.4.4)

More should be said concerning PM chemical components (Section 2.4.4, Pages 2-35- 2-36). The ISA notes that “Fourier Transform Infrared Spectroscopy has been applied to OC and organic functional group determination in national networks (see Section 2.4.6 for monitoring PM_{2.5} species)...” (Page 2-36, Lines 4-6). This is misleading as nothing on functional group determination is discussed in Section 2.4.6 of Monitoring Networks. Fourier Transform Infrared Spectroscopy (FTIR) qualitatively identifies organic functional group in OC, but its ability to quantify concentrations needs to be justified.

The statement that “New advances in PM speciation analysis has included new network applications for OC analysis and better characterization of sampling errors of major PM components” (Page 2-36, Lines 2-4) needs to be elaborated. It should include recent advancement in the multiwavelength organic and elemental carbon (OC and EC) analyses that separates brown carbon (BrC, those are abundant in the smoldering-phase of biomass burning) from black carbon (BC, surrogate of diesel-engine exhaust and/or flaming-phase of biomass burning). PM_{2.5} OC and EC carbon measurements by seven wavelengths (405 to 980 nm) have been initiated for samples collected at both the CSN and IMPROVE networks since January 2016 (Chen et al., 2015; Chow et al., 2015a; 2018). As fires account for ~one third of PM_{2.5} emissions, separating BrC and BC allows a better quantification of biomass burning impacts on PM_{2.5} mass.

Relevant studies on PM_{10-2.5} mass and chemical composition (e.g., Cheng et al., 2015; Clements et al., 2012; 2013a; 2013b; 2014a; 2014b; 2016; Hueglin et al., 2005; Liu and Harrison, 2011) need to be acknowledged. Primary biological aerosol particles (PBAP) contributions to coarse PM, speciation of PBAP on PM_{10-2.5} and PM₁₀ samples should be acknowledged. Recent research on PBAP speciation should be discussed. The statement that “Considerable research has also focused on measurement of particulate organic species, elemental analysis, and single particle mass spectrometric analysis, and some novel sampling and analytical approaches for measurement of PM components, but these are beyond the scope of this review because they have not been used for interpreting health and welfare impacts” (Page 2-36, Lines 22-26) is incorrect. There are ample studies that address the potential climate and health effects of bioaerosols and organic materials (e.g. Alexis et al., 2006; Bauer et al., 2008; Behbod et al., 2013; Chen et al., 2007; Frohlich-Nowoisky et al., 2016; Luo et al., 2007; McNamara et al., 2013; Menetrez et al., 2007; Sandstrom et al., 2005). Advances in PBAP speciation since the 2009 ISA should be addressed.

Ambient Concentrations (Section 2.5)

Ambient PM_{2.5} concentrations should be compared with the current 12 µg/m³ annual average and 35 µg/m³ 24-hour average NAAQS. Figure 2-13 (Page 2-46) shows the 3-year averages of 24-hour PM_{2.5} concentrations from 2013-2015, based on EPA’s 2016 analysis of the Air Quality System network. Annual averages for the most recent 3-years (e.g., 2015-2017) should be used for comparison. Sampling sites or areas exceeding the annual averages need to be

highlighted. Similar comparisons need to be made for 98th percentile 24-hour PM_{2.5} concentrations exceeding 35 µg/m³. Figure 2-14 (Page 2-47) shows sites exceeding 24-hour PM_{2.5} NAAQS in several of the Western and Midwestern states, but the discussion only mentions sites in the Northwest exceeding 40 µg/m³.

PM_{2.5} statistics in Table 2-4 (Page 2-48) need to be clarified. Define “N” which seems to represent different numbers of sites and/or valid data points for the entire AQM data base. The site(s) with the maximum (28.8 µg/m³) and second highest (26.3 µg/m³) annual PM_{2.5} concentrations should be highlighted. The negative (-2.1 µg/m³) hourly PM_{2.5} concentrations at the 1 percentile in Table 2-4 should be eliminated or explained. Short-duration negative values are possible, especially on the TEOM, when material collected in the previous hour evaporates in a subsequent hour when the temperature increases.

The ISA emphasizes the reduction of sampling errors, but no details besides organic artifacts and ammonium nitrate volatilization in PM_{2.5} samples are discussed. As the subtraction method is used to derive PM_{10-2.5} mass by two collocated PM₁₀ and PM_{2.5} FRMs, error propagation (Watson et al., 1983; 2001) should be applied to estimate the uncertainties in PM_{10-2.5} mass associated with the subtraction method.

How many sites are collocated with both FRMs and FEMs? Collocated precisions between FRM and FEM should be given. Annual averages in Table 2-4 includes both FRM and FEM, assuming only one of the collocated measurements is used in the calculation. Table 2-4 shows large differences between the maximum 24-hour concentration of 167.3 µg/m³ for a FRM and 270.1 for a FEM. Specific site(s) and date(s) deserve more discussion as these levels are ~5 to 8-fold higher than the 24-hour PM_{2.5} NAAQS. Similarly, special attention should be given to the maximum and second highest 24-hour PM₁₀ FRM concentrations of 3,972 µg/m³ (during the 4th quarter) and 3,916 µg/m³ (during the 2nd quarter) listed in Table 2-5 (Page 2-51). These concentrations exceeded 24-hour PM₁₀ by ~26 fold. Comparisons can be made with and without intermittent events (e.g., dust or fires) to provide an overall perspective on PM₁₀ distributions.

Table 2-6 (Page 2-54) shows that 24-hour average PM_{10-2.5} concentrations were 5.7 µg/m³ for “FRM+IMPROVE,” but 12.4 µg/m³ for FEM -- attributing this over twofold difference to site locations (Page 2-52, Lines 11-14). The 24-hour FRM concentration is 8.9 µg/m³ for PM_{2.5} (Table 2-4) and 21.1 µg/m³ for PM₁₀ (Table 2-5), with a calculated PM_{10-2.5} of 12.2 µg/m³. This level is closer to the average FEM PM_{10-2.5} mass than the 5.7 µg/m³ (in Table 2-6) derived from a combination of FRM and IMPROVE PM_{10-2.5} samples. Since regional-scale IMPROVE PM concentrations are expected to be lower than those of urban-scale NCore sites, calculations of “FRM+IMPROVE” should also be listed with the 24-hour average PM_{2.5} and PM₁₀ concentrations (Tables 2-4 and 2-5) for comparable comparison. As minus a negative PM_{2.5} (shown in Table 2-4) will result in a positive value, were the negative PM_{10-2.5} concentrations (-0.1 to -0.6 µg/m³) in Table 2-6 (Page 2-54) due to similar levels of PM₁₀ and PM_{2.5}? These negative values should either be replaced with “not detectable” or presented with the propagated uncertainties that represent measurement errors.

PM_{2.5} to PM₁₀ ratios (Section 2.5.1.1.4)

Both the “Summary” box (Page 2-1) and Section 2.4.6 Monitoring Network (Page 2-41, Lines 14-16) show that the national multipollutant monitoring network includes simultaneous measurement of PM_{2.5} and PM_{10-2.5} using FRMs at 78 sites. However, only 28 sites are used to

calculate $PM_{2.5}/PM_{10}$ ratios. Table 2-7 (Page 2-56) uses data up to 2015, more recent data (e.g., up to 2017) that contains additional sites should be used for comparison. Average ratios will better represent the fraction of $PM_{2.5}$ in PM_{10} as compared to the ratio of averages (i.e., dividing the 3-year average $PM_{2.5}$ to 3-year average PM_{10} concentrations by site) presented in the ISA.

Currently Table 2-7 is ranked from high to low $PM_{2.5}/PM_{10}$ ratios. Grouping by geographical location or site type within each state will be helpful for cross comparisons. The ISA shows "... $PM_{2.5}/PM_{10}$ ratios ranging from 41 to 61% of all urban sites except Dayton, OH..." (Page 2-55, Lines 17-18), but Dayton, OH is listed as rural site in Table 2-7 (it is most likely an urban- or neighborhood-scale site).

The interpretation of $PM_{2.5}/PM_{10}$ ratios needs to be further examined. The ISA states that "The lower $PM_{2.5}/PM_{10}$ ratios indicate a generally higher fraction of $PM_{10-2.5}$ in the Eastern U.S. than was reported in the 2009 PM ISA" (Page 2-57, Lines 2 and 3), but the low $PM_{2.5}/PM_{10}$ ratios (<0.50) were found in MI, CA, OK, NM, OH, and CO, none of which are eastern states. This sentence also contradicts the statement that " $PM_{10-2.5}$ made a greater contribution to PM_{10} not only at most western sites, but also in the Midwest (Cleveland, Detroit)" (Page 2-57, Lines 5-7).

Satellite Remote Sensing Measurements (Section 2.5.1)

Satellite remote sensing is described in Section 2.4.5 (Pages 2-36 to 2-39) without much follow-up in Section 2.5.1 on spatial distribution. Only a short paragraph with one reference (Lary et al., 2014) on Page 2-47 (Lines 1-3) notes that "Specific regional concentration patterns are also evident from $PM_{2.5}$ data derived from satellites (see Section 2.4.5), including the higher average abundance in the eastern half than in the western half of the U.S..." Examples of spatial distribution patterns can be displayed to illustrate the utility of using satellite measurements to estimate exposure.

Spatial Distribution of Ultrafine Particles (Section 2.5.1.1.5)

A general description of ultrafine particle number, surface area, and mass is given in Section 2.4.3 (Pages 2-29 to 2-32), but interpretation needs to be enhanced. Ultrafine particle concentrations vary by location and time, even over short distances. A better documentation (e.g., distance to heavily-trafficked roadways, inlet heights, monitor types, and upper and lower sizes measured) at the New York and Buffalo urban sites and the Steuben County background site is needed to justify the representativeness of diurnal variations in particle number concentrations. The zone of representation (e.g., micro-, middle-, neighborhood-, or urban-scale) for the long-term measurements (2002 to 2009) at the Rochester, NY, site should be stated. Given an eight-year average concentration in three size fractions (i.e., 0.01-0.05 μm , 0.05-0.1 μm , and 0.1 to 0.5 μm) shows that 90% of total particles are smaller than 0.1 μm from one reference (Wang et al., 2011) does not provide sufficient information on the diurnal, seasonal, or annual variations of ultrafine particle concentrations. As the Scanning Mobility Particle Sizer (SPMS) is used, particle mass, surface area, and size distribution should be presented.

The ISA notes that there are 23 sites acquiring ultrafine particle counts along with 36 roadside sites, implying that more data on ultrafine particle concentrations and particle size distributions can be compared and contrasted by zone or representation and region. In addition, spatial variability of roadside measurements with black carbon (BC) and NO/NO₂ can also shed some light on the characteristics of near-road exposures.

Spatial Distribution of PM_{2.5} Components (Section 2.5.1.1.6)

Figure 2-19 (Page 2-62) shows contributions of six major chemical components (i.e., sulfate, nitrate, OC, EC, crustal material, and salt) to PM_{2.5}. Does the fractional abundance in Figure 2-19 represent the ratio of chemical component to PM_{2.5} mass or the sum of the “six components”? The mass reconstruction should account for hydrogen, nitrogen, sulfur, and oxygen associated with OC (i.e., organic mass [OM]) (Chow et al., 2015b). While the OM to OC ratio need to be estimated, ammonium concentrations can be obtained from the CSN network or estimated from the IMPROVE network (based on the stoichiometric chemistry of ammonium sulfate, ammonium bisulfate, and ammonium nitrate) (Chow et al., 1994). There are similar issues with Figures 2-25 and 2-26 (page 2-78 and 2-79) and Figure 2-31 (Page 2-86) that need to be revised.

Spatial Distribution of PM_{10-2.5} Components (Section 2.5.1.1.7)

Greater elaboration is needed on PM_{10-2.5} composition. Although the ISA states that new research on sources of PBAP are summarized (in Section 2.3.3, Page 2-20, Lines 16-24), only one paragraph with two references (Barberan et al., 2015; Després et al., 2012) is provided. Several recent review articles should be recognized, synthesized, and critically evaluated (Bowers et al., 2013; Deguillaume et al., 2008; Gonzalez-Martin et al., 2014; Grahame et al., 2014; Lee, 2011; Mauderly and Chow, 2008; Mohler et al., 2007; Moon et al., 2012; Reinmuth-Selzle et al., 2017; Sun and Ariya, 2006; Tischer and Heinrich, 2013; Yao, 2018). Retrospective analysis of archived PM₁₀ samples in Central California, Chow et al. (2015c) found that agricultural activities contributed important amounts to PM₁₀ mass and organic carbon (OC), dominated by fungal spores (i.e., 5.4-5.8% PM₁₀ mass and 11.5-14.7% OC). The sum of fungal spores, pollen grains, and plant detritus accounted for an average of 11-15% PM₁₀ and 24-33% OC mass. This and other relevant studies (e.g. Bozzetti et al., 2016; Chen and Hildemann, 2009; Diociaiuti et al., 2001; Heinrich et al., 2003; Hiranuma et al., 2011; Menetrez et al., 2007) should be examined.

Temporal Variations of PM_{2.5} Trend (Section 2.5.2.1.1)

The PM_{2.5} trend analysis uses different time periods that make cross comparisons difficult. Figure 2-20 (Page 2-72) compares 3-year annual average PM_{2.5} between 2003-2005 and 2013-2015 time periods, while average periods for concentration trends varies: 2005-2014 in Figure 2-21 (Page 2-73), 2000-2015 in Figure 2-22 (Page 2-74), and 2001-2016 in Figure 2-28 (Page 2-82). For the two whisker plot comparisons, Figure 2-21 shows average PM_{2.5}, while Figure 2-24 (Page 2-76) shows the second highest PM₁₀ concentrations without explanation. It noted that “Most sites in the Eastern U.S. show decreasing concentrations over this period, consistent with the data of Table 2-5” (Page 2-74, Lines 4-7), but Table 2-5 only shows nationwide summary statistics, no specific sites. While the emphasis was on the nationwide decreasing trend, more discussion is needed to explain the increases in 3-year annual average PM_{2.5} (Figure 2-20) in the Western states and 98th percentile 24-hr PM₁₀ (Figure 2-23) in the Central Great Plains and Western states.

Background Particulate Matter Trend (Section 2.5.4)

The IMPROVE database (CIRA, 2018) shows long-term PM_{2.5} and coarse (termed PM_{2.5-10}) averages at the continental-scale Jarbidge Wilderness (JARB1) site with averages of 3.0 and

4.4 $\mu\text{g}/\text{m}^3$, respectively, consistent with the ISA estimate for $\text{PM}_{2.5}$. Some mention should be made of the coarse particle background concentrations. Figure 1 shows several excursions for both $\text{PM}_{2.5}$ and $\text{PM}_{2.5-10}$, which a cursory examination of the chemical compositions indicates fires and dust events. Several, and possibly many, of these excursions are due to natural events, although others may be of anthropogenic origin, as stated in the ISA. For contrast, a global-scale time series for Mauna Loa (MOLA2) is shown in Figure 1, where the average $\text{PM}_{2.5}$ was 0.85 $\mu\text{g}/\text{m}^3$. Several excursions are also evident in these data, which an examination of the chemistry attributes to Asian dust and possibly some volcanic emissions.

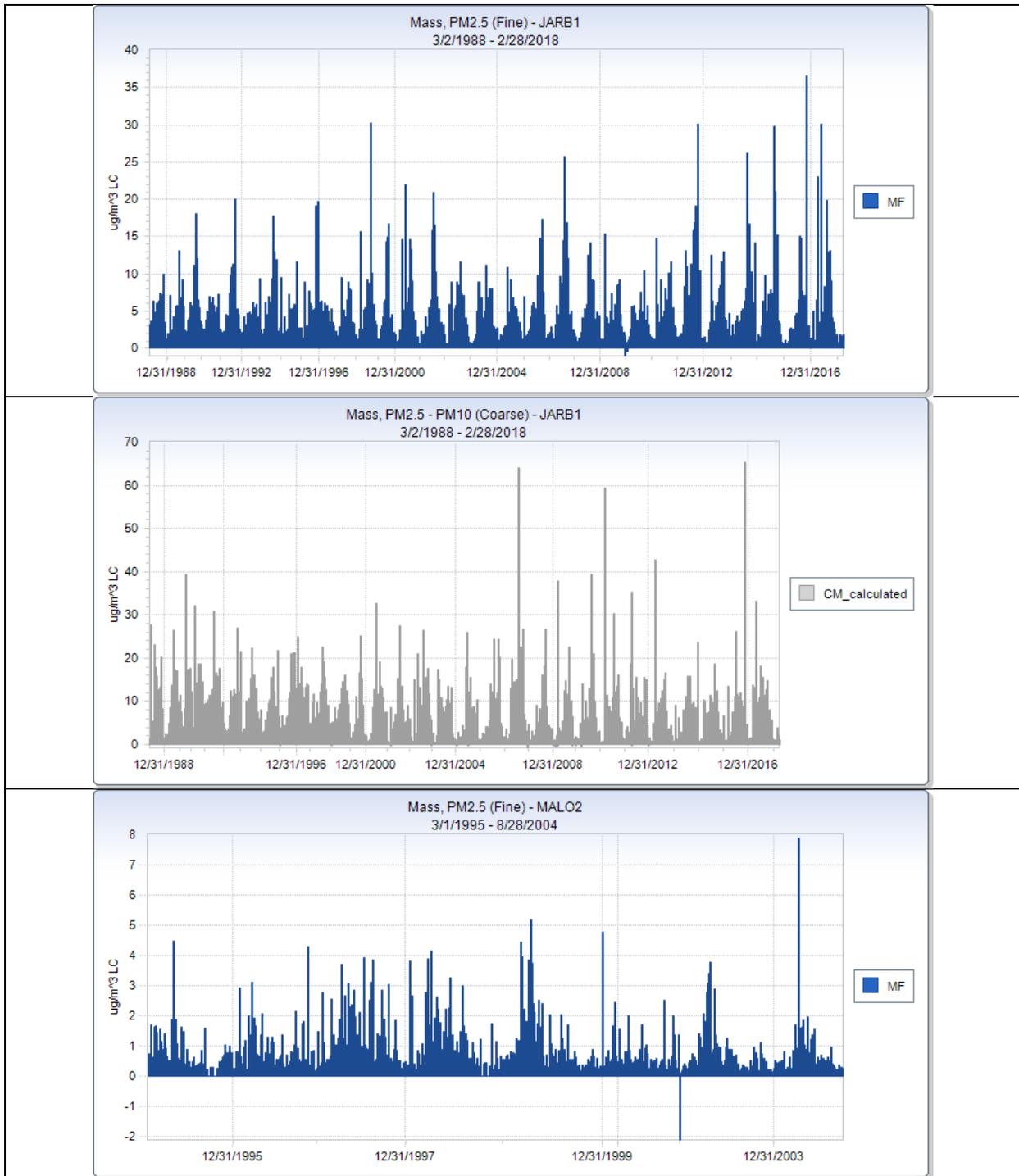


Figure 1. Time series of $\text{PM}_{2.5}$ and $\text{PM}_{\text{coarse}}$ at the continental-scale Jarbidge Wilderness (JARB1) and global-scale Mauna Loa (MALO2) IMPROVE sites ($\text{PM}_{2.5-10}$ only available at the JARB1 site).

Editorial Comments

- Page 2-6, Lines 21-22: The statement that nucleation mode particles are only a minor contribution to PM surface area needs to be justified, possible with some references.
- Page 2-4: Revise Figure 2-1 caption to read “Comparison of particle size distributions by particle number, surface area, and mass. The integrated area under the number, area, and mass size-distributions are proportional to the total number, surface area, and mass concentrations.”
- Page 2-28, Lines 10-17: For the three federal equivalent methods, operating principles for Tapered Element Oscillating Microbalance (TEOM) and optical particle counters should be given along with beta attenuation monitor.
- Pages 2-46, 2-47, 2-50, 2-52, and 2-84: Number of sites used to calculate average PM concentrations in Figures 2-13 to 2-16 and Figure 2-30 should be given
- Pages 2-56 and 2-57: Add concentration unit in $\mu\text{g}/\text{m}^3$ for Table 2-7. “Landscape” should be changed to “Zone of Representation” consistent with PM network guidance (U.S.EPA, 1997). Some of these sites are probably on a neighborhood-scale. Note that PM concentrations in either $\mu\text{g m}^{-3}$ or $\mu\text{g}/\text{m}^3$ are used on Figures and Tables; consistency ($\mu\text{g}/\text{m}^3$) is preferred.
- Page 2-60, Figure 2-8: Add the particle number concentration unit in the # counts/ cm^3 on Y-axis.
- Pages 2-62, 2-78, 2-79 and 2-86 for Figures 2-19, 2-25, 2-26, and 2-31: Equations to calculate crustal material and sea salt $\text{PM}_{2.5}$ should be given.
- Page 2-76, Lines 4-7: The statement that “In a Los Angeles field study $\text{PM}_{10-2.5}$ decreased by $0.39 \mu\text{g}/\text{m}^3$ from 19 to $15 \mu\text{g}/\text{m}^3$ for the period 1999 to 2009 compared to $0.92 \mu\text{g}/\text{m}^3$ for $\text{PM}_{2.5}$ over the same period (Cheung et al., 2012b)” is inconsistent; $\text{PM}_{10-2.5}$ was reduced by $4 \mu\text{g}/\text{m}^3$, not $0.39 \mu\text{g}/\text{m}^3$.
- Page 2-81, Line 15: Specify the organic matter (OM) to OC ratio used.
- Page 2-89, Line 28, Figure 2-31 includes period of 2013-2015, not 2012-2014.
- Page 2-90, Figure 2-33: The selected sites should be regrouped to represent geographical regions. Also, the state should be included in the Y-axis label.

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WRITTEN STATEMENT
**Public Comment on the
CASAC Review of EPA’s Integrated Science Assessment (ISA) for Particulate Matter
(External Review Draft – October 2018)**

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Comments on Particulate Matter ISA Chapter 11: Mortality

The charge for this chapter of the ISA is assess whether there is new information since the 2009 PM ISA that further informs our understanding of the relationship between exposure to PM and mortality, and to assess whether there is new information regarding alternative indicators (PM_{2.5} and PM₁₀), averaging times (24 hour and annual averages), and level of the PM NAAQS. Overall there have been substantial contributions to the body of literature addressing these issues since 2009. This Chapter provides a thorough, balanced, and well organized synthesis of this extraordinary body of evidence. I will follow the outline of this chapter in my comments.

11.1 Short-Term PM_{2.5} Exposure and Total Mortality

The 2009 PM ISA found a causal relationship between short-term PM_{2.5} exposure and mortality. The body of evidence for a causal relationship has only increased since then.

There have been a very substantial number of new epidemiologic analyses of mortality associated with short term PM_{2.5} exposures in multiple cities across the United States. These studies have been built on advanced methods for estimating daily ambient PM_{2.5} concentrations using multiple sources including ambient monitors, satellite observations, and land use regression. These approaches have allowed the estimation of daily exposures at fine spatial resolution in areas previously not included in the national ambient monitoring network. This approach has allowed examination of the associations of short-term PM_{2.5} exposures and mortality in large multi-city analyses, or most significantly in the entire US Medicare population¹. The ISA appropriately focused on this substantial body of multi-city analyses. A major contribution of these multi-city studies is documenting the generalizability of the PM_{2.5} – mortality associations to the entire US population.

These multi-city studies confirm the previous observation in the 2009PM ISA of a specific PM_{2.5} association with respiratory and cardiovascular mortality, supporting the biological plausibility of these associations.

An important question in all of these epidemiologic analyses has been the potential that the observed PM_{2.5} associations with mortality have been confounded by co-pollutants. The examination of this question in the large multi-city analyses has been particularly informative given the heterogeneity of the co-pollutant exposures across these cities. The ISA clearly shows that adjustment for gaseous co-pollutants does not materially affect the PM_{2.5} associations, indicating that such confounding is not substantial. In addition, in a smaller set of analyses, adjustment for coarse particles (PM_{2.5-10}) does not substantially modify the observed PM_{2.5} associations.

There is evidence for heterogeneity of the PM_{2.5} – mortality association across different cities/regions. One apparent modifying factor is the use of air conditioning. This is interesting in that changes in climate leading to higher mean temperatures and more frequent heat wave events will lead to more usage of air conditioning in regions which had previously not needed such controls. Adaptation to climate change will therefore potentially reduce indoor exposures to PM_{2.5}, and affect the co-benefits from reductions of carbon emissions. On the other hand, this tertiary modification of the mortality association does not modify the need to control PM_{2.5} to protect the public health.

PM_{2.5} is a complex mixture of components from many sources. There are a limited number of studies which have examined the effects of specific components due to the limited routine collection of such ambient exposure data. As elegantly illustrated in Figure 11-13 and 11-14, there is consistent evidence of associations with PM_{2.5} mass, but no consistent associations with any individual component of PM_{2.5}. Likewise, the examination of sources of PM_{2.5} have not provided a clear message that any specific source category is more toxic.

Possibly the most important contribution of the multi-city analyses since the 2009 PM ISA has been the examination of the concentration response function at levels below the current 24-hour NAAQS of 35 µg/m³. The large, multicity analyses have examined the shape of the concentration response function at the low ambient levels observed in the United States over the last couple of decades, using methods that allow flexible forms of the CR function. These analyses do not show evidence of deviations from a linear function, or evidence of a threshold even in communities with mean 24-hours average concentrations less than 20 µg/m³.

The evidence collected since the 2009 PM ISA only confirms the determination of a causal relationship between short-term PM_{2.5} exposure and mortality. Moreover, there is evidence of short-term PM_{2.5} exposure and mortality associations at concentrations below the current 24-hour NAAQS.

11.2 Long-Term PM_{2.5} Exposure and Total Mortality

The 2009 PM ISA found a causal relationship between long-term PM_{2.5} exposure and mortality. The body of evidence for this determination of a causal relationship has dramatically increased since then.

The evidence in 2009 was largely based on the Harvard Six Cities and the American Cancer Society studies. The originally published studies from 1993 and 1995 have been elaborated upon with extended follow-up and additional analyses which have provided a richer and deeper understanding based on these cohorts. This ISA presents and summarizes these follow-up analyses of these two seminal studies. Because of my intimate association with these two cohorts, I will leave it to others to comment on this body of work. I will only say that in my opinion the ISA provides a thorough and balanced synthesis of what we have learned since the

2009 PM ISA from these analyses of the Harvard Six Cities and American Cancer Society cohorts.

A fundamental step in scientific investigation is the reproduction of findings by independent investigators with independent samples. The most significant change in the evidence for long-term PM_{2.5} and mortality associations since the 2009 PM ISA is the very substantial number of independent analyses of mortality associations with long-term PM_{2.5} from other North American and European cohorts. These new analyses are largely possible because of advances in PM_{2.5} exposure modelling which allow estimation of individual PM_{2.5} concentrations at the residential level based on ambient monitoring, land use regression, transport and transformation models, and satellite remote sensing. The size of these new additional studies has also increased. Recall that the Six Cities study was based on only 8411 adults in six communities, that is there were only six exposure levels in that study². The American Cancer Society study included 295,223 subjects with PM_{2.5} concentrations, but there were only 51 PM_{2.5} exposure levels³. The European ESCAPE study⁴ included 367,383 participants from 22 prospective cohorts in 13 European countries. In this case however, individual PM_{2.5} concentrations were estimated for each individual. The recent MEDICARE cohort study⁵ included 60,925,443 MEDICARE recipients with annual average PM_{2.5} estimated at 39,716 different ZIP Codes across the continental United States. The statistical power of these analyses is extraordinary, such that even the small increased risks associated with PM_{2.5} are detectable.

The most important finding from these new studies is the quantitative consistency of the mortality associations with long-term PM_{2.5}. Anecdotally, consider the original findings from the Harvard Six Cities Study, published in the *New England Journal of Medicine* on December 9th 1993². Each 10 µg/m³ increase in PM_{2.5} was associated with a 14% increase in mortality (95% CI 7% to 22%). Exactly twenty years later, on December 9th 2013, the results of the European ESCAPE study were published online in the *Lancet*². They reported that each 10 µg/m³ increase in PM_{2.5} was associated with a 13% increase in mortality (95% CI 1% to 25%). While such quantitative agreement is not universal, the ISA review shows extraordinary agreement between these new independent cohort studies and the original Harvard Six Cities and American Cancer Society results.

When we discuss the hazard as death in these cohort studies, the outcome is actually time to death. That is they are studies of life expectancy. A new set of studies, of which I was a co-author, has examined cross-sectional associations between change in county-specific life expectancy and change in PM_{2.5} concentrations across the United States^{6,7}. These difference-in-difference methods are used in economics to mimic an experimental research design using observational study data. Thus these analyses provide additional analytic evidence of a causal relationship between long-term PM_{2.5} and mortality.

As with the short-term PM_{2.5} and mortality associations, there is the potential that the observed long-term PM_{2.5} associations with mortality have been confounded by co-pollutants. A limited number of cohort studies examining possible confounding by co-pollutants. Adjustment for ambient O₃ concentrations, as summarized in Figure 11-20, shows little evidence that the PM_{2.5} associations are confounded in 17 North American studies. The evidence is more limited but not supportive of confounding of the PM_{2.5} associations by NO₂ and other co-pollutants (Figure 11-21).

While potential threshold levels are of significant interest, only a limited number of studies have examined the shape of the concentration-response function. These analyses do not suggest any deviation from a linear concentration-response down to the lowest observed annual mean PM_{2.5} concentrations. The Di et al ⁵ analyses of the MEDICARE cohort (60,925,443 persons living in 39,716 different ZIP Codes, that is PM_{2.5} exposure levels) provides the most compelling evidence of a linear concentration-response function across the range of current PM_{2.5} exposures in the United States (6.21 to 15.64 µg/m³; 5th and 95th percentiles respectively). There is no evidence of a threshold down to the lowest observed annual average PM_{2.5} concentration in the continental United States (Figure 11-22, panel C).

Given the evidence of increased mortality or shortened life expectancy with long-term PM_{2.5} exposure, is there evidence of benefits if exposures are decreased. That is, are these effects of chronic exposure cumulative and irreversible over a lifetime? Examination of the window of exposure suggests that PM_{2.5} exposures of the most recent years are the most relevant. This suggests that improved air quality should be associated with reduced mortality and improved life expectancy. Indeed follow-up analyses of the Six Cities cohort ⁸ and the analyses of life expectancy associated with improved PM_{2.5} in the United States ^{6,7} provide evidence that the mortality effects of long-term PM_{2.5} exposure are reversible, even at ambient PM_{2.5} concentrations below the current NAAQS.

The evidence collected since the 2009 PM ISA only confirms the determination of a causal relationship between long-term PM_{2.5} exposure and mortality. Moreover, there is very strong epidemiologic evidence of long-term PM_{2.5} exposure and mortality associations at concentrations below the current annual NAAQS.

11.3 Short-Term PM_{10-2.5} Exposure and Total Mortality

The 2009 PM ISA concluded that the evidence is "suggestive of a causal relationship between short-term exposure to PM_{10-2.5} and mortality." This determination was based on a limited number of studies, often from single cities.

Additional studies since then, mainly multicity studies, have added to our understanding. Nevertheless, the body of evidence is not nearly as compelling as that for PM_{2.5}. This chapter provides a thorough compilation of the available evidence. The meta-analysis of Adar et al ⁹, while lacking the most recent studies, provides a thoughtful review of the available evidence for mortality and morbidity effects of both short- and long-term PM_{10-2.5} exposures. They found that the PM_{10-2.5} associations were not robust to adjustment for PM_{2.5}. They noted that the PM_{10-2.5} associations are highly heterogeneous, especially compared to the PM_{2.5} associations. This could suggest publication bias, that is nonsignificant associations are less likely to be published. PM_{10-2.5} is subject to much more exposure misclassification, leading to a bias towards null associations. Methods for measuring PM_{10-2.5} are subject to measurement error. Spatial variation of PM_{10-2.5} is much larger than for PM_{2.5}. Adar and colleagues ⁹ concluded that there was suggestive evidence for increased mortality with higher levels of short-term, PM_{10-2.5} concentrations. The evidence presented in this chapter of the ISA is consistent with that conclusion. Thus the 2009 determination of a "suggestive causal relationship" is still appropriate.

11.4 Long-Term PM_{10-2.5} Exposure and Total Mortality

The 2009 PM ISA reported that the evidence was “inadequate to determine a causal relationship” between long-term PM_{10-2.5} exposure and mortality.

In response to the call for additional investigations of the effect of PM_{10-2.5} exposure, several cohort studies incorporated PM_{10-2.5} exposure into their analyses. Almost all have found null associations with PM_{10-2.5} exposure. Moreover, when PM_{2.5} has been included in the analyses, the PM_{10-2.5} exposure associations have been diminished. That is the PM_{10-2.5} associations cannot be separated from those of PM_{2.5}. Thus the evidence not only continues to be inadequate to determine a causal relationship of long-term PM_{10-2.5} exposure with total mortality, the body of evidence appears to be moving towards no association.

11.5 Short-Term UFP Exposure and Total Mortality

The 2009 PM ISA concluded that the “epidemiologic evidence is inadequate to infer a causal relationship between short-term UFP exposure and mortality.”

As clearly summarized in the ISA, the epidemiologic evidence since the 2009 PM ISA is limited and inconsistent. Epidemiology analyses, particularly analyses of short-term exposures, depend on consistent long-term exposure monitoring. Without a regulatory requirement for UFP monitoring, there is no such monitoring network. Without such monitoring, there will be no direct epidemiologic evidence for regulation, only inferred associations based on measured co-pollutants or modelled exposures. There is an additional challenge to monitoring in locating monitors to estimate population exposures. The short half-lives and large spatial variability of UFP makes siting monitors for a population based study problematic.

One might ask, if UFP have such short half-lives, where are they going? They are not being removed from the atmosphere. Rather they agglomerate to form larger particles, that is PM_{2.5}. They do not lose their chemical toxicity, although in growing larger they do become more efficient in being transported to the gas exchange regions of the lung. It might be helpful to think of PM_{2.5} as the progeny of the UFP. Therefore it is not surprising that the health effects of UFP in real world population studies cannot be differentiated from their direct progeny, PM_{2.5}.

11.6 Long-Term UFP Exposure and Total Mortality

The 2009 PM ISA reported that no epidemiologic studies evaluated the effects of long-term UFP exposure and mortality, concluding that the evidence was “inadequate to determine if a causal relationship exists between long-term UFP exposure and mortality.”

New epidemiologic evidence has failed to show a consistent association of short-term UFP exposure and total mortality. For the same reasons state above for short-term UFP and totality associations, it is not surprising that there is no evidence of long-term UFP and total mortality association observed other than through the well-established associations with PM_{2.5}.

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WRITTEN STATEMENT
**Public Comment on the
CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter
(External Review Draft – October 2018)**

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DISCLAIMER

H. Christopher Frey is the Glenn E. and Phyllis J. Futrell Distinguished University Professor in the Department of Civil, Construction, and Environmental Engineering at North Carolina State University. He was Chair of the EPA Clean Air Scientific Advisory Committee (CASAC) from 2012 to 2015. He was a member of the chartered CASAC from 2008 to 2012. He was chair of the CASAC Lead Review Panel (2011-2013), CASAC Ozone Review Panel (2012-2014), and CASAC Oxides of Nitrogen Review Panel (2013-2015). He served as a member of two CASAC PM Review Panels (2007-2010, 2015-2018), a Carbon Monoxide Review Panel (2008 to 2010), two Oxides of Nitrogen Review Panels (2008-2009; 2015-2017), two Sulfur Oxides Review Panels (2008-2009, 2015-2018), and a SO_x/NO_x Secondary Standard Review Panel (2009-2011). From 2012 to 2018, Dr. Frey was a member of the EPA Science Advisory Board. These are Dr. Frey's personal views. They do not represent any official position of NCSU, EPA, the CASAC, or the SAB.

1.0 INTRODUCTION

This written statement is organized as follows:

- Section 2: Executive Summary of Major Findings and Recommendations (same as Tables 1 and 2, respectively, from the main letter).
- Section 3: Explanation of Major Findings and Recommendations
- Section 4: Comments on the Integrated Science Assessment
- Section 5: Analyses of the May 9, 2018 “Back to Basics” and October 31, 2017 “Strengthening and Improving Membership on EPA Federal Advisory Committees” Memoranda
- Section 6: EPA Should Reinstate the CASAC PM Review Panel
- Appendix 1: Email sent to Members of the CASAC Particulate Matter Review Panel
- Appendix 2: Email sent to Candidates for the Ozone Review Panel

2.0 Executive Summary of Major Findings and Recommendations

The **8 Major Findings** and **44 Recommendations** are given in Tables 1 and 2, respectively. These correspond to Tables 1 and 2, respectively of the written statement co-signed by 15 former members of the 2015 to 2018 CASAC Particulate Matter Review Panel.

The 15 former members include:

- Two former chairs of the chartered CASAC (Frey, Diex Roux)
- Eight former members of the chartered CASAC (Allen, Chow, Diex Roux, Frey, Harkema, Kenski, Poirot, Sheppard)

Table 1. Major Findings^a

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- MAJOR FINDING 1:** The myriad of changes to the NAAQS review process are collectively harmful to the quality, credibility, and integrity of the scientific review process and CASAC as an advisory body.
- MAJOR FINDING 2:** The current 7-member CASAC does not have the depth or breadth of expertise needed for the particulate matter review, nor could a group of this size cover the needed scientific disciplines.
- MAJOR FINDING 3:** The late 2020 deadline for completing the Particulate Matter (PM) review does not provide sufficient time to complete the “thorough review” of the “latest scientific information” of the “kind and extent” of “all identifiable effects” mandated by the Clean Air Act for the review of NAAQS, even if the committee were supported by a robust panel of experts in the multiple disciplines involved.
- MAJOR FINDING 4:** 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. The statute requires only “one person representing State air pollution control agencies.”
- MAJOR FINDING 5:** An underlying principle is to maintain distinction between science and policy issues. The Pruitt May 9, 2018 memorandum violates this principle by commingling science and policy considerations.
- MAJOR FINDING 7:** The current framework for causal determinations used in the ISA has been well-vetted by CASAC and has stabilized over multiple reviews. However, there is room for more transparent communication of specific causal determinations in the ISA.
- MAJOR FINDING 8:** There are numerous scientific issues in the external review draft of the Integrated Science Assessment for Particulate Matter that require revision.
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^a These major findings are from Table 1 in Frey, H.C., A.V. Diex Roux, G. Allen, 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),” Letter and Attachments from Members of the former EPA CASAC Particulate Matter Review Panel submitted to Clean Air Scientific Advisory Committee and U.S. Environmental Protection Agency Docket EPA–HQ–ORD–2014-0859, December 10, 2018.

Table 2. Recommendations^b

With regard to **MAJOR FINDING 1**: Changes to the NAAQS review process are harmful.

Recommendation 1: The CASAC should recommend, and we recommend, that the EPA rescind the October 31, 2017 and May 9, 2018 memoranda by former Administrator Scott Pruitt.

Recommendation 2: CASAC should recommend, and we recommend, wider consideration of approaches to streamlining the NAAQS review process, including opportunity for input from EPA staff in ORD and OAQPS, CASAC, and other stakeholders including the public.

Recommendation 3: CASAC should advise EPA, and we advise EPA, that, if it wishes to change the criteria for appointments to EPA advisory committees including CASAC, it should provide opportunity for input on such criteria from EPA staff in ORD and OAQPS, the EPA Science and Technology Policy Council, CASAC, and other stakeholders including the public.

Recommendation 4: CASAC should not agree to changes to the review process or to the schedule proposed by EPA.

With regard to **MAJOR FINDING 2**: Lack of breadth and depth of expertise.

Recommendation 5: We advise, and CASAC should advise, the current Acting Administrator that CASAC does not have adequate breadth and depth of scientific expertise 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.

Recommendation 6: We remind CASAC and EPA, and CASAC should remind the current Acting Administrator, that it has been long-standing practice, for four decades, to augment the 7-member CASAC with additional independent expert consultants, and this augmentation is essential to a high-quality review.

Recommendation 7: We remind the current Acting Administrator, as should CASAC, that in all past reviews conducted by CASAC, it has always been the 7-member chartered CASAC that approves the content of letter reports and attachments transmitted from CASAC to the Administrator. This is clearly indicated in CASAC's charter with Congress.

Recommendation 8: We call for the immediate formation of an Ozone Review Panel and for the reinstatement of the CASAC PM Review Panel.

Continued on next page

^b These recommendations are from Table 2 in Frey, H.C., A.V. Diex Roux, G. Allen, 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)," Letter and Attachments from Members of the former EPA CASAC Particulate Matter Review Panel submitted to Clean Air Scientific Advisory Committee and U.S. Environmental Protection Agency Docket EPA-HQ-ORD-2014-0859, December 10, 2018.

Table 2. Recommendations, *Continued*

With regard to **MAJOR FINDING 3**: Inadequate review time.

Recommendation 9: CASAC should reject EPA's proposed accelerated schedule. EPA should allow time for an adequate review by relaxing its fall 2020 deadlines for final rules for both ozone and PM.

Recommendation 10: CASAC should reject EPA proposals for only one review draft of an Integrated Science Assessment, and a Policy Assessment with embedded Risk and Exposure Assessments. EPA should allow for multiple drafts as needed, including separate drafts of the health and welfare REAs prior to a draft of the PA.

Recommendation 11: We advise the current Acting Administrator, as should CASAC, that the CASAC, supported by an augmented panel of scientific experts, requires typically two years to finish this review, contingent on timing and quality of EPA assessment documents.

Recommendation 12: We remind CASAC and EPA, and CASAC should remind EPA, that the courts have recognized the importance of CASAC's role and the need for adequate scientific review time.

Recommendation 13: Delays in initiation of the review cycle by EPA should not infringe on the adequacy of the time frame needed by CASAC to properly do its job with adequate quality and integrity. CASAC should affirm this recommendation.

Recommendation 14: We affirm, and CASAC should affirm, the important role of public comments.

Recommendation 15: EPA should immediately begin the review cycle for carbon monoxide. CASAC should form and EPA should approve a Carbon Monoxide Review Panel augmented with additional experts. EPA should allow adequate time for this review.

Recommendation 16: EPA should immediately begin the review cycle for lead. CASAC should form and EPA should approve a Lead Review Panel augmented with additional experts. EPA should allow adequate time for this review.

Recommendation 17: EPA should immediately begin the review cycle for oxides of nitrogen. CASAC should form and EPA should approve an Oxides of Nitrogen Review Panel augmented with additional experts. EPA should allow adequate time for this review.

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Table 2. Recommendations, *Continued*

With regard to **MAJOR FINDING 4**: Committee composition is based on non-scientific criteria.

Recommendation 18: Scientific expertise for panels should be relevant to the particular review. Different NAAQS reviews require different expertise. We recommend, and CASAC should recommend, that membership criteria for the chartered CASAC and for its augmented panels should emphasize scientific expertise, not geographic diversity nor affiliation with state, local, and tribal agencies, other than to meet the Clean Air Act requirement for “one person representing State air pollution control agencies.”

Recommendation 19: We recommend, and CASAC should recommend, that receipt of an EPA research grant should not disqualify membership on the CASAC or CASAC review panels.

Recommendation 20: We recommend, and CASAC should recommend, that CASAC members should not be dismissed *en masse* or appointed *en masse*, and turnover in a given year should be limited to a minority fraction of the total panel. Members should be eligible for reappointment to a second term especially if such appointments would provide continuity, key scientific expertise, and institutional memory. CASAC should include members with prior experience with the review process from prior service on CASAC or CASAC review panels.

With regard to **MAJOR FINDING 5**: Science and policy are commingled.

Recommendation 21: CASAC should reject EPA’s proposal to combine documents such as the ISA, REA, and PA in NAAQS review as a matter of routine procedure. Further, the CASAC review of the REA should not be concurrent with the PA. EPA should not commingle the first draft of REAs with the first draft of the PA. EPA should revise the review schedule such that CASAC is provided with a staggered sequence of first draft documents for the ISA, REAs, and PA, with time allowed for CASAC and public input on the first draft of a document to be addressed prior to issuing the first draft of the successive document.

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Table 2. Recommendations, *Continued*.

With regard to **MAJOR FINDING 6**: Inappropriate strategy to review implementation effects.

Recommendation 22: CASAC should not commingle deliberations regarding potential adverse effects of implementation with scientific issues regarding review and revision of NAAQS pertaining to public health and welfare.

Recommendation 23: CASAC and EPA should consider both adverse and beneficial effects of NAAQS implementation.

Recommendation 24: To develop advice on implementation effects, CASAC should be augmented with a panel of appropriately selected national and international experts. Such a panel may be able to address more than one NAAQS.

Recommendation 25: To avoid illegally commingling implementation issues when formulating a NAAQS, review of implementation effects should be done on a separate schedule than review regarding science pertaining to retaining or setting standards.

Recommendation 26: EPA and CASAC must take a scientific approach to providing advice regarding implementation effects, and such a review should be done with the same scientific rigor as the CASAC review of other aspects of the process.

Recommendation 27: EPA should develop one or more appropriate and relevant implementation assessment documents, which could build upon existing documents such as retrospective and prospective studies of the benefits and costs of the Clean Air Act. Such documents from EPA should be developed with the same level of scientific rigor and analysis as the other assessment documents, with similar requirements in regard to the supporting literature.

Recommendation 28: EPA and CASAC should recognize that the first attempt at doing this will involve the development of new data, methods, and analyses of adequate scientific validity and policy-relevance, which will take time.

With regard to **MAJOR FINDING 7**: Causal Framework

Recommendation 29: The state of the science of causal inference methodology is insufficient to recommend replacing the ISA's approach to causal determinations or for differently weighting studies used in the causal determinations based on a new criterion of how they apply causal inference methods. Therefore, the causal framework as stated in the Preamble to the ISAs should be retained in this review cycle.

Recommendation 30: The causal framework is not consistently and transparently applied in the external review draft of the PM ISA. Therefore, the framework should be consistently and transparently applied.

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Table 2. Recommendations, *Continued*.

With regard to **MAJOR FINDING 8**: The external review draft of the PM ISA requires extensive revisions.

Recommendation 31: A second draft of the ISA is needed and should be subject to a proper review by an appropriately constituted CASAC PM Review Panel.

Recommendation 32: Material on low cost sensors should be added to the ISA, per CASAC's advice on the PM Integrated Review Plan.

Recommendation 33: Numerous revisions are needed for Chapter 2 to more accurately reflect the current status of measurement methods, data, and interpretation of data.

Recommendation 34: The relationship between PM_{2.5} and UFP requires more detailed characterization and assessment.

Recommendation 35: A more thorough treatment of PM components is needed in the context of air quality measurement and exposure assessment.

Recommendation 36: More attention is needed to exposure microenvironments that are associated with the potential for high exposure to PM, including (for example) in-vehicle, on-road, and near-road (including schools near roads).

Recommendation 37: Study selection should be done more consistently or exceptions should be more clearly justified.

Recommendation 38: There should be more consistency and transparency in the application of the causal framework, including identification and explanation of studies or factors that led to up or down weighing of determinations, and more critical assessment of issues such as mixtures, copollutant models, and exposure error.

Recommendation 39: The ISA does a very good job of describing and synthesizing new evidence pertaining to exposure to PM_{2.5} and premature mortality. The assumption that the C-R relationship is linear, with no threshold, is reasonable and consistent with available scientific evidence.

Recommendation 40: The causal determination for short term exposure to coarse PM and respiratory effects should be informed by a more detailed critical evaluation of the supporting science so that the basis of the finding is more complete and transparent.

Recommendation 41: The causal determination for long term exposure to UFP and nervous system effects should be informed by a more detailed critical evaluation of the supporting science so that the basis of the finding is more complete and transparent.

Recommendation 42: With regard to populations with pre-existing cardiovascular or respiratory disease, a more thorough critical evaluation is recommended to support or possibly revise the 'suggestive' findings with respect to being at-risk populations.

Recommendation 43: Recent work regarding alternative scene-dependent haze metrics as visibility preference indicators is not mentioned and should be cited and evaluated.

Recommendation 44: As noted in individual member comments, and more generally, additional literature should be cited and incorporated. The end date for the literature review should be specified. Literature published up to the end date should be reviewed.

3.0 MAJOR FINDINGS AND RECOMMENDATIONS

These major findings and recommendations are supported with details in subsequent sections.

MAJOR FINDING 1: The myriad of recent changes to the NAAQS review process based on the October 31, 2017 and May 9, 2018 memoranda^{1,2} from Administrator Scott Pruitt are collectively harmful to the quality, credibility, and integrity of the scientific review process and to CASAC as an advisory body.

Recommendation 1: The CASAC should emphasize that the quality, credibility, and integrity of the review process depends on multiple facets of how the review is structured, including the sequence of documents, the opportunity to review revised drafts, augmentation of the CASAC with additional experts for each review (i.e. for ozone and for PM), opportunity for public input, adequate time in which to conduct the review, engagement of experts based on scientific expertise and not based on geography or affiliation, and engagement of experts with or without EPA research grants based foremost on the relevance of their scientific expertise. **Thus, simply changing one or two of these facets alone will not assure the quality, credibility, and integrity of a “thorough review” based on the “latest scientific knowledge”** as required by Sections 108 and 109 of the Clean Air Act. **The CASAC should recommend, and we recommend, that the EPA rescind the October 31, 2017 and May 9, 2018 memoranda by former Administrator Scott Pruitt .**

Recommendation 2: In attempting to alter the NAAQS review process, EPA should have followed the kind of open and transparent process undertaken in 2006.³ 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. **CASAC should recommend, and we recommend, wider consideration of approaches to streamlining the NAAQS review process, including opportunity for input from EPA staff in ORD and OAQPS, CASAC, and other stakeholders including the public.**

Recommendation 3: In revising criteria for membership on EPA Federal Advisory Committees in the October 31, 2017 memorandum¹ from former Administrator Pruitt, EPA should have recognized that such committees may serve different purposes, and should have acknowledged Federal guidance on peer review.⁴ The membership criteria for a scientific review committee should not be the same as the membership criteria for a stakeholder committee. **CASAC should advise EPA, and we advise EPA, that, if it wishes to change the criteria for appointments to EPA advisory committees including CASAC, it should provide opportunity for input on such criteria from EPA staff in ORD and OAQPS, the EPA Science and Technology Policy Council, CASAC, and other stakeholders including the public.**

Recommendation 4: As a group independent from EPA, **CASAC should not agree to recent changes to the NAAQS review process or to the schedule proposed by EPA.**

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MAJOR FINDING 2: Acting Administrator Andrew Wheeler appointed five members to the CASAC on October 10, 2018.⁵ The 7-member CASAC is comprised of four members from state agencies, one member from a Federal agency, a consultant, and an academic researcher. In the same October 10, 2018 press release that announced the new CASAC membership, the Acting Administrator announced that only the 7-member CASAC would conduct reviews of both the ozone and particulate matter standards and that the reviews would be conducted simultaneously on an expedited schedule. On October 11, 2018, members of the CASAC PM Review Panel, which was formed in 2016, were informed that their services were no longer needed, and candidates for the CASAC Ozone Review Panel were informed that a panel would not be formed, even though EPA requested nominations for such a panel in July 2018.^{6,7} The 1800+ page Integrated Science Assessment for Particulate Matter was released four days later, on October 15, 2018.⁸ **The current 7-member CASAC does not have the depth or breadth of expertise needed for the ozone and particulate matter reviews, nor could a group of this size cover the needed scientific disciplines.**

Recommendation 5: We advise, and CASAC should advise, the current Acting Administrator that CASAC does not have adequate breadth and depth of scientific expertise 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.^{4,5} According to November 7, 2018 “determination” memos from the EPA SAB office, the CASAC has no epidemiologists, even though epidemiology is a key scientific discipline related to both the ozone and PM reviews.^{9,10} 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.

Recommendation 6: We remind CASAC and EPA, and CASAC should remind the current Acting Administrator, that it has been long-standing practice, for four decades, to augment the 7-member CASAC with additional independent expert consultants, and this augmentation is essential to a high-quality review. It has been long-standing practice since the 1970s (see Section 6) to augment the 7-member CASAC with additional independent expert consultants, 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. It is not sufficient, as the Administrator suggested, to state that the 7 member committee meets the minimum requirements of the law.

Recommendation 7: We remind the current Acting Administrator, as should CASAC, that in all past reviews conducted by CASAC, it has always been the 7-member chartered CASAC that approves the content of letter reports and attachments transmitted from CASAC to the Administrator. This point is clearly stated in CASAC’s charter.¹¹ CASAC should remind the Administrator that based on long-standing well-established practice, consultants who augment the CASAC to form a review panel provide input and advice that ultimately is considered and vetted by the CASAC, and that it is the CASAC and not its independent consultants who decide

on what advice is transmitted to the Administrator. Thus, forming an augmented panel is not mutually exclusive with only the 7-member CASAC providing advice to the Administrator.

Recommendation 8: We call for, and CASAC should call for, the immediate formation of an Ozone Review Panel and for the reinstatement of the CASAC PM Review Panel. CASAC should call for the formation of an Ozone Review Panel and for the reinstatement of the CASAC PM Review Panel that was disbanded on Oct 11, 2018,⁷ only four days before the first draft PM ISA was released on Oct 15, 2018.⁸ CASAC should make these recommendations to the Administrator as soon as possible. EPA should approve these review panels.

MAJOR FINDING 3: The late 2020 deadline for completing the particulate matter review does not provide sufficient time to complete the “thorough review” of the “latest scientific information” of the “kind and extent” of “all identifiable effects” mandated by the Clean Air Act for the review of NAAQS, even if the committee were supported by a robust panel of experts in the multiple disciplines involved.

Recommendation 9: CASAC should reject EPA’s proposed accelerated schedule. EPA should allow time for an adequate review by relaxing its 2020 deadline and instead allow adequate time to complete the particulate matter NAAQS review process. Based on analysis of the most recently completed review cycles for primary NAAQS for each of the six criteria pollutants, the average amount of time it has taken from CASAC’s first public review meeting on the first external review draft of an ISA to CASAC’s final public review meeting on the policy assessment is 2.1 years. Additional time is needed by EPA after receiving ‘closure’ on CASAC’s advice to formulate and publish its proposed rule, obtain and respond to public comment, and formulate and publish its final rule. On average for the most recently completed review cycles of the criteria pollutants, it has taken EPA an average of 1.9 years to finalize a rule after receiving CASAC’s advice. Thus, it is unrealistic that this review can be completed within two years. Realistically, the remainder of the current review for PM will take four years, conditional on the timing and quality of EPA assessment reports. The quality and credibility of the review will also depend on whether CASAC is augmented with an appropriately constituted PM Review Panel. The actual time to completion could be less but this would depend on interim findings from EPA staff and CASAC in the course of preparing and reviewing the ISA, REA, and PA. To allow adequate time for review, the schedule should be set based on established experience with similar reviews.

Recommendation 10: CASAC should reject EPA proposals for only one review draft of an Integrated Science Assessment, and a Policy Assessment with embedded Risk and Exposure Assessments. EPA should allow for multiple drafts as needed, including separate drafts of the health and welfare REAs prior to a draft of the PA. CASAC may decide later that the first draft of any of these documents are adequate for their intended purpose, but CASAC should not feel constrained to review only a single draft of each document, and EPA should provide for the possibility and opportunity for CASAC to review a second draft of either the ISA, REAs, or the PA.

Recommendation 11: Given that the duration of CASAC’s role in the most recent six primary NAAQS reviews averaged 3.2 years (see Section 5 for details), and that the amount of time needed from CASAC’s review of a first draft of the ISA to its final advice on the PA averaged 2.1 years, EPA’s proposal for CASAC to execute its role in the remainder of the current particulate matter review in only one year is unprecedented, unrealistic, and infeasible if the CASAC is to

conduct a review with adequate quality, credibility, and integrity. **We advise the current Acting Administrator, as should CASAC, that the CASAC, supported by an augmented panel of scientific experts, requires typically two years to finish this review, contingent on timing and quality of EPA assessment documents.**

Recommendation 12: We remind CASAC and EPA, and CASAC should remind EPA, that even when EPA has been under a court order or a consent decree to complete a NAAQS review by a court-ordered or court-approved deadline, **the courts have recognized the importance of CASAC's role and the need for adequate scientific review time.** Therefore, EPA should not impose a reduced duration schedule for the scientific review that compromises the scientific review.

Recommendation 13: The CASAC should note that the duration of time to complete a NAAQS review depends in part on CASAC but also on EPA. In particular, EPA controls the timeline with regard to when a new review is initiated. Lapses of time between the end of a prior review up until the start of a new review are entirely at the discretion of the EPA. In the case of the PM review, EPA did not start the review process until 23 months after the prior review cycle was completed, and substantially delayed the draft IRP and the first draft of the ISA. **Delays in initiation of the review cycle by EPA should not infringe on the adequacy of the time frame needed by CASAC to properly do its job with adequate quality and integrity. CASAC should affirm this recommendation.**

Recommendation 14: We affirm, and CASAC should affirm, the important role of public comments in CASAC's review of the NAAQS, noting that a compressed and curtailed review process leads to fewer public meetings and, therefore, fewer opportunities for CASAC to be informed by public comment. CASAC should further note that the shortened duration for the ozone NAAQS scientific review results in fewer opportunities for public input to CASAC. Therefore, CASAC should advise the Administrator that, 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.

Recommendation 15: CASAC should advise that, if EPA wishes to fulfill the statutory requirement for a review every five years, **EPA should immediately begin the review cycle for carbon monoxide**, for which the most recent final rule was promulgated on August 31, 2011. However, EPA should allow a five year duration for the cycle, including adequate time for CASAC to formulate its advice based on "thorough review" and the "latest scientific knowledge," as required by the Clean Air Act. **CASAC should form and EPA should approve a Carbon Monoxide Review Panel augmented with additional experts. EPA should allow adequate time for this review.**

Recommendation 16: CASAC should advise that, if EPA wishes to fulfill the statutory requirement for a review every five years, **EPA should immediately begin the review cycle for lead**, for which the most recent final rule was promulgated on October 18, 2016. However, EPA should allow a five year duration for the cycle, including adequate time for CASAC to formulate its advice based on "thorough review" and the "latest scientific knowledge." **CASAC should**

form and EPA should approve a Lead Review Panel augmented with additional experts. EPA should allow adequate time for this review.

Recommendation 17: CASAC should advise that, if EPA wishes to fulfill the statutory requirement for a review every five years, **EPA should immediately begin the review cycle for oxides of nitrogen**, for which the most recent final rule was promulgated on April 6, 2018. EPA should allow a five year duration for the cycle, including adequate time for CASAC to formulate its advice based on “thorough review” and the “latest scientific knowledge.” **CASAC should form and EPA should approve an Oxides of Nitrogen Review Panel augmented with additional experts. EPA should allow adequate time for this review.**

MAJOR FINDING 4: Acting Administrator Andrew Wheeler, in making new appointments to the CASAC on October 10, 2018,⁵ has implemented provisions of former Administrator Pruitt’s October 31, 2017 memorandum.¹ **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. The statute requires only “one person representing State air pollution control agencies”.** The appointment of five members at one time is highly unusual, leading to a high degree of turn-over and inexperience on the current CASAC.

Recommendation 18: Scientific expertise for panels should be relevant to the particular review. Different NAAQS reviews require different expertise. We recommend, and CASAC should recommend, that membership criteria for the chartered CASAC and for its augmented panels should emphasize scientific expertise, not geographic diversity nor affiliation with state, local, and tribal agencies, other than to meet the Clean Air Act requirement for “one person representing State air pollution control agencies.” CASAC has always fulfilled this requirement.

Recommendation 19: **We recommend, and CASAC should recommend, that,** per long standing prior practice from the formation of CASAC until October 2017, nationally and internationally prominent researchers who hold peer-reviewed independently managed research grants from the U.S. Environmental Protection Agency are able to offer independent scientific advice to the agency. Per the peer review bulletin of the Office of Management and Budget, for scientists who hold federal research grants, “there generally should be no question as to that scientist’s ability to offer independent scientific advice to the agency on other projects.”⁴ Therefore, **receipt of an EPA research grant should not disqualify membership on the CASAC or CASAC review panels.** Further, we point out, and CASAC should point out, that it is illogical to allow persons from state, local, and tribal governments who hold EPA grants to serve on CASAC while preventing persons of other affiliations who hold grants, such as academia, from serving. Moreover, allowing members with funding from regulated industries to serve creates an appearance of lack of impartiality.

Recommendation 20: While there are benefits to having turnover of membership on the chartered CASAC, there are also significant benefits to continuity and knowledge provided by having some previous members continue to serve for a second term and to have staggered, overlapping terms. Thus, **members should not be dismissed *en masse* or appointed *en masse*, and turnover in a given year should be limited to a minority fraction of the total panel. Members should be eligible for reappointment to a second term especially if such appointments would provide continuity, key scientific expertise, and institutional memory.**

MAJOR FINDING 5: An underlying principle of changes to the NAAQS review process that were implemented in 2006 and revised in 2009 **is to maintain distinction between science and policy issues.**^{3,12} **The Pruitt May 9, 2018 memorandum violates this principle by commingling science and policy considerations** via combining steps that should be kept separate.²

Recommendation 21: CASAC should reject EPA's proposal to combine documents such as the ISA, REA, and PA in NAAQS review as a matter of routine procedure. Further, the CASAC review of the REA should not be concurrent with the PA. EPA should not commingle the first draft of REAs with the first draft of the PA. EPA should revise the review schedule such that CASAC is provided with a staggered sequence of first draft documents for the ISA, REAs, and PA, with time allowed for CASAC and public input on the first draft of a document to be addressed prior to issuing the first draft of the successive document. A decision to combine the REA into the PA, or to draft them concurrently, is doubly premature. First, the REA should not be prepared until the ISA has been adequately reviewed, since the REA is based on the air quality criteria established by and set forth in the ISA. This means that, at the earliest, the REA cannot be credibly prepared until CASAC review of the first draft of the ISA. If CASAC finds that the scientific basis of the review has changed since the last review such that a separate REA is needed, then EPA should provide CASAC with a draft REA. Second, the REA should be properly reviewed before the first draft of the PA. The PA cannot credibly set forth a policy-relevant summary of the REA without adequate review of the REA to know what elements reliably to highlight. Thus, CASAC should receive a first draft of the REA in a review step prior to receiving a first draft of the PA, such that CASAC's scientific advice on the REA is known, at least in large part, prior to the formulation of the first draft of the PA.

MAJOR FINDING 6: While it is appropriate for EPA to ask CASAC to provide advice regarding "any **adverse public health, welfare, social, economic, or energy effects** which may result from various **strategies for attainment and maintenance,**" the Clean Air Act, as interpreted by Federal Courts including the U.S. Supreme Court, is very clear that cost of implementation, and technical feasibility of implementation, are impermissible issues to consider when setting the NAAQS. Setting of NAAQS must be based solely on considerations of public health and public welfare. In 2014, the CASAC provided advice to the Administrator regarding how CASAC's role in reviewing adverse effects of NAAQS implementation should be structured.¹³ This advice was not taken into account in the May 9, 2018 memorandum by Administrator Pruitt.

Recommendation 22: With regard to a request from EPA for CASAC to provide advice regarding "any **adverse public health, welfare, social, economic, or energy effects** which may result from various **strategies for attainment and maintenance**" of NAAQS, **CASAC indicated how such advice should be developed in a June 26, 2014 letter to the Administrator.**¹³ Because it is illegal to consider cost or feasibility of attainment when setting a NAAQS, **CASAC should not commingle deliberations regarding potential adverse effects of implementation with scientific issues regarding review and revision of NAAQS pertaining to protection of public health and welfare.**

Recommendation 23: In its June 26, 2014 letter, CASAC noted that not all implementation effects are adverse; therefore, "any comprehensive assessment would include both adverse and beneficial effects."¹³ Most obviously, there are economic benefits from avoided morbidity and avoided premature mortality. Therefore, in considering effects of implementation of NAAQS,

CASAC and EPA should consider both adverse and beneficial effects of NAAQS implementation.

Recommendation 24: To develop advice on implementation effects, in 2014 CASAC advised that “the SAB Staff Office would form an ad hoc CASAC panel to obtain the full expertise necessary to conduct such a review.”¹³ The expertise to address social, economic, and energy effects differs from that needed to address other aspects of CASAC’s mandate. Thus, **CASAC should be augmented with a panel of appropriately selected of national and international experts** to conduct such a review. **Such a panel may be able to address more than one NAAQS.**

Recommendation 25: To avoid illegally commingling implementation issues when formulating a NAAQS, review of implementation effects should be done on a separate schedule than review regarding science pertaining to retaining or setting standards.

Recommendation 26: EPA and CASAC must take a scientific approach to providing advice regarding implementation effects based on valid methods and data. Such advice cannot be based merely on anecdotes or stakeholder opinions. Such a review should be done with the same scientific rigor as the CASAC review of other aspects of the process

Recommendation 27: EPA should develop one or more appropriate and relevant implementation assessment documents, which could build upon existing documents such as retrospective and prospective studies of the benefits and costs of the Clean Air Act.^{14,15,16} Such documents from EPA should be developed with the same level of scientific rigor and analysis as the other documents, with similar requirements in regard to the supporting literature. EPA should allow adequate time for review and revision of such documents, with an emphasis on scientifically valid data, methodologies, and analyses relevant to such a review.

Recommendation 28: Because neither EPA nor CASAC have previously conducted an assessment of “adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance,” EPA and CASAC should recognized that the first attempt at doing this will involve the development of new data, methods, and analyses of adequate scientific validity and policy-relevance, which will take time. Thus, such an activity cannot be compressed to a short-time period to meet a near-term EPA self-imposed deadline. In any case, as noted above, this assessment should be kept separate from review of the NAAQS.

MAJOR FINDING 7, Recommendations 29 and 30: See Letter for Details

MAJOR FINDING 8, Recommendations 31 to 44: See Letter for Details

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4.0 COMMENTS ON THE INTEGRATED SCIENCE ASSESSMENT FOR PARTICULATE MATTER

4.1 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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5.0 Analyses of the May 9, 2018 “Back to Basics” and October 31, 2017 “Strengthening and Improving Membership on EPA Federal Advisory Committees” Memoranda

H. Christopher Frey, Ph.D.

On May 9, 2018, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt issued a memorandum titled “Back-to-Basics Process for Reviewing National Ambient Air Quality Standards” (NAAQS).¹ This appendix provides context for NAAQS review and an analysis of the memorandum.

5.1 Statutory Mandate for Scientific Review of the NAAQS

Section 109 of the Clean Air Act (CAA) requires the EPA Administrator to “complete a thorough review” of the NAAQS at five-year intervals. The CAA further requires the Administrator to “appoint an independent scientific review committee” that “shall complete a review” of existing NAAQS and that “shall recommend to the Administrator any new” NAAQS and “revisions of existing criteria and standards as may be appropriate.” CAA Section 108 states that the standards “shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of such pollutant in the ambient air.” The EPA Clean Air Scientific Advisory Committee (CASAC) is chartered under this mandate.

5.2 Recent History of the NAAQS Review Process

The process for NAAQS review was revised in 2006 based on consultations within EPA, including the Office of Air and Radiation (OAR) and the Office of Research and Development (ORD), with current and former members of CASAC, and with other stakeholders.² The revised process included four major components: planning; integrated science assessment (ISA); risk and exposure assessment (REA); and policy assessment (PA). Separation between these review steps enables differentiation and transparency regarding scientific issues, which are the main focus of the ISA and a major focus of the REA, and policy issues, which is the main focus of the PA.

The ISA reviews, synthesizes, and evaluates policy-relevant science to establish key scientific findings. Such findings include, for example, characterization of physical and chemical processes that lead to ambient air pollutant concentrations, evaluation of air quality monitoring and modeling methods, spatial and temporal variability in ambient concentrations, quantification of background concentrations, quantification of human human exposure, dosimetry and mode of action, identification of adverse effects, causal determination between exposure and adverse effects, characterization of populations potentially at increased risk, environmental and ecosystem effects, and interactions with climate change.^{3,4}

The REA is a quantitative analysis of exposure and risk based upon scientific evidence established in the ISA. The REA builds upon the findings of the ISA, such as regarding key adverse effects and populations at increased risk, to provide details regarding input data and modeling methods and results for assessment of exposure and risk.^{5,6} The PA was initially in the form of an advanced notice of proposed rulemaking (ANPR). An April 2007 memorandum modified the process to enable CASAC to review a second draft of the REA and for the REA to be finalized before an ANPR was issued.⁷ In May 2009, Administrator Lisa Jackson deleted the ANPR and replaced it with a policy assessment (PA).⁸ The ANPR is a regulatory document that involves input from politically-appointed leadership, whereas the PA is a staff evaluation of the policy implications of the scientific and technical information in the ISA and REA.

The PA includes assessment by EPA staff of whether the current standard is adequate and, if not, options for the indicator (pollutant), level, averaging time, and form of possible alternative standards.^{9,10} Taking into consideration the PA, CASAC formulates its advice regarding whether an existing NAAQS should be retained or revised, and whether a new NAAQS is recommended. CASAC logically provides this advice before EPA formulates a proposed rule.

Planning has typically included an integrated review plan (IRP) for the review cycle, and a scope and methods plan (SMP) or similar planning document for the REA.^{11,12} The scientific basis of the review is logically established in the ISA before the REA can be completed. The methodology, input data, and results of the REA have been scientifically reviewed before the PA is finalized.

5.3 Brief Primer on CASAC

CASAC is comprised of seven members appointed by the EPA Administrator, referred to as the “chartered CASAC”. For each NAAQS review, CASAC forms a panel augmented with additional experts and has done so since the 1980s. The augmented panels include multiple experts in each of the many scientific disciplines that pertain to the ISA, REA, and PA. In addition to its mandate under the CAA, CASAC is subject to the Federal Advisory Committee Act (FACA). CASAC meetings must be announced in the *Federal Register*, the public must be allowed to attend, and CASAC must allow for public comments. Public comments provide an opportunity for stakeholder input to the review process. For a full review cycle, there is an initial teleconference to convey individual member comments on the IRP, followed by four face-to-face meetings that typically take two days each and focus on: (1) first draft of the ISA and draft of the REA scope and methods plan; (2) 2nd draft of the ISA and 1st draft of the REA; (3) 2nd draft of the REA and 1st draft of the PA; and (4) 2nd draft of the PA. Panelists receive a draft document (often hundreds of pages, sometimes over a thousand pages) and charge questions from EPA approximately 30 to 60 days prior to a meeting, and submit individual written comments before the meeting.

During the public meeting, the review panel is asked to develop consensus responses to charge questions provided by EPA, but may also provide other advice it deems to be appropriate. After the public meeting, panelists develop a written draft of the responses to charge questions, and may update their individual comments. Although consensus is sought, and often achieved, panelists are always able to convey their individual comments. The panel chair develops a draft letter to the Administrator that conveys the key aspects of CASAC’s advice. The draft letter and responses to charge questions are reviewed and deliberated at a teleconference open to the public. The statutory CASAC completes a public “quality review” of each draft report before it is transmitted to the Administrator.

The duration from receipt of a draft EPA report by panelists to the delivery of advice from CASAC to the Administrator is typically 3 to 5 months. EPA staff usually have a good idea of the main points of CASAC’s advice at the conclusion of the first public meeting on a particular document, which is typically within 2 months of panel members receiving a draft.

5.4 The Five Year Requirement

EPA has generally failed to meet the CAA requirement for a five year review cycle for the NAAQS. For the most recent reviews of the primary NAAQS that focus on public health, including carbon monoxide, lead, nitrogen dioxide, ozone, and particulate matter (PM), the review cycle took between 4.0 years to 7.1 years from the initial call for information for the ISA to the publication of the final rule, with an

average of 5.9 years. The current review for sulfur oxides is past the proposed rule stage, but not yet finalized, at just over 5 years. However, EPA is generally completing the review process in a more timely manner than in the past.

Based on the time from the consultation on the IRP to its final advice on the PA, the duration of CASAC's role in the most recent six NAAQS reviews focused on public health has been 2.2 years to 4.7 years, with an average of 3.2 years. The scientific aspects of these review cycles have been thorough and of high-quality, and have resulted in CASAC advice based on the "latest scientific knowledge" as required under the CAA. The separation between the ISA, REA, and PA facilitates separation of science and policy advice by CASAC. CASAC has also been careful to distinguish policy advice from scientific advice.^{13,14}

The most recent review of the carbon monoxide NAAQS was started over 13 years from the prior review completed in 1994, and it is now over 7 years since the last revision of the CO standard in 2011. For the other five criteria pollutants, the amount of time that elapsed from the end of the prior review cycle to the start of the next ranged from 0.5 years to 2.9 years, with an average of 1.6 years. For the five most recent completed primary NAAQS reviews, it has taken EPA between 1.1 to 3.4 years to finalize a rule, with an average of 1.9 years, after CASAC completed its final advice on the most recent policy assessment.

The May 2018 memorandum quotes selectively from CASAC letters from ca. 2006-2008 regarding putative problems with the current review process, implying that these quotes evince CASAC support for speeding up the process.¹ Those letters in fact addressed concerns with the review process prior to modification or during the early part of the learning curve for the new process. There were early challenges with the revised process as both EPA staff and CASAC were determining and clarifying the scope and methods relevant to each review step. A comment from a 2008 letter from CASAC is given without proper context: while it was true at that time that early drafts of ISAs did not exclusively focus on scientific evaluation of the most relevant scientific studies, lessons learned from CASAC's 2008 and other advice have subsequently led to more focused literature reviews and scientific assessments. As another example, CASAC panels for each criteria pollutant deliberated regarding EPA staff proposals for an updated framework for determination of causality of adverse effects from exposure to air pollutants, leading to improved formulation and clarity of the framework and improved consistency and transparency of its application over time. Thus, the issues raised based on the cited letters from a decade ago are of limited current relevance.

5.5 Wait, and Then Hurry Up!

The May 2018 memorandum states that the NAAQS review will be completed by October 2020 for ozone and by December 2020 for particulate matter.¹ Administrator Pruitt took office on February 17, 2017. EPA did not announce the start of the current ozone review until June 26, 2018. Although the current PM review has nominally been underway for more than two years, EPA did not release the first draft of the ISA until October 2018.¹⁵ There are approximately two years from now to the deadlines indicated in the May 2018 memorandum. EPA has never completed a NAAQS review cycle in such a short time.

5.6 Can the Review Process be Shortened?

The ISA is critically important to establishing the scientific findings regarding the determination of causality of short and long term exposures with regard to adverse effects, and the data and methods relevant to later steps of the review. For each primary NAAQS, two drafts of the ISA were reviewed by CASAC. However, in the case of lead and ozone, a third draft of the ISA was required because CASAC found that the second draft did not adequately address CASAC's prior comments. CASAC has recognized that the ISA, as well as the REA and PA, do not have to be perfect, but must be adequate for their intended purpose, taking into account the CAA mandate that NAAQS be based on "a thorough review" and the "latest scientific knowledge."

The ISA may appropriately contain more information than is later used directly in rulemaking, including scientific questions for which the answer was a null finding. For example, in the previous PM review, a scientific assessment was made that there was insufficient health effects evidence to justify developing a new standard for ultrafine particulate matter (UFP).^{3,9} EPA and CASAC considered UFP in deciding, at that time, not to recommend a standard for UFP. Identification of key uncertainties is also critical to CASAC's mandate to advise the administrator of areas where new science is needed that may be relevant in the next review cycle.

In cases for which there has been limited new information since the last review, the REA either has been omitted, relying instead on the REA from the prior review cycle, in which case the REA is either minimally updated or combined into the PA. CASAC has been amenable to these adjustments to the review process, *when appropriate*. However, the duration of the review process does not appear to be highly correlated with whether a separate REA is produced. For example, from the initial call for information for the ISA to the publication of the proposed rule, the reviews for which there was not a separate REA took 58 to 66 months. The review for sulfur oxides, with only a single draft of the REA, took 61 months. In contrast, the reviews for carbon monoxide, ozone, and particulate matter, for which there were two drafts of the REA, took 41, 75, and 60 months, respectively.

5.7 Combining Multiple Steps into One Step

The May 2018 memo states that EPA "shall consider combining" the ISA, REA, and PA "into a single review."¹ One of the benefits of sequencing these documents is to avoid a problem with an initial draft of one document, such as the ISA, from propagating to later steps in the REA and PA.³ Combining these documents into one review could lead to an inadequately developed scientific basis, a premature risk and exposure assessment, and a poorly supported policy assessment. Furthermore, the sequence of these documents increases transparency regarding science and policy issues.

A single review step would imply that EPA staff working on the REA and PA are presuming the outcome of the ISA before the content of the ISA has stabilized based on CASAC review. Combining these steps would presume that the policy outcome is known before the scientific assessment has been finalized. A rushed combined process would be inherently less transparent.

One of the key reasons why EPA discontinued the use of an ANPR and replaced it with a policy assessment was because the former was "vulnerable to the introduction of policy options that are not supported by the relevant scientific information," whereas the PA "presents a transparent staff analysis of policy options...to consider prior to rulemaking."⁸ Publication of a PA prior to a proposed rule enables

EPA to demonstrate that it has completed a science-based review and fosters the identification and evaluation of science-based regulatory alternatives.

Merely because EPA might proffer a combined assessment for CASAC to review does not mean that CASAC must concur that the combined assessment is adequate. Scientific shortcomings in a combined assessment could lead to CASAC requests for revised drafts. Logistically, there is also the challenge of asking CASAC to compress its review activities into a much shorter time frame. It is debatable whether a CASAC panel could easily digest a combined ISA-REA-PA and deliberate on its advice without additional review and meeting time, while maintaining the level of quality consistent with current practice and the mandate of the CAA.

5.8 Sudden Death: Eliminating the PM and Ozone Review Panels

On October 11, 2018, members of the CASAC PM Review Panel received an email from EPA stating that “your service on the panel has concluded.” The PM Review Panel was appointed in 2015 and originally had 26 members. Also on October 11, 2018, candidates for the CASAC O₃ Review Panel were informed that “the Agency will not form a CASAC Ozone Panel.” The ozone review panel for the review cycle completed in 2015 had 20 members. There was no prior consultation with members of the PM Review Panel, nor any public indication that elimination of the panels was being considered, nor any public process for providing input related to this issue.

In an October 10, 2018 press release, EPA announced that the chartered 7-member CASAC would conduct the reviews of both the ozone and PM NAAQS simultaneously. Thus, instead of having approximately 20 or more experts review separate planning, ISA, REA, and PA documents over a period of typically three years, a committee of only seven members will conduct a review in a period that would have to be only about one year, taking into account time for EPA to develop and publish proposed and final rules. Furthermore, rather than have two mostly non-overlapping groups of experts conduct the reviews, subject to approval by the chartered CASAC, the same group of seven will review these two NAAQS concurrently. For PM in particular, there has been a tremendous amount of new research since the last review, as indicated by the over 1800 page length of the first draft ISA released just days after the PM Review Panel was disbanded.¹⁵ EPA has argued that the CAA does not require that CASAC be augmented with additional experts. This rote response does not address the question of what is needed to provide the requisite “thorough review”. In fact, it has been clear for four decades that a seven member group does not have the breadth and depth of scientific expertise needed for these reviews, nor does the CAA prevent the formation of panels.

5.9 Transforming CASAC from a Scientific to a Stakeholder Committee

Over the decades, CASAC members have been appointed based on their scientific expertise. In contrast, an October 31, 2017 memo from Administrator Scott Pruitt requires that members of EPA federal advisory committees should “reflect prominent participation from state, tribal, and local governments,” and that priority should be given to “geographic diversity.”¹⁶ There is no mention of the importance of having experts of high stature that represent the wide range of scientific disciplines, and the depth of knowledge and experience, necessary to the work of committees such as CASAC or the EPA Scientific Advisory Board (SAB). On October 10, 2018, EPA announced that Acting Administrator Wheeler appointed five new members to the 7-member chartered CASAC. The current CASAC is comprised of representatives from four state agencies, one federal agency, a consulting firm, and one academic

researcher. For the most part, these members were selected for their geographic location or affiliation, rather than primarily based on depth of expertise.

In the context of the ozone review, the CASAC does not include nationally or internationally recognized experts in epidemiology, which is a key scientific discipline. The CASAC lacks nationally or internationally recognized experts in exposure assessment. The CASAC lacks the diversity of multiple expert perspectives on toxicology, including from experts who are at the forefront of toxicological research and recognized as national or international experts. The CASAC lacks adequate breadth and depth of expertise in air quality science, including measurements of background concentrations. The CASAC also lacks proper coverage of expertise pertaining to issues related to the scope of public welfare, such as effect of tropospheric ozone on climate and vegetation. CASAC has typically been comprised of leading nationally and internationally recognized scientific experts, who are active in research in their respective fields and at the forefront of the latest scientific knowledge, not stakeholders selected for their geographic location or governmental affiliation.

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.”¹⁶ This is illogical 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.”¹⁷ A 2013 report by the EPA Office of Inspector General reaffirmed that receipt of an EPA research grant is not a conflict of interest.¹⁸ 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 same appearance of conflict of interest.

The October 31, 2017 memo calls for greater turnover in membership of EPA advisory committees but fails to acknowledge that there are benefits of continuity and knowledge provided by having some previous members continue to serve.¹⁶ Under this new policy, well-qualified scientists have been “rotated” off of the CASAC, in favor of new members without subject matter expertise, selected instead for their affiliation or geographic location.

5.10 CASAC Advice on Implementation of NAAQS

The CAA states that CASAC shall advise the Administrator EPA regarding “any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance” of NAAQS. However, past EPA administrations have typically not asked CASAC for this advice, nor have EPA staff prepared scientific assessment documents for CASAC review that would be

relevant to developing such advice. The May 2018 memorandum indicates that EPA will include a charge question to CASAC seeking such advice.¹

In a June 26, 2014 letter to the Administrator, CASAC outlined how such advice would need to be developed, taking into account that it is illegal to consider cost or technological feasibility when setting a NAAQS.¹³ CASAC stated that it did not want to commingle deliberations regarding potential adverse effects of implementation with scientific issues regarding review and revision of NAAQS. CASAC noted that not all implementation effects are adverse; therefore, “any comprehensive assessment would include both adverse and beneficial effects.” For example, there are economic benefits from avoided morbidity and premature mortality. CASAC further advised that “the SAB Staff Office would form an ad hoc CASAC panel to obtain the full expertise necessary to conduct such a review.” The expertise to address social, economic, and energy effects differs from that needed to address other aspects of CASAC’s mandate. Review of implementation effects should be done on a separate schedule than review regarding science pertaining to retaining or setting standards. Furthermore, EPA should recognize that as a scientific advisory committee, it would be CASAC’s responsibility to take a scientific approach to providing advice regarding implementation effects based on valid methods and data, and that such advice cannot be based merely on anecdotes or stakeholder opinions.

CASAC historically relies on EPA staff to prepare draft documents and does not have the resources to commission its own studies. The May 2018 memorandum indirectly acknowledges that CASAC needs to be provided with relevant documents. To clearly separate its advice on implementation versus advice on the standards themselves, an appropriately formulated separate CASAC NAAQS implementation review panel should be provided with a separate draft implementation assessment document. It is likely that there will be a significant learning curve for the both the agency and CASAC in dealing with assessment of implementation issues, which should be recognized in setting schedules. The timing of CASAC advice regarding implementation logically would not be the same as that regarding whether to revise a standard, to avoid conflating implementation issues with the development of advice regarding the setting of NAAQS.

5.11 Lack of Transparency about Transparency

The story is not complete without mentioning the proposed rule regarding purported “transparency” in regulatory science. This proposed rule could have the effect of banning some scientific studies that have been influential in prior NAAQS reviews. As the SAB has pointed out, this proposed rule was not developed based on a transparent process.¹⁹ For example, there was no consultation with the SAB or CASAC, nor were EPA staff scientists or external scientists consulted or offered the opportunity for input. Policies regarding how science is conducted at EPA are usually developed as guidance documents, not as regulations. Although increased transparency is a broadly shared goal in the scientific community, there are legitimate scientific studies — replicated many times over — for which the underlying data are necessarily based on confidential human subject data. Both the courts, and OMB in its rules implementing the Data Quality Act, have recognized the appropriateness of utilizing such studies in the regulatory process.

5.12 A Way Forward

EPA is a science-based agency with a science-based mission to protect the public health, as mandated by the laws under which EPA must operate. The combined effect of multiple rushed and poorly founded ad hoc initiatives, including the October 31, 2017 and May 8, 2018 memoranda, a proposed rule to ban the use of particular types of valid scientific studies, the conversion of CASAC to a stakeholder committee, and the summary dismissal of an existing review panel, arbitrarily undermines the application and evaluation of science in the NAAQS review process.

A two year time frame for NAAQS review by a reconstituted CASAC, for which a highly qualified augmented review panel was dismissed for one pollutant and not formed for another, will create problems that could call into question the quality and adequacy of the review. Although EPA is required to complete NAAQS reviews in five years, EPA clearly has needed additional time to conduct the mandated "thorough review" of the "latest scientific information". In some cases, EPA has been sued and courts have supervised the timing of the review process. Court approved or ordered completion schedules have taken into account the need for adequate scientific review time. For example, under consent decrees for the recent nitrogen dioxide and sulfur oxides reviews, EPA followed an appropriate process that preserved the integrity of the scientific review. In the current cases for PM and ozone, EPA has spent a lot of time in getting the reviews underway.

EPA could shorten the length of the review process by reducing the time between the conclusion of the prior review and the start of the next review. EPA could also potentially reduce review time if it is able to commit staff resources to the ISA, REA, and PA to shorten the calendar time, but not the scope and quality, of the development effort for each draft report submitted to CASAC. To maintain the credibility of the process, CASAC should continue to review separate ISA, REA, and PA documents, and complete its advice on the PA prior to EPA formulating and issuing a proposed rule. EPA should abandon the arbitrary constraints imposed on CASAC membership. CASAC should continue to engage additional experts as has been the case for four decades, should reinstate the PM Review Panel, and should form an ozone review panel.

EPA staff in ORD and OAR should be lauded for their good faith efforts over the years to shorten the review time for NAAQS, as illustrated by the development and implementation of new processes since 2006. CASAC has generally tried to honor EPA's schedule needs by recognizing that assessment documents must be adequate for their intended purpose but do not need to be perfect. The May 2018 memorandum was not developed based on an open and transparent process. For example, there was no consultation with CASAC. If EPA wants to revise the NAAQS review process, it should do so via an open and transparent process similar to that undertaken in 2006. Such a process would lead to a more accurate understanding of the key needs and challenges of a NAAQS review and perhaps effective ideas for more timely reviews.

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6.0 CASAC Should Recommend Formation of an Particulate Matter Review Panel

Section 109 of the Clean Air Act (CAA) requires the EPA Administrator to “complete a thorough review” (emphasis added) of the NAAQS at five-year intervals. The CAA further requires the Administrator to “appoint an independent scientific review committee” that “shall complete a review” of existing NAAQS and that “shall recommend to the Administrator any new” NAAQS and “revisions of existing criteria and standards as may be appropriate.” CAA Section 108 states that the standards “shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of such pollutant in the ambient air” (emphasis added). The EPA Clean Air Scientific Advisory Committee (CASAC) is chartered under this mandate.

The 7-member chartered CASAC has routinely been augmented with additional expert consultants to form review panels for particular criteria pollutants pertaining to review of primary and secondary standards. The review panels are chaired by a member of the chartered CASAC and include members of the chartered CASAC. According to the CASAC charter with Congress, panels are allowable and are advisory to CASAC. The 7-member chartered CASAC must approve any draft reports prepared by a review panel before such a report can be transmitted to the EPA Administrator. The augmented panels are created because **the 7 members of the chartered CASAC do not have the breadth and depth of scientific expertise to adequately cover the myriad of scientific issues that must be addressed as part of the NAAQS review process.** Such review panels have been formed subject to the provisions of the Federal Advisory Committee Act and all applicable procedures and policies of the EPA Science Advisory Board office.

6.1 October 10, 2018 Press Release

In an October 10, 2018 press release, Acting Administrator Wheeler announced that the 7-member chartered CASAC is “tasked ... with leading the review of science for any necessary changes to the NAAQS for ozone or particulate matter.” The press release further indicated that “these changes” will be finalized by late 2020. The next day, emails were sent to members of the existing CASAC PM Review Panel indicating that the panel was disbanded and to candidates for the CASAC Ozone Review Panel indicating that a panel would not be formed (see Appendix 1 and 2, respectively).

While there have been many occasions on which there have been simultaneous CASAC reviews of two or more NAAQS, such reviews have been conducted by augmented review panels, thus including a larger number of persons that collectively had more depth and breadth of expertise. Furthermore, the EPA is proposing that CASAC complete its reviews of both ozone and PM on a highly expedited time frame.

Furthermore, **the October 10, 2018 press release was announced without any prior public process for obtaining input from EPA staff, CASAC, or other stakeholders.** As such, **the decision announced in the October 10 press release, as confirmed the next day with an email to members of the CASAC PM Review Panel, to disband the CASAC PM Review Panel is arbitrary.** The ill-founded nature of this decision is readily apparent from the long history of the use of augmented CASAC panels and from EPA’s intent to form a PM Review Panel as indicated in a Federal Register notice of February 4, 2015. **No reasonable explanation was offered regarding why the EPA chose to disband the PM Review Panel only four days before releasing the external review draft of the Integrated Science Assessment for Particulate Matter.** Reportedly, EPA has claimed that it can legally ask the 7-member chartered CASAC

to conduct the review. There is no question that the 7-member chartered CASAC must approve any report from CASAC to the EPA Administrator, which has been long established practice, but as the track record of four decades clearly indicates, CASAC benefits from and requires the input of additional scientific experts in formulating its advice to the Administrator. **The arbitrary decision of the Acting Administrator is detrimental to the quality of the scientific review process.**

6.2 2015-2018 CASAC Particulate Matter Review Panel

On February 4, 2015, the EPA Science Advisory Board (SAB) office announced in a Federal Register notice (Volume 80, Number 23, pages 6086-6089) a **“Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel.”** 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:

“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.**” [emphasis added]

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 **“Formation of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel.”** 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.”

The November 17, 2015 memorandum is known as a “determination” memorandum because it determines the formation and membership of the panel. The determinations in the memorandum included the type of review body, the nature of the review, types of expertise needed, financial conflict of interest considerations, applicability of “lack of impartiality” regulations, other considerations, how individuals were selected, and the selected members of the CASAC PM Review Panel.

Beyond the breadth of scientific topics listed here, **it has also been common practice that each panel has more than one expert in a given scientific discipline, so as to achieve a balanced representation of the current state of science pertinent to a review.**

On October 10, 2018, EPA issued a press release that: (a) “tasked” the chartered CASAC with “leading the review of science for any necessary changes to the NAAQS for ozone or particulate matter”; and (b) stated that such changes “would be finalized by late 2020”. **On October 11, 2018, an email from Khanna Johnston to Aaron Yeow of the EPA SAB office** was forwarded to members of the CASAC PM Review Panel that **stated “the CASAC PM Review Panel will no longer be involved with the Agency’s PM NAAQS review and your service on the panel has concluded.”** Four days later, on October 15, 2018, the first external review draft of the Integrated Science Assessment for Particulate Matter (EPA/600/R-18/179) was released. The draft ISA document has 1,881 pages.

On November 7, 2018, a new determination memorandum was issued from Aaron Yeow to Thomas H. Brennan in the EPA SAB office. The memorandum states that the “the seven-member Chartered CASAC will serve as the body to review the remaining key science assessments for the agency’s PM NAAQS review” but **offers no explanation for reason(s) why the CASAC PM Review Panel would no longer be involved.** The memorandum states that the chartered CASAC has “expertise in toxicology, engineering, medicine, ecology, and atmospheric science.” Compared to the November 17, 2015 determination memorandum, the following scientific areas are not specifically mentioned: air quality and climate responses, atmospheric chemistry, dosimetry, 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. Engineering was not mentioned in the November 17, 2015 determination memorandum and it is not clear why engineering was added in the November 7, 2018 determination memorandum. The scientific areas of “medicine, ecology, and atmospheric science” in the November 7, 2018 determination memorandum are stated broadly and not with the specificity (e.g., controlled clinical exposure, light extinction, visibility impairment, related welfare effects, climate response, atmospheric chemistry) as in the November 17, 2015 determination memorandum. **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, controlled clinical studies, and others.**

6.3 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^a

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

^aAll of this information was obtained from www.epa.gov/casac by review CASAC reports posted online.

Table 2. Summary of Primary NAAQS Review Panels By Number of Consultants^a

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

^aAll of this information was obtained from www.epa.gov/casac by review 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.**

6.4 CASAC Does Not Have Adequate Breadth and Depth of Expertise to Review the Particulate Matter Standard

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 both breadth and depth of expertise. **The particulate matter review requires many other scientific disciplines as illustrated by the list given in the February 4, 2015 Federal Register request for nominations and the November 17, 2015 determination memorandum.**

The 7-member chartered CASAC does not have the breadth of deep expertise required for a review of the particulate matter NAAQS 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”. 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 summarized in Table 1.

The 7-member chartered CASAC is not required to agree with decisions of the EPA that adversely affect the quality of the scientific review process. The CASAC should recognize that it does not have adequate expertise to conduct the scientific review of the particulate matter NAAQS without

augmentation by “nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to PM,” including multiple experts in key disciplines to assure rigorous depth. **The CASAC should recommend that the CASAC Particulate Matter Review Panel be reinstated.**

On November 7, 2018, a memorandum from Aaron Yeow to Thomas Brennan, titled “Determinations Associated with the Clean Air Scientific Advisory Committee (CASAC) Review of the Particulate Matter National Ambient Air Quality Standards (NAAQS),” was issued. This memorandum attempts to justify that the 7-member chartered CASAC is an adequate body to conduct the review of the particulate matter NAAQS. The memorandum states that the 7-member chartered CASAC has “expertise in toxicology, engineering, medicine, ecology, and atmospheric science.” **Compared to the November 17, 2015 determination memorandum for the PM Review Panel, the 7-member chartered CASAC lacks expertise in the following key areas: air quality and climate responses, atmospheric chemistry, dosimetry, 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.** Engineering was not mentioned in the November 17, 2015 determination memorandum and it is not clear why engineering was added in the November 7, 2018 determination memorandum. The scientific areas of “medicine, ecology, and atmospheric science” in the November 7, 2018 determination memorandum are stated broadly and not with the specificity (e.g., controlled clinical exposure, light extinction, visibility impairment, related welfare effects, climate response, atmospheric chemistry) as in the November 17, 2015 determination memorandum. **Thus, the 7-member chartered CASAC is an inadequate group for conducting an assessment of the ISA, and requires augmentation with additional experts representing missing scientific disciplines. Furthermore, it is not adequate in many cases to have only one member who has expertise in a particular discipline.** For example, it is very clear that review of particulate matter requires expertise related to toxicological studies, epidemiological studies, clinical human studies, dosimetry, air quality measurement, exposure assessment, visibility, and so one, for which relevant multiple expert perspectives, knowledge, and experience are needed to ensure a credible review.

Thus, the 7-member CASAC does not meet EPA’s own stated requirements for a properly constituted panel qualified to review the particulate matter NAAQS.

Although not specifically detailed here, similar comments have already been provided to CASAC at its November 29, 2018 teleconference pertaining to the need to form a CASAC Ozone Review Panel.

6.5 CASAC Should Recommend the Immediate Formation of the Ozone and PM Review Panels

The CASAC should recommend that the Ozone and PM Review Panels be formed that are augmented with additional scientists to ensure both the breadth and depth of expertise required for thorough and credible reviews. EPA should approve formation of an Ozone Review Panel and reinstatement of the PM Review Panel. Failure to form these panels assures lack of credibility of the scientific review of the NAAQS.

Appendix 1: Email sent to Members of the CASAC Particulate Matter Review Panel

From: Johnston, Khanna
Sent: Thursday, October 11, 2018 4:41 PM
To: Yeow, Aaron <Yeow.Aaron@epa.gov>
Subject: CASAC PM Panel Thank you for your service

Aaron,

Can you please forward this email to CASAC PM panel?

Appreciated.

Dear CASAC PM Review Panel members,

Yesterday evening on October 10, 2018, Acting Administrator Andrew Wheeler announced five new members of the chartered Clean Air Scientific Advisory Committee (CASAC). Additionally, consistent with the Clean Air Act and CASAC's charter, Mr. Wheeler tasked the seven-member chartered CASAC to serve as the body to review key science assessments for the ongoing review of the particulate matter National Ambient Air Quality Standards (NAAQS).

<https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee>

Therefore the CASAC PM Review Panel will no longer be involved with the Agency's PM NAAQS review and your service on the panel has concluded. The agency thanks you for your public service on the CASAC PM Panel these past several years and for your contribution in protecting public health and safeguarding our nation's air.

Please feel free to reach out to me or the CASAC Designated Federal Officer, Aaron Yeow, if you have any questions. My team and I are grateful for having the pleasure of working with you as esteemed colleagues over the years on topics and issues that have so greatly benefited the American public.

Thank you kindly,

Khanna

Khanna Johnston, Acting Director | Science Advisory Board | U.S. Environmental Protection Agency

1200 Pennsylvania Ave, NW (MC-1400R) | Washington DC 20460 | work 202.564.2820

Appendix 2: Email sent to Candidates for the Ozone Review Panel

From: Johnston, Khanna
Sent: Thursday, October 11, 2018 4:46 PM
To: Yeow, Aaron <Yeow.Aaron@epa.gov>
Subject: CASAC Ozone Panel Thank you for your interest. Providing an update.

Aaron,

Can you please forward this email to CASAC Ozone Panel Candidates?

Appreciated.

CASAC Ozone Panel Candidates,

Yesterday evening on October 10, 2018, Acting Administrator Andrew Wheeler announced five new members of the chartered Clean Air Scientific Advisory Committee (CASAC). Additionally, consistent with the Clean Air Act and CASAC's charter, Mr. Wheeler tasked the seven-member chartered CASAC to serve as the body to review key science assessments for the ongoing review of the ozone National Ambient Air Quality Standards (NAAQS).

<https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee>

Therefore the Agency will not form a CASAC Ozone Panel. We thank you for your interest and encourage you to participate in CASAC activities through our public involvement process.

Please feel free to reach out to me or the CASAC Designated Federal Officer, Aaron Yeow, if you have any questions.

Thank you kindly,

Khanna

Khanna Johnston, Acting Director | Science Advisory Board | U.S. Environmental Protection Agency

1200 Pennsylvania Ave, NW (MC-1400R) | Washington DC 20460 | work 202.564.2820

WRITTEN STATEMENT

**Public Comment on the
CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter
(External Review Draft – October 2018)**

PREPARED BY:

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SUBMITTED TO

**Docket ID No. EPA-HQ-OAR-2018-0279
U.S. Environmental Protection Agency
Washington, DC**

DATE

December 10, 2018

General Comments:

The EPA authors are to be commended for a clearly written and comprehensive first draft of the Integrated Science Assessment (ISA) for Particulate Matter (PM). The magnitude of peer-reviewed papers in the scientific literature to be reviewed since the last ISA is enormous and the authors have done an exceptional job in identifying pertinent data from a wide range of disciplines and incorporating it in a well-organized, analytical and integrative manner. Most importantly, the rationale for causality determinations are clearly presented, justified and summarized in the text and by way of tables.

Specific Comments:

I have a few targeted suggestions for your consideration in the revision of the Preface, Executive Summary (ES) and Integrated Summary (Chapter 1) of your draft document and for the external review process as a whole. These are listed below but not prioritized.

- In section P.3 of the Preface, Process for Developing Integrated Science Assessments, page P-13, Authors should briefly describe the writing and internal review process of the ISA (e.g., selection, expertise and roles of the authors, contributors, and reviewers). The review process by the CASAC are briefly described, but there is no description of the writing and internal review processes that went into the formulation of this draft ISA.
- Examples from epidemiological studies, similar to those given from toxicology studies, should be included in Table P-2., Weight of evidence for causality determinations.
- A table for the “Summary of suggestive of, but not sufficient to infer, as causal relationship” should also be included in the ES in a format similar to those for “Causal and Likely to be a causal relationships” along with a brief discussion in the text. Since the

number of scientific papers on PM exposure effects related to Metabolic Outcomes (e.g. Type 2 diabetes, obesity) and Reproductive Health Outcomes (e.g., fertility pregnancy, birth) are clearly increasing at an alarming rate, this should be noted as an area of concern that needs to be closely monitored and re-evaluated in future ISAs. It is noted that Table 1-5, Summary of causality determinations do include all causality determinations, including suggestive and inadequate determinations, in Chapter 1, p.1-62.

- Since central nervous system health outcomes have been determined to be “likely to be causal”, the CASAC should seek the review of experts in this field to further access this determination.
- Since metabolic and reproductive health outcomes have been determined to be “suggestive of causality”, it is also important that experts in these fields be added to the review process to further access and verify these determinations.
- In Chapter 1, Integrated Summary, the importance of new and past epidemiology studies in causality determinations are clearly highlighted, as well as toxicology studies that add plausibility to the epidemiological associations. Therefore, it is important that the CASAC add an additional member(s) to their committee with a strong background and recognized expertise in epidemiology, since there appears to be a current lack of expertise in this area.
- Plausible modes of action (or biological mechanisms) underlying specific causal or likely to be causal health effects related to PM exposure should be briefly provided in Chapter 1, where appropriate.

Respectfully submitted,
Jack R. Harkema

WRITTEN STATEMENT

**Public Comment on the
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PREPARED BY:

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SUBMITTED TO

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U.S. Environmental Protection Agency
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I have reviewed the Integrated Science Assessment for Particulate Matter Executive Summary, Chapter 1: Integrated Synthesis, and Chapter 2: Sources, Atmospheric Chemistry, and Ambient Concentrations. My overarching impression is that these chapters are extremely well written, comprehensive and yet concise, considering the massive amount of information that has been collected and summarized. The organization of the ISAs seems to be converging into this particular structure, with the Executive Summary giving key concepts and findings, the first chapter a synthesis of the entire document, and then subsequent chapters covering individual topics in depth. It is an effective and efficient way to organize the information. The consistent use of hyperlinks to navigate through the document and HERO for references is a great help to the reader.

Despite all these outstanding features, one surprising shortcoming should be addressed before the ISA is finalized. Both the ES and Chapters 1 and 2 clearly state EPA's intent to focus this ISA on PM_{2.5}, PM_{10-2.5} and UFP. PM₁₀ is not on the list. We still have a PM₁₀ NAAQS, so I am puzzled by the choice to leave PM₁₀ largely unexamined. Even though the PM₁₀ standard is meant to protect the public from PM₁₀₋₂₅, the ISA should provide the information needed to assess the adequacy (or inadequacy) of the indicator as it currently exists. The ISA should discuss EPA's rationale for not giving PM₁₀ the same level of attention and detail as the other size fractions. Even if plenty of evidence supports changing the indicator to PM_{10-2.5} it seems prudent to have a comprehensive body of evidence in the ISA on both in order to make a case for either changing or not.

Please add a table of acronyms and abbreviations. Even when reading an electronic version, it is not possible to search for many abbreviations because they are common letter combinations that may appear hundreds of thousands of times.

Throughout the document, many figures are fuzzy or pixelated. The problem is most apparent in color graphics but also shows up in black and white figures. When printed some become illegible; even when viewing them on a computer screen there are resolution issues, especially with the maps in Chapter 2. This makes it difficult to detect some of the spatial patterns that are discussed there. Better resolution graphics would be helpful. The content and format of the graphics are excellent and it is a shame for them to be blurry and unreadable.

The Executive Summary is great, especially the tables summarizing causality determinations and the Key Findings section at the end. Other than the previous request to justify the lack of PM10 data, I have no additional suggestions for changes.

Chapter 1 is an excellent synthesis. The summary bullets at the beginning are a nice way to set the stage. Although I did not read all 1800 pages of the ISA, the parts I did read were accurately summarized in this synthesis. The characterizations of various studies were helpfully balanced with data on bias and uncertainty. For the first time in many reviews of ISAs, I feel like the issues around uncertainty were covered adequately in the first draft. The chapter did a good job distinguishing the studies that contained new information relevant to causality determinations. Section 1.5, Policy Relevant Considerations, was especially useful in that regard. These policy relevant considerations might also be helpful if they were included in the subject-matter chapters as well. Chapter 6 included some related policy discussion, but I don't think the other chapters addressed policy directly.

Chapter 2 is a fair and balanced summary of both old and new work characterizing particulate matter in the ambient air. I particularly like the careful attention to distinguishing recent data that indicates a change in our understanding since the 2009 ISA. The discussions on PM components in each size fraction (Sections 2.5.1.1.6, 2.5.1.1.7, 2.5.1.1.8, 2.5.2.1.5) need some clarification; it is not clear if 'sulfate' means just the ion, SO₄, or if it means ammonium sulfate. Similar clarification is needed for all the components. If these are mostly referring to reconstructed mass, a reference should be given to the method used.

Section 2.5.2.1.2 on PM10 trends is one of the few places where PM10 gets its own section, but the data presented left me confused. I can't reconcile the nationwide decrease in 98th percentile contributions shown in Fig. 2-23 with the apparent lack of trend in Fig. 2-24. Aren't there a few more ways to poke at this data and come up with an explanation?

Minor wording changes, typos, etc.:

p. ES-5, Figure ES-2: Caption should be 'Long-term trend in national monthly *mean and 90th percentile*... It does not show annual averages.

p. ES-16, line 35: exits -> exists

p. ES-18, line 9: occurrent -> occurred

p. 1-4, line 15: were -> was

p. 1-11, line 5: PM.5 *concentrations* exhibit...

- p. 1-12, lines 30-31: This sentence mixes percents and ug/m3 concentrations. It is difficult to make meaningful comparisons when units are mixed like this. Can you please standardize these?
- p. 1-29, line 12: collosum -> callosum
- p. 2-3, line 29: delete 'above'
- p. 2-14, lines 2-5: Figure 2-5 actually shows 2002 NEI emissions, not 2006. Lines 4-5 say VOCs cannot be compared, but they are shown in the figure. Not clear.
- p. 2-28, line 11: measures -> measure
- p. 2-28, line 13: records -> record
- p. 2-31, line 32: not clear; possibly reword as: "...fraction of the particles large enough to be detected may be increasing..."
- p. 2-33, line 34: last sentence is garbled, needs to be reworded.
- p. 2-36, line 1: Section 2.4.5 should be Section 2.4.6
- p. s-63, line 29: I suggest adding 'different' after 'exhibit'
- p. 2-66, line 13: the reference to Section 2.5.1.1.6 is not right. I think this should be 2.3.2.2.
- p. 2-66, line 33: ...fate of the reactive...
- p. 2-68, line 21: 'geographic information system' is incorrect but I'm not sure what you mean to say here – maybe geographic coordinates?
- p. 2-73, Fig. 2-21: please update these trends. Data are complete through 2017.
- p. 2-73 line 5 and Fig. 2-22: This figure shows long-term trend in national monthly *mean and 90th percentile*... It does not show annual averages (same as Fig ES-2)
- p. 2-81, line 16: it looks like 6.5 should be -6.5.
- p. 2-87, line 16: Figure 2-18 shows the UFP daily maximums occurred during the afternoon, not evening. Also, I'm not sure that 3 sites in New York constitute 'diverse geographic locations'.
- p. 2-89, line 9: was -> were

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PREPARED BY:
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DATE
December 10, 2018

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CASAC advisory experience: Statutory CASAC: 2002-2007; PM NAAQS Review Panels: 2001-2006, 2008-2012, 2015-2018; Ozone NAAQS Review Panel: 2005-2008, 2010; Lead NAAQS Review Panels: 2006-2008, 2008-2013; SOx/NOx Secondary NAAQS Review Panels 2008-2011, 2015-present; Ambient Monitoring and Methods Subcommittee: 2004-2010.

Other scientific advisory experience: NARSTO External Review Panel "Rethinking NARSTO" 2008-2009; US EPA Council on Clean Air Compliance Analysis, and CCACA Atmospheric Modeling Subcommittee: 2009-2014; National Research Council, Board on Environmental Studies and Toxicology: 2010-2013; US EPA Science Advisory Board: 2013 - present.

Preface

P-3, lines 21-30: (or somewhere else up-front), You could provide a brief explanation for why particles > 10 microns are not currently regulated.

P-13, lines 11-17 (or top of P-14): Somewhere in this section you could mention what cutoff date was employed in the literature review (and what exceptions might be made and why).

Executive Summary

ES-4, line 23: This seems like an overly brief summarization of NCore - which also includes PM_{2.5} composition and continuous hourly (as well as 24-hr filter-based) measurements of PM_{2.5} and at many sites continuous PM_{10-2.5}.

ES-4, line 31: The reference to Figure 2-22 is OK (although the link-clicking reader of the e-document is transported to a distant new section of the report, from which it's tedious to return), while the same figure is reproduced as ES-2 on the next page (ES-5), which is otherwise not referred to in the text.

ES-4, lines 31-32: The observation that average PM_{2.5} has declined by 5 ug/m³ misses half the point of the figure - which shows that "both average and peak PM_{2.5} concentrations have declined by nearly half in the past 10 years."

ES-6, lines 4, 5: You could add "particle composition" to the list of factors influencing F_{inf}. For example, NH₄NO₃ does not persist indoors, as it rapidly dissociates to "sticky", gaseous NH₃ and HNO₃.

ES-6, line 18: You could add "and temporally" after "spatially".

ES-6, line 22 to ES-7, line 13: This summary of dosimetry refers qualitatively to fractions of particles in different size ranges entering, depositing and being retained in different regions of the lung, and also describes quantitatively (0.02% or less of 5 to 200 nm gold particles) of ultra-fines are taken up in the blood or organs. This may create a misleading impression that only 0.02% of ultra fine particles are relevant to effects. You could supplement this with quantitative estimates of fractions of coarse, fine and ultra-fine particles retained in the lung.

ES-14, line 6: "concludes" should be "conclude".

ES-14, lines 21-30: Here or elsewhere, when you complain about inadequacy of UF data, you might also comment on what efforts are underway to improve this - or what it would take...

ES-18 line 11: Change "amount" to "proportion". Sulfate decreases have generally been steepest, but concentrations of EC, OC and NO₃ have also declined in many regions. See for example

Ridley et al. (2018) Organic aerosol trends in the US, Proceedings of the National Academy of Sciences Jan 2018, 115 (2) 290-295; DOI:10.1073/pnas.1700387115.

Marais et al. (2017) Evidence of 1991–2013 decrease of biogenic secondary organic aerosol in response to SO₂ emission controls, *Environ. Res. Lett.* 12 054018.

Pusede et.al. (2016) On the effectiveness of nitrogen oxide reductions as a control over ammonium nitrate aerosol, *Atmos. Chem. Phys.*, 16, 2575–2596.

ES-18 lines 14-16: You could add something like “and through the effects of light-absorbing BC and mineral dust deposited on snow and ice.”

ES-20, line 12: Decide what your “key” findings are and state them. Don’t give “examples”.

ES-20 lines 15-21: These 2 sentences say more or less the same thing. The repeated phrase “continues to support” seems like a weak way to state this. Could you say something like “confirms and enhances” or “supports and builds upon”? Instead of saying “and in some cases strengthens and extends the evidence base for other health effects”, why not just list the (few) other effects for which new evidence strengthens/extends the evidence base?

ES-20, line 24: The phrase “inclusion of less urban areas” seems a bit vague. Do you mean “smaller urban areas”, “rural as well as urban areas”, “broader geographical regions”...? An important point that you don’t state clearly is that more recent studies substantially extend the geographical coverage of areas considered in epidemiological studies and where clear PM_{2.5} health effects have been observed.

ES-20, lines 29-34: These 2 bullets differ from others in that there’s no reference to recent studies. Is that the intent? In general, throughout the exec sum, it’s not always clear whether you’re talking about what’s new or what’s based on the cumulative body of knowledge. It might be helpful to break out separate sections on what’s been confirmed and what’s been enhanced or changed since the last review.

ES-21, lines 1, 2: It’s not clear if or how the phrase “with less certainty in the shape of the curve at lower concentrations (i.e., below about 8 µg/m³)” is intended to reflect new information. Is there less certainty now than there used to be, or has the concentration below which there is less certainty remained the same or decreased? A related point is there’s no mention of whether recent studies have more clearly indicated mortality or morbidity at levels below the current NAAQS.

Integrated Synthesis

1-1, 1st bullet: This “likely to be a causal relationship” for respiratory effects seems inconsistent with the previous page statement (ES-20, lines 15-21) that “**many recent studies** ... report consistent positive associations between short- and long-term PM_{2.5} exposure and **respiratory** and cardiovascular effects and mortality...(further supporting) **large body of previously published studies** reporting positive PM_{2.5} associations with **respiratory** and cardiovascular effects and mortality.”

1-1: This is a nice, tight summary of PM_{2.5} health effects (only). I like it better than the “key findings” in the Executive Summary. Notably, however, it omits any findings of (inconclusive) effects from other PM size fractions, and also omits findings of (strong, positive) associations between PM_{2.5} and welfare effects. Also missing is an answer to whether there’s any indication of PM health (or welfare) effects at levels below the current daily and/or annual standards.

1-1, last bullet: It’s interesting to see that the elderly are **not** identified as disproportionately at risk. Is this a change from the previous PM ISA?

1-5, line 6: I think you’ve got the time periods backwards here. It should say “decreased from a 3-year average of 12 µg/m³ for 2005-2007 to 8.6 µg/m³ for 2013–2015”.

1-7, lines 3-6: The “half-day to 3 day size growth period” and the “up to 1 km distance from roadways” seem inconsistent with each other (that’s a pretty low wind speed). Wouldn’t a higher deposition velocity for UFP vs. FP also contribute to the relatively short UFP transport distances?

1-9, lines 28-29: You could add “at night” to the list of satellite limitations - which would be more important for some species - like ammonium nitrate and SOA - than for other species.

1-10, lines 7-9: It’s a bit of a stretch to claim that sparse data preclude assessing trends in PM_{10-2.5} concentrations over time. There are certainly lots of long-term collocated PM₁₀ and PM_{2.5} sites (including the whole IMPROVE network) from which you could conduct a trends assessment. I think it would generally show that coarse mass hasn’t decreased much anywhere and has increased in some regions and seasons (in Spring in large sections of the West and in Summer/Fall in the central US).

1-10, line 13: This 17% to 20% reduction in average sulfate is notably smaller than the roughly 28% reduction in national average PM_{2.5} you cite (for a somewhat shorter time period) in the preceding paragraph. It would be informative to report trend info over consistent time periods, but it seems clear that declines in most other species have also contributed significantly to the overall PM_{2.5} decline.

1-10, lines 20-32 (and elsewhere): I think this discussion generally pertains to annual average PM_{2.5} patterns, rather than 24-hr. For example, I think most areas with current 24-hr design values > 35 ug/m³ are in the West (including, but not exclusively in) CA. It would be helpful to be clear about what averaging times you’re talking about. Shorter-duration peak (hourly) concentrations are also likely to be even more concentrated in western mountain valleys with more extreme topography/ stronger inversions.

1-11, lines 7-8: I agree this is true - but don’t think you can claim to know it and also blame (on preceding page) lack of data on an inability to describe about coarse particle patterns or trends.

1-11, lines 16-18: This seems like a lazy analysis. You have plenty of sites with collocated PM₁₀ and PM_{2.5} sampling that were operational for the past 10-15 years. Also, this makes me wonder what's the real value (other than to show general progress) of reporting national average patterns and trends - when regional differences are so great - and nobody's exposed to the national average of anything.

1-11, line 21: I think you could say "in the Spring or Summer". See for example:

Hand et al. (2017), Spatial and seasonal variability in fine mineral dust and coarse aerosol mass at remote sites across the United States, *J. Geophys. Res. Atmos.*, 122, 3080–3097.

1-11, lines 26-27: This seems like a non-sequitur to the preceding sentence. It tells nothing about space or time patterns. Also, you've previously emphasized that particle sizes captured by UFP samplers are highly dependent on instrumental specifics.

1-12, lines 14-15: Although it's likely that a majority of biological material would also be characterized as "organic matter" by current analytical methods. Conversely, what are the sources of coarse particle organic matter which are not biological material?

1-12, lines 25-34: In this summary of "natural" US background sources, you might include some mention of mixed natural and anthropogenic influences. For example, natural sea salt and dust, react with nitric acid to form NaNO₃ and CaNO₃ particles. "Biogenic" VOC emissions (which may be increased by climate changes) can be more efficiently converted to organic aerosols through reactions catalyzed by acidic sulfate and nitrate. Human disturbances of soil surfaces increases "natural" dust emissions. Anthropogenic influences on climate can increase frequency and severity of wildfires and dust storms...

1-13 to 1-16: The summary of recent advances in PM (primarily PM_{2.5}) exposure assessment is especially well done!

1-16, line 37 through 1-17, line 3: The first sentence of this paragraph refers to studies of health effects of PM species, but the following paragraph refers only to correlations between PM species and mass. The correlations with mass have minimal relevance to the species effects - other than as confounding factors. It would be more useful here to provide some examples from studies which have looked specifically at health effects from different PM_{2.5} species.

The phrase "The recent peer-reviewed literature showed ..." gives an impression that what follows is generally found in many/most recent studies which considered correlations between fine mass and PM species. Logically this would be true for major mass-contributing species, however, I would be surprised to see very high correlations between fine mass and V at many sites, nationwide. V and Ni are good tracers for emissions from residual oil combustion. This influence would be primarily limited to the Northeast urban corridor (winter-only), major marine ports, and sections of the Gulf

Coast. However, even in such locations, it would be very unlikely if residual oil combustion were the predominant source of PM_{2.5} mass. Possible confounding influences include high correlations between residual oil emissions and other space heating emissions (wood-burning, distillate oil, increased idling of gasoline & diesel vehicles) - all of which co-occur during periods of coldest temperatures - which also tend to be periods of low wind speeds and thermal inversions.

That being said, I think a number of recent studies have noted relatively strong associations between PM V and/or Ni and adverse health effects - stronger, in some cases than associations with PM_{2.5} mass. Also, I would have expected relatively strong (past) correlations between PM_{2.5} and Se (coal tracer), especially if seasonally adjusted to account for secondary SO₄. If that's no longer the case - and if V correlates better than Se with PM, that would be an important change in source influence.

1-21 through 1-23: The presentation of new (and older) evidence, plausibility, consistency, etc. for respiratory health effects is persuasive (and employs causality language similar to that used to describe cardiovascular effects). Yet respiratory effects remain only "likely to be causal". Could you add a clear statement on the reasons why respiratory effects are only "likely"? What, specifically, makes you doubt causality?

1-24, lines 12-15: This justification for causality finding for cardio effects is nearly identical to the justification for respiratory effects on p. 22, lines 1-4 (with different example effects). See previous comment.

1-33 through 1-39: Table 1.2 is an excellent, concise summary of health effects, with helpful links to more detailed text and tables in the relevant chapters. When summarizing effects from short-term exposures, would it be possible to present the range of short-term exposures at which effects were indicated (rather than, or in addition to the longer-term means) at which short term effects were observed?

1-57, Section 1.6.1: The discussion of visibility impairment is exceptionally brief, relative to other sections (and to the detail presented in chapter 13). One general criticism is that I think that the importance of PM speciation to light extinction is overemphasized - relative to the strength and functional utility of the relationship between (unspeciated) PM_{2.5} mass and light extinction. A very accurate assessment of PM effects on light extinction can be made from detailed measurements of PM species, size distributions and relative humidity. But an accurate assessment can also be made using PM_{2.5} mass measurements alone - which are available at more sites and with higher (hourly) time resolution than PM species data.

Its true (as stated on p 1-58, lines 3-4) that light extinction efficiencies (per unit mass) can vary by up to a factor of 10 among PM_{2.5} species. But this range from 1 m²/g (for fine soil) to 10 m²/g (for fine EC) describes the most extreme differences between the 2 smallest contributors to PM_{2.5} mass at most sites and seasons. Dry light extinction efficiencies for the major mass-contributing species are much more similar among species (3 m²/g for sulfates and nitrates and 4 m²/g for organics - in the "original

IMPROVE algorithm”). More complex ranges of extinction efficiencies, for lower and higher species concentrations are used in the new IMPROVE algorithm - but again these are quite similar for the major species: sulfates, nitrates and organics. Extinction efficiencies increase with RH for hygroscopic sulfates and nitrates, although the importance of these increases are minimized as S and N emissions decrease, and when considering daytime visibilities - at lower RH levels. Furthermore, an argument could be made that influence of “natural” RH variability should be removed from the regulatory metric. T A “generic” PM_{2.5} mass extinction efficiency of about 5 m²/g does an excellent job replicating actual light extinction levels, and could be applied to readily available hourly PM_{2.5} data.

The original 1971 secondary PM NAAQS, based primarily on visibility protection, used a PM mass indicator (TSP). Visibility-related secondary PM NAAQS considered by EPA Staff and CASAC in three subsequent PM NAAQS reviews (1987, 1997, 2006) all considered PM_{2.5} mass indicators - based on the very strong relationship to light extinction. The most recent PM NAAQS review completed in 2012 considered a more refined indicator of “PM light extinction” (with an hourly averaging time). Much of the early discussion and support of this indicator by EPA Staff and CASAC were based on an assumption that this would be measured directly (which it could have been by combination of nephelometer & Aethalometer - or more recently by cavity ring-down techniques). However, relatively late in the review process, it became clear that EPA lacked the resources (will) to develop, test, implement such a network. A “pilot network” to evaluate this approach was recommended by CASAC, but never implemented. Subsequently, a complex combination of hourly PM_{2.5} mass, RH data, and 24-hr every 3rd or 6th day PM_{2.5} speciation data was developed to estimate hourly, daytime PM_{2.5} light extinction.

While this is a feasible and reasonable calculation, I don’t think it necessarily represents a superior indicator to PM_{2.5} mass (combined with a generic PM_{2.5} mass extinction efficiency). The correlation between PM_{2.5} mass and light extinction is stronger than that between any criteria pollutant and any health or welfare effect, and hourly PM_{2.5} mass data are readily available in existing monitoring networks. It would also be beneficial for other reasons to place more scrutiny on the quality of hourly PM_{2.5} data.

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, 2018 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 b a relatively straightforward GIS exercise to

characterize distances to prominent landscape features in population centers throughout the country and then use PM_{2.5}-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 Molenaar (Molenaar 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.

Malm, W.C., Molenaar, J.V., Pitchford, M.L., Deck, L.B. (2011) Which visibility indicators best represent a population's preference for a level of visual air quality?, Paper 2011-A-596-AWMA, Air & Waste Management Assn. 104th Annual Conference, Orlando, FL, June 21-24, 2011.

Malm, W. C. (2016) Visibility: the seeing of near and distant landscape features, Elsevier, Inc., ISBN: 978-0-12-804450-6

Malm, W., B. Schichtel, J. Molenaar, A. Prenni, and M. Peters (2018). Which visibility indicators best represent a population's preference for a level of visual air quality?. *Journal of the Air & Waste Management Association*. 10.1080/10962247.2018.1506370.

Molenaar, J. V., & Malm, W. C. (2012). Effect of clouds on the perception of regional and urban haze. Paper presented at the Specialty Conference on Aerosol and Atmospheric Optics: Visibility and Air Pollution, Whitefish, MT.

WRITTEN STATEMENT

**Public Comment on the
CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter
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SUBMITTED TO

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General Comments

I believe the current External Review Draft of the PM ISA (ver Oct 2018) represents a coherent, comprehensive, and well-written report on the state-of-the-science regarding PM health effects. The EPA staff involved in preparing this draft deserve considerable credit for compiling and summarizing this body of evidence, which builds on our knowledge of exposure and risk associated with PM, since the previous 2009 document was published. I want to draw specific attention to areas within the current ISA that reflect the current state-of-the-science, including discussions involving susceptibility by disease co-morbidity and enhanced focus on pollutant infiltration as a key PM exposure factor and potential effect modifier of epidemiologic results.

- Based on the scientific evidence I've reviewed within this draft, I generally agree with the causality determination decisions proposed by EPA staff. An exception, however, relates to the decision to retain the 'likely to be causal' status for both short- and long-term PM exposure and corresponding respiratory health effect. The current ISA reviews hundreds of observational and controlled results suggesting casual links between PM2.5 and adverse acute and chronic respiratory response. In my reading of the ISA, I think 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.

Much of the decision to retain the 'likely to be causal' status, rather than revise to 'causal', seems to be based on the somewhat equivocal observational findings and the lack of a clear respiratory response in the few controlled studies. Clearly and not surprisingly, some heterogeneity in observed respiratory response is due to the corresponding chemical and physical complexity of PM, itself. Thus, expecting to see similar epidemiologic results for PM2.5, across studies, conducted in different

locales and seasons, with differing PM sources and compositions, is not, in my opinion, realistic, nor a major concern related to its causal relationship with these endpoints. Notably, this is not the case for the other single chemical NAAQS pollutants, such as NO₂, O₃, or CO, where I would expect greater homogeneity in observed response across studies.

I think it's also worth noting that the decision to change the causal determination status for the short-term NO₂ – acute respiratory effects relationship to causal was based on similar range of weight-of-evidence, where there was uncertainty in the epidemiologic results, but evidence from a controlled human exposure study (examining air responsiveness in asthmatics following chamber exposures to NO₂) that was deemed sufficient in establishing biological plausibility and causal determination.

- I have concerns about the weight given to results from two- or multi-pollutant epidemiologic models (co-pollutant models) in decisions related to causal determination status. Although I may have missed this in my review of the sections I read, I did not see any acknowledgement that co-pollutant models may have limitations in assessing potential confounding. 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. Modeling PM, or its co-pollutants, with higher order pollutant terms could be a more appropriate means of addressing confounding in these circumstances. What specifically are the implications for the observed epidemiologic results from improper modeling of confounding? Is bias likely to occur, or a lack of precision?
- 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. A key area of research, including major initiatives supported by EPA, have been undertaken since the last ISA to assess the effects of pollutant **mixtures**, using a range of statistical approaches including joint effects or effect modification settings. Despite this, the issues of the role of PM within a mixture receives scant attention in the current ISA draft (see sections 5.1.10.1.1 and 6.1.14.1.1, for example). I believe the recent scientific interest and attention to the issues of mixture, however uncertain the current findings may be at this time, warrant much greater attention in this ISA.

Comments on Integrated Synthesis

- While the discussion on differential PM infiltration from outdoors and its impact as a key exposure factor is important, this paragraph seems a bit disjointed within the Integrated Synthesis. A key (translational) understanding involving differential infiltration that is never really discussed explicitly throughout the ISA, is that a single PM NAAQS, promulgated and applied nationally, will not provide the same amount of protection by location or even by season within a location. I acknowledge that this is a difficult, and probably not an especially useful observation to make given the current process for setting standards, but it is the scientific basis for the epidemiologic analyses many of us have conducted examining infiltration as a potential effect measure modifier.

- See comment above related to PM within a pollutant mixture. I think a brief discussion on the state of mixture-related research should be mentioned in the Integrated Synthesis.

Comments on Chapter 3

- Page 3-6. Lines 1-2. The notion that epidemiologic studies use ambient monitors as surrogates of population exposures is still true, but less so since the last PM ISA. As evident from the current scientific literature on PM exposure and nicely detailed throughout Chapter 3, there has been substantial development in new methods for assigning PM exposure on both individual and population scales. These methods (e.g., satellite remote sensing, LUR, hierarchical and spatiotemporal models) have also been used widely in PM epidemiologic modeling. In light of this, I feel that this statement and parts of Section 3.2.2, in general, come off as being overstated and slightly outdated in reflecting the state of PM exposure science. Moreover, the heavy focus on ambient monitoring as an exposure surrogate slightly contradicts the opening sentences of Section 3.3.5, which appropriately note changes in how exposure assignment for PM is conducted today.
- I believe a major omission in throughout the ISA, but also within Chapter 3 is the virtual non-existent discussion of in-vehicle PM exposure or the importance of the commuting or in-vehicle microenvironment towards total daily exposure (Liu and Frey, 2011). It is also quite likely that exposure to extremely elevated PM levels ('exposure peaks') occur while in vehicle for many Americans. Full disclosure that I have in the past examined in-vehicle PM exposures within my research portfolio, and several papers from these studies cited throughout the ISA. Despite this, I'm very surprised by the virtual lack of attention paid to on-road sources of PM and corresponding in-vehicle exposures.

WRITTEN STATEMENT
**Public Comment on the
CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter
(External Review Draft – October 2018)**

PREPARED BY:
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Professor
University of Washington School of Public Health**

SUBMITTED TO
**Docket ID No. EPA-HQ-OAR-2018-0279
U.S. Environmental Protection Agency
Washington, DC**

DATE
December 10, 2018

Who I am and why I am commenting

As a biostatistician by training, my research focuses on better understanding of the health effects of environmental and occupational exposures, with particular emphasis on study design and exposure modeling. Much of my applied work has been in air pollution epidemiology studies, most recently the 10-year EPA-funded MESA Air study and now the ACT-AP study, cohort study of the effects of air pollution on cognitive decline, dementia, and Alzheimer's disease in the elderly. I served one term as a member of the chartered Clean Air Scientific Advisory Committee (CASAC) from October 2015 through October 2018. I have also been a member of multiple CASAC review panels, including: Ozone (2005-8 with some follow-ups in 2010 & 2011); NO_x and SO_x (2007-2010); NO_x (2013-2016); SO_x (2014-2018); and PM (2015 until it was disbanded in 2018). As a member of the chartered CASAC during 2018, I requested that the CASAC convene to discuss the May 9, 2018 "Back to basics" memo because I was concerned that the revisions to the process would not preserve the quality and integrity of the CASAC review. (See my July 1, 2018 comments to the chartered CASAC, appended.) This did not happen. Because I have profound concerns about the degradation of the scientific input to EPA in support of the Clean Air Act (CAA), I feel a responsibility to my fellow Americans to volunteer my time at this critical juncture to do what I can to speak up for the integrity of the scientific review process and ensure that the CAA does the job it is supposed to do, namely to protect the public health with an adequate margin of safety. The views I express below do not represent any official position of UW, EPA, or the CASAC.

Concerns about the CASAC review process and the proposed schedule: As I cover in more depth in my July 1, 2018 comments to CASAC on the "back to basics" memo, and now informed by additional developments in October 2018 that included disbanding the PM Review Panel, the revised process and proposed schedule will risk jeopardizing public health because:

- The new process threatens the quality and integrity of the external scientific review provided to EPA.
- There is a lack of breadth and depth of expertise on the chartered CASAC, or among any group of seven scientists, to accomplish the role mandated by the CAA. Not only does there need to be a diversity of disciplines represented, but there should also be multiple experts from each discipline in order to represent fully multiple scientific perspectives. The current review structure with only the seven chartered CASAC members conducting the full review suggests to me that the intent of CASAC's role, as mandated in the CAA, cannot be fulfilled. Of particular concern, the current review group has no epidemiologists, yet much of the most informative scientific evidence for the causal effects of PM relies on epidemiologic studies.
- The revised process is too rushed and creates new opportunities for inadequate reviews to be done.
- There is a lack of breadth and depth of expertise on the chartered CASAC, or among any group of seven scientists, to accomplish the role mandated by the CAA. Not only does there need to be a diversity of disciplines represented, but there should also be multiple experts from each discipline in order to represent fully multiple scientific perspectives. The current review structure with only the seven chartered CASAC members conducting the full review suggests to me that the intent of CASAC's role, as mandated in the CAA, cannot be fulfilled. Of particular concern, the current review group has no epidemiologists, yet much of the most informative scientific evidence for the causal effects of PM relies on epidemiologic studies.

Key points on the PM ISA:

Overall assessment: Overall the document is of high quality, well-organized, and clearly communicated. It reflects generally strong attention to previous CASAC panel comments and responsiveness by EPA staff. There is room to improve the document; I provide suggestions for only a few sections.

Additional overarching comments

- I reviewed Chapter 8 in depth, and incorporated into this review input from Rachel Shaffer and Gail Li. See our detailed comments on this chapter, appended. Overall the chapter is well done and reached reasonable causality conclusions that reflect the current state of the science.
- There are still some details in the exposure modeling section that warrant improvement. While I will not develop these comments here, comments I would provide if I were still a member of the PM Review Panel are consistent with comments I have previously provided CASAC on other ISAs, specifically NO_x, SO_x.
- The current framework for causal determinations used in the ISA has been well-vetted by CASAC and has stabilized over multiple reviews. However, there is room for more transparent communication of specific causal determinations in the ISA. That is where I suggest CASAC target their focus on improvement. The state of the science of causal inference methodology is insufficient to recommend replacing the ISA's approach to

causal determinations or for differently weighting studies used in the causal determinations based on a new criterion of how they apply causal inference methods.

Comments on Chapter 8 of the PM ISA External Review Draft

Lianne Sheppard, Rachel Shaffer, Gail Li

Overall assessment

While there are details that can and should be improved, overall the chapter was well done and we believe it reached reasonable causality conclusions. Although the following comments are written in first person, all of us contributed input into this document and we all agree on its content.

Cross-chapter and overarching comments

- Overall, the ISA does a good job of reviewing the growing evidence of the association between particulate matter and nervous system effects. EPA presents a balanced review of the data, communicating the strengths and uncertainties in the data. In particular, it is very helpful and important to document the apical endpoints even if the full mechanism/mode of action is not certain (as is done in the figures). This helps to drive future research to fill these gaps and is alignment with the weight of evidence criteria, which do not require full description of mechanism for causality determinations.
- Based on the preface to this ISA, it seems that *in vitro* evidence can be used in studies of biological plausibility. However, it does not seem like there is sufficient review of relevant *in vitro* studies. This could help fill in some of the mechanistic gaps where information is limited. Consistency for figures & tables
 - When possible, I would recommend using consistent language for what is inside the boxes across the different biological pathway figures in this section, so that they can be more easily compared (ie: if someone wanted to look at what is known for PM2.5 vs. PM10 vs. UFP?) Currently, there are difference in how some of the apical endpoints are written for each of the sections
 - I would also recommend consistency in the organization of the "summary of evidence" tables. For example, some of the tables have a subsection called "overall" while others do not.
- It is good that EPA has acknowledged and reviewed the growing evidence of the importance of the olfactory transport route for humans and animals in Chapter 4.
- All consolidated effect estimates figures: These are quite blurry in the document and difficult to read. The technology for including them in the document should be improved.
- All tables summarizing study characteristics:
 - It is helpful to have the consolidated summaries.
 - It would be helpful to have a more consistent understanding of how exposure was characterized across studies. The best descriptions include a reference to the paper where the exposure approach was published. It is difficult to tell how reasonable many of the exposure estimates are; this is important because the results are based upon these.

- While I hesitate to suggest changes that take away from the nuance of the reporting and results, I find that the list of endpoints examined without any prioritization does not optimally support my review of the evidence. What about adding a different font, e.g. boldface, for any endpoints discussed in the text
- It would be helpful to connect the biological pathways for the three exposures considered (PM_{2.5}, PM coarse, UFP) for short-term and long-term exposures, respectively. Currently they are presented as though they are distinct and unrelated. Indicating the coherence (or lack thereof) between them would facilitate understanding. While there may be more or less evidence supporting various pathways across the three size fractions of PM, the total number of potential pathways presumably don't vary by size fraction. In contrast, if there is reason to believe that a particular pathway is not active for a particular size fraction, this would be useful to call out. Would it be useful to present the biological pathway diagrams for short- and long-term PM at the beginning of the chapter, and then highlight parts of these where there is evidence for each size fraction?
- The summary tables (Tables 8-7, 8-20, 8-23, 8-26, 8-31, 8-38) appear to be missing a distinguishing marker on whether the components in the table up-weigh or down-weigh the association. For example, in Table 8-20 there is nothing to visually distinguish the "consistent evidence from multiple toxicological studies at relevant PM_{2.5} concentrations" from "limited toxicological evidence at relevant PM_{2.5} concentrations" Perhaps another column in the table to highlight whether evidence in this area contributes positively or negatively? (ex: simple up, down, or neutral arrows?)
- Is there another section of the document that considers the potential role of noise in the epidemiologic studies and reported associations?
- There are some additional references we suggest incorporating.
- The summary sections are a good synthesis of the emerging data.

8.1: Short term PM_{2.5} exposure & Nervous System Effects

- P 8-20 line 9: Should refer to section 8.2.9
- **8.1.4: Diseases of the Nervous System and Depression**
 - Additional references:
 - Gao, Q., et al. "Particulate matter air pollution associated with hospital admissions for mental disorders: A time-series study in Beijing, China." *European Psychiatry* 44 (2017): 68-75.
 - Casas, Lidia, et al. "Does air pollution trigger suicide? A case-crossover analysis of suicide deaths over the life span." *European journal of epidemiology* 32.11 (2017): 973-981.

8.2: Long term PM_{2.5} exposure & Nervous System Effects

- **8.2.1: Biological Plausibility**
 - There is not an adequate discussion of the role of oxidative stress as one of the potential pathways for PM_{2.5} effects on the CNS. Perhaps this can be considered part of the inflammation pathway? But, regardless, there should be more mention in this section, with follow-up in Section 8.2.3. The following papers can provide information on the topic:

- Heusinkveld, Harm J., et al. "Neurodegenerative and neurological disorders by small inhaled particles." *Neurotoxicology* 56 (2016): 94-106.
- Block, Michelle L., and Lilian Calderón-Garcidueñas. "Air pollution: mechanisms of neuroinflammation and CNS disease." *Trends in neurosciences* 32.9 (2009): 506-516.
- **Figure 8-2: Potential biological pathways for nervous system effects following long term PM2.5 exposure**
 - As noted above for the text, oxidative stress should be included on this figure
 - Very minor, but unclear as to why there are two separate boxes for "cognitive decrements and behavioral effects" and "cognitive issues; some APOE allele-dependent;" these could be combined for efficiency and clarity
 - The box for AD/PD, hospital admissions, and emergency department visits should be edited to clarify that they are AD/PD-related hospital admissions/ED visits, rather than hospital admissions related to other nervous system conditions
 - The following relationships could be added as pathways leading to cognitive decrements and behavioral effects as they are well established in the field of dementia and depression research generally. Blue boxes that should also lead to yellow "cognitive decrements and behavioral effects":
 - Elevated blood pressure (Li et al. , 2007); (Wang et al. , 2009).
 - Metabolic syndrome and myocardial infarction (Kivipelto et al. , 2005); (Crane et al. , 2013); (Gallagher et al. , 2016).
 - Activation of sympathetic nervous system (Rothman & Mattson, 2010); (Li et al. , 2006); (Wang et al. , 2013); (Alexopoulos, 2005).
- **8.2.3: Brain Inflammation and Oxidative Stress**
 - Additional references:
 - Guerra, R., et al. "Exposure to inhaled particulate matter activates early markers of oxidative stress, inflammation and unfolded protein response in rat striatum." *Toxicology letters* 222.2 (2013): 146-154.
 - Gerlofs-Nijland, Miriam E., et al. "Effect of prolonged exposure to diesel engine exhaust on proinflammatory markers in different regions of the rat brain." *Particle and fibre toxicology* 7.1 (2010): 1.
 - Levesque, Shannon, et al. "Air pollution & the brain: Subchronic diesel exhaust exposure causes neuroinflammation and elevates early markers of neurodegenerative disease." *Journal of neuroinflammation* 8.1 (2011): 105.
 - Campbell, Arezoo, et al. "Particulate matter induced enhancement of inflammatory markers in the brains of apolipoprotein E knockout mice." *Journal of nanoscience and nanotechnology* 9.8 (2009): 5099-5104.
 - Oppenheim, Hannah A., et al. "Exposure to vehicle emissions results in altered blood brain barrier permeability and expression of matrix metalloproteinases and tight junction proteins in mice." *Particle and fibre toxicology* 10.1 (2013): 62.

- Hullmann, Maja, et al. "Diesel engine exhaust accelerates plaque formation in a mouse model of Alzheimer's disease." *Particle and fibre toxicology* 14.1 (2017): 35.
- Later sections of the document (ex: section 8.2.6) reference this section as providing *in vivo* experimental evidence for the link between air pollution exposure and Alzheimer's Disease (AD)-like brain changes. However, it does not seem that there is sufficient coverage of this topic in this section itself, given that most of the text is just limited to discussion of inflammation and oxidative stress. I recommend that a short section on AD markers should be added, since animal studies on this topic are not covered in section 8.2.6. Alternatively, animal studies documenting AD-related brain changes could be discussed in section 8.2.6 with the analogous human studies. The references listed above could be included in a discussion on this topic. Relevant *in vitro* studies (or the ecological studies from Mexico) could also be included to provide evidence, given the limited studies in this area to date.
- **8.2.4: Morphologic Changes in the Brain**
 - Additional epidemiological study to include on the topic of morphological changes:
 - Power, Melinda C., et al. "The Association of Long-Term Exposure to Particulate Matter Air Pollution with Brain MRI Findings: The ARIC Study." *Environmental health perspectives* 126.2 (2018): 027009.
- **8.2.5: Cognitive and Behavioral Effects**
 - Minor point, but the figure legends for 8-3 and 8-4 are identical. These should be distinguished to provide more clarity for the reader
 - P 8-34, line 7: Sections refer to page numbers, not section headings.
 - P 8-35: Reporting of the Cacciottolo 2017 results state the exposure was binary, but Figure 8-3 and the related information in the supplement state the increment was 5 ug/m³ PM_{2.5}.
 - Figure 8-4: Consider changing the scale of the plot since the Weuve et al results appear to be 0 on this scale and the Shinkowski results are already uninformative on the plot at the current scale. More importantly, it is unclear that the estimates can be compared in this figure since they are for different tests that have different units. Better would be to convert all results to an index based on years of aging. This was reported in the text for the Weuve study (p 8-38) but not mentioned for the other studies. Also, based on reporting in S8-2, it does not appear that all results are indeed standardized to a 5 ug/m³ increment of PM_{2.5}.
 - Table 8-13 and related text: I don't think there is sufficient clarity on which analyses are cross-sectional and which are longitudinal. This makes it difficult to adequately compare the findings across studies. While some studies are purely cross-sectional and labeled as such (e.g. Altshire & Cummins, Altshire, Gatto, Schikowski), the longitudinal studies don't all seem to be addressing change over time. The text indicates some are looking acceleration in decline while others at incidence, prevalence, or even cross-sectional analyses. Based on the summarization in the

- document, it is not clear that all these results should be summarized in one figure (figure 8-4).
- Figure 8-5 calls the Kim et al 2016 cohort Medicare; it should be the Korean NHID.
 - Additional references on cognitive effects:
 - Salinas-Rodríguez, Aarón, et al. "Exposure to ambient PM 2.5 concentrations and cognitive function among older Mexican adults." *Environment international* 117 (2018): 1-9.
 - Tallon, Lindsay A., et al. "Cognitive impacts of ambient air pollution in the National Social Health and Aging Project (NSHAP) cohort." *Environment international* 104 (2017): 102-109.
 - Additional references for anxiety/depression/psychological distress:
 - Pun, Vivian C., Justin Manjourides, and Helen Suh. "Association of ambient air pollution with depressive and anxiety symptoms in older adults: results from the NSHAP study." *Environmental health perspectives* 125.3 (2016): 342-348.
 - Kioumourtzoglou, Marianthi-Anna, et al. "The association between air pollution and onset of depression among middle-aged and older women." *American journal of epidemiology* 185.9 (2017): 801-809.
 - Sass, Victoria, et al. "The effects of air pollution on individual psychological distress." *Health & place* 48 (2017): 72-79.
 - **8.2.6: Neurodegenerative Diseases**
 - Additional reference:
 - Carey, Iain M., et al. "Are noise and air pollution related to the incidence of dementia? A cohort study in London, England." *BMJ open* 8.9 (2018): e022404.
 - **8.2.8: Components and sources of PM2.5**
 - I don't think this subsection does an adequate job of distinguishing the different exposures in the different studies. I believe that the exposure assessment challenges are greater for sources (or mixtures) and components, but there does not appear to be any acknowledgement of this.
 - Table 8-19: It is unclear what all the exposures are in this table
 - **8.2.9: Summary & Causality Determination**
 - Good summary & synthesis of the emerging data
 - Some of the summary text in this section seems limited. For example, in the discussion of animal evidence of neuroinflammation, only hippocampus changes are reviewed, even though the associated table (8-20) describes effects on multiple brain regions. These could be briefly highlighted or at least alluded to in the text.
 - Organizationally, the ordering of Table 8-20 should mirror the discussion in this summary section.

8.4: Long term PM10-2.5 exposure & Nervous System Effects

- **Table 8-25:** This summarizes long-term coarse PM (PM_{10-2.5}) exposure effects. The exposure assessment column and means should make this clear within cells (if there are differences across studies) or in the headings.
- **8.4.3: Cognitive and Behavioral Effects in Adults**
 - Additional references:
 - Zhang, Xin, Xi Chen, and Xiaobo Zhang. "The impact of exposure to air pollution on cognitive performance." *Proceedings of the National Academy of Sciences* 115.37 (2018): 9193-9197.
 - Ranft, Ulrich, et al. "Long-term exposure to traffic-related particulate matter impairs cognitive function in the elderly." *Environmental research* 109.8 (2009): 1004-1011

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- ROTHMAN, S. M. & MATTSON, M. P. (2010). Adverse Stress, Hippocampal Networks, and Alzheimer's Disease. *Neuromolecular Medicine* **12**, 56-70.
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- WANG, L. Y., MURPHY, R. R., HANSCOM, B., LI, G., MILLARD, S. P., PETRIE, E. C., GALASKO, D. R., SIKKEMA, C., RASKIND, M. A., WILKINSON, C. W. & PESKIND, E. R. (2013). Cerebrospinal fluid norepinephrine and cognition in subjects across the adult age span. *Neurobiology of Aging* **34**, 2287-2292.

Comments on the Back-to-Basics Process for Reviewing NAAQS

Lianne Sheppard, PhD

Comments to chartered CASAC on July 1, 2018 with minor edits in advance of the PM ISA review December 12-13, 2018

Below I discuss topics that I believe need CASAC comment in response to the May 9, 2018 "back-to-basics" memo from Scott Pruitt. I shared these recommendations with the chartered

CASAC on July 1, 2018 and requested follow-up. In a September 4, 2018 email to the chartered CASAC, the CASAC Chair declined to follow up, indicating he did not think there was a need to develop a further response.

- **Structure of the current and revised NAAQS review process**

- I believe the current review process works well and that all the current separate steps are needed and useful.
- The current NAAQS process optimizes quality and assures that CASAC's feedback is integrated meaningfully.
- The proposed combined review for the ISA, REA, and PA will
 - Increase the workload for EPA and CASAC
 - Make it more difficult to separate scientific and policy considerations appropriately
 - Jeopardize quality and diminish the utility of CASAC feedback
- CASAC's role has always been to review EPA's work, not to generate content. The new process appears to be relying on CASAC to identify the key studies to be considered.

- **Content of reviews**

- It is essential that any NAAQS review process keep separate topics appropriate for reviewing and recommending NAAQS from those relevant to their implementation; the latter are not allowed during the standard setting process.
- I am not aware that CASAC has ever provided advice on implementation of the standards. I don't see how it is feasible or appropriate for CASAC to provide implementation guidance concurrently with NAAQS reviews.
- Regarding the new advice requested of CASAC: We need to prepare for this as I am unaware that CASAC has ever provided these new assessments.

- **Schedule**

- If the aim, as stated, is to adhere to the mandated review schedule for all criteria pollutants, then why is the ozone review being moved ahead of other criteria pollutants that were last reviewed prior to ozone?
- Conducting multiple reviews at the same time creates a significant new challenge for EPA and CASAC. This applies both to considering distinct pollutants concurrently and to combining the multiple reviews (i.e. of the ISA, REA, PA) for each pollutant.
- I suggest CASAC review and comment on the planned schedules for all criteria pollutant reviews. The PM review is already behind its previously published schedule.
- One way to streamline the process would be to increase EPA staffing to reduce the delay between the steps in the current process. Increased EPA staffing is much more likely to successfully compress the schedule than the proposed process of conducting multiple reviews (i.e. of the ISA, REA, and PA) simultaneously.

- **Charge questions:** I have concerns about the added value of the new standardized charge questions.

- I believe that in general charge questions should be tuned to the purpose of each document under consideration. For instance, charge questions on policy topics are premature during the Integrated Science Assessment review.

- There may be added value in proposing some new principles for charge questions that address the topics covered in the new standardized charge questions. With that in mind, the new standardized charge questions should be reconsidered and the guiding principles for the new questions should be less prescriptive. In particular, guidelines for standardized charge questions should ensure all charge questions
 - Are fit for purpose for the specific pollutant and document under review
 - Help focus CASAC's attention on the key considerations relevant to each specific review
 - Ensure questions of implementation do not become comingled with the scientific review
- **Workload:** The new process appears to considerably increase the workload of EPA and CASAC.
 - I believe that combining the ISA, REA, and PA documents into one review is unrealistic from a workload perspective and will be counterproductive to the goal of streamlining and speeding up the review process. The REA builds on the ISA; the PA builds on both the REA and ISA.
 - The overlap of the PM and O3 reviews is a workload challenge for EPA (and to a lesser degree CASAC), particularly given the size of the literature for these two pollutants.
 - In considering the new process's impact on CASAC's workload, we should distinguish between 1) new tasks that may not be the best use of CASAC's time and expertise and 2) the impact of a compressed schedule. While it could be appropriate to ask CASAC to step up to accommodate a compressed schedule, the addition of new tasks is a separate consideration.
- **Key overarching principles** that should be adhered to
 - EPA documents and CASAC's reviews should reflect the best current scientific information
 - Our focus is on protecting public health and the environment
 - The review process addresses an adequate margin of safety, as mandated by the Clean Air Act
 - CASAC's role is to conduct expert scientific review of EPA's work. While it is intended that CASAC will be constructed to have the breadth of expertise to identify key gaps and key studies, its role is not to be a primary source for comprehensively identifying the key studies and gaps to be considered by EPA.
 - The process for revising the NAAQS review process should be inclusive, with meaningful involvement of the public and EPA staff, as was done during the previous process overhaul (in the 2006-2009 time period).

In conclusion, I believe there are many important topics that CASAC should address in response to the May 9 revised NAAQS process memo. Before CASAC provides its official advice to EPA, there should be an opportunity for EPA and the public to provide input. Then the chartered CASAC should write a letter to the Administrator, with consensus and individual comments appended. This is the process CASAC has previously followed whenever it provided advice to the Administrator.

WRITTEN STATEMENT

**Public Comment on the
CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter
(External Review Draft – October 2018)**

PREPARED BY:

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SUBMITTED TO

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The ISA recognizes the increasing contribution of organic aerosol (OA) to PM_{2.5} and the substantial contribution of secondary organic aerosol (SOA) to OA. The contributions of biogenic volatile organic compounds (VOCs) and aromatic VOCs as precursors to SOA are recognized, including the importance of isoprene. Chapter 2 reviews the literature documenting the ways in which anthropogenic emissions play a role in the formation of SOA from biogenic VOCs. **However, the Executive Summary does not adequately acknowledge the substantial contributions of anthropogenic emissions to the formation of SOA from biogenic VOCs. This should be rectified.**

The Executive Summary does not explain that a substantial fraction of SOA formed from biogenic VOCs is controllable through reduction in anthropogenic emissions. The Executive Summary only conveys that: ““Compositional analyses have shown that organosulfates and organonitrates often account for a large fraction of SOA, up to 5–10% for organosulfates and up to 10–20% for organic nitrates ([Section 2.3.2.3](#)).”” Instead, these major points from Chapter 2 should be in the Executive Summary:

Several anthropogenic emissions play a role in the formation of SOA from biogenic VOCs. For example:

1. Model predictions suggest that more than 50% of biogenic SOA in the Eastern U.S. could be controlled by reducing anthropogenic NOX emissions. And,

2. SOA formed by acid-catalyzed reactions of isoprene epoxydiol, enabled by acidic sulfate (the IEPOX-SOA factor), accounted for one-third of organic aerosol measured in both urban and rural locations in the Southeastern US. (references below, and in 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.

OTHER COMMENTS

Page ES-6 line 4 and Page 1-16 line 4 (and Chapter 3): Infiltration factor also varies with PM composition. To some degree this is because different PM species have different size distributions, but also because outdoor-to-indoor transport alters the gas-particle partitioning of semi-volatile PM components.

Lunden, M.M., Revzan, K.L., Fischer, M.L., Thatcher, T.L., Littlejohn, D., Hering, S.V. and Brown, N.J., 2003. The transformation of outdoor ammonium nitrate aerosols in the indoor environment. *Atmospheric Environment*, 37(39-40), pp.5633-5644.

Hodas, N. and Turpin, B.J., 2014. Shifts in the gas-particle partitioning of ambient organics with transport into the indoor environment. *Aerosol Science and Technology*, 48(3), pp.271-281.

Meng, Q.Y., Turpin, B.J., Lee, J.H., Polidori, A., Weisel, C.P., Morandi, M., Colome, S., Zhang, J., Stock, T. and Winer, A., 2007. How does infiltration behavior modify the composition of ambient PM_{2.5} in indoor spaces? An analysis of RIOPA data. *Environmental science & technology*, 41(21), pp.7315-7321.

Page ES-6 Lines 6-12: These lines appear to discuss 2-3 studies that account for infiltration of PM indoors in the assessment of health effects from ambient PM_{2.5}. Studies such as these are important. I am concerned about the words: “simulating indoor concentrations produced unbiased health effect estimates.” This phrase seems to imply that the results of this one study should be prioritized over the body of work. I recommend changing the text to read: “studies such as these that simulate indoor concentrations of ambient PM_{2.5} produce health effect estimates unbiased by losses due to infiltration”

Page ES-20, Line 22: “New PM2.5 exposure assignment methods” should be “New PM2.5 exposure assessment methods”

Page 1-5 Line 5: “Ambient annual average PM2.5 concentrations in the U.S. on average were 3.4 $\mu\text{g}/\text{m}^3$ lower in the period from 2013–2015 than in the period from 2005–2007 decreased from a 3-year average of 12 $\mu\text{g}/\text{m}^3$ for 2013–2015 to 8.6 $\mu\text{g}/\text{m}^3$ for 2005–2007, continuing the downward trend in national ambient PM2.5 concentrations.”

This sentence is not correct. “2013-2015” and “2005-2007” should be switched, I believe.

Page 1-14, line 25 “Without accompanying geographic positioning system (GPS) or time-activity diary data, it is impossible to distinguish ambient PM exposure from exposure to PM of nonambient origin in these studies.” To clarify, change to “in personal monitoring studies”

WRITTEN STATEMENT

**Public Comment on the
CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter
(External Review Draft – October 2018)**

PREPARED BY:

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SUBMITTED TO

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DATE

December 10, 2018

General

The important changes since the 2009 ISA are:

- 1) cancer is now determined as likely to be causal (from suggestive, previously);
 - 2) nervous system effects from long-term exposure as likely to be causal;
 - 3) nervous system effects from long-term exposure to ultrafine PM as likely to be causal.
- Justification for all of these changes is well-supported in the ISA.

I very much liked the inclusion of tables in each section of this ISA that summarized explicitly the evidence and studies that were used in making the individual causal determinations.

I will focus on six specific issues.

1. PM and cancer.

Integrated Synthesis and Chapter 10.

In light of the recent 2013 International Agency for Research on Cancer (IARC) determination that the evidence was sufficient to designate outdoor air pollution, and PM in particular, a lung carcinogen, one wonders, understandably, why the ISA stopped short of agreeing with IARC. IARC is not known for making rash decisions regarding carcinogenicity.

Clearly, using the approach to determining causality in the ISA, it was concluded that the evidence did not quite support reaching a determination of causal. I frankly don't see much difference in the strength of evidence between PM and cancer and PM and cardiovascular disease, say, the latter being determined to be causally related to PM. One relative weakness in the lung cancer evidence is the sparsity of animal toxicological data, but that seems to be more than made up for by the evidence on PM and mutagenicity, other DNA damage and cytogenetic effects, as well as on PM composition which includes well-known carcinogens. Also, the volume of epidemiologic studies is less, but consistency of findings is comparable. The relative

sparsity of epidemiological studies assessing confounding by co-pollutants seems to have also played a role, but I don't believe there is much suspicion as to the carcinogenicity of non-PM co-pollutants, so this should not carry as much weight here as it does in assessment of other health outcomes. Regardless, if the "likely to be causal" determination for cancer is to be upheld, it would help to, in a nutshell, state what the issue was the precluded a determination of "causal" and why there was disagreement with the IARC assessment.

2. **PM and cardiovascular disease.**

Integrated Synthesis and Chapter 6.

The weighting of inconsistent evidence is challenging, especially for cases where a determination of "causal" has already been made, as in the case of long-term PM exposure and cardiovascular disease. Figure 6.19 (p. 6-189), which summarizes the epidemiologic evidence, would benefit from a column showing the number of deaths for each category that were used in the analyses, even though there is little space left for this. This would help in assessing the importance of some more recent cohort studies for which the findings are null. For example, findings from the large Canadian CanCHEC cohort study were null for ischemic heart disease (Weichenthal 2016a) as were those from the much smaller Health Professionals Follow-Up Study cohort of men (Pruett 2011) and those from the Trucking Industry Particle Study (Hart 2011). Parenthetically, findings from the latter study was characterized as showing "a modest positive association" (line 18, p. 6-188), whereas the findings were essentially null and should be characterized as such.

Also, some information presented in the Integrated Synthesis seems to be inconsistent with that reported in Chapter 6 and in the papers themselves. Specifically, in the Integrated Synthesis (p.1-26), it is stated that "recent analyses of other cohorts of women (i.e., Nurses' Health Study, California Teachers Study) that were comparable to WHI in that they considered menopausal status or hormone replacement therapy *did not show* [italics mine] consistent positive associations with CHD, myocardial infarction or stroke." My reading of these studies, and as described in Chapter 6, is that they in fact report positive associations with these outcomes, with the exception of myocardial infarction.

3. **PM (and ultrafine PM) and central nervous system (CNS) effects.**

Integrated Synthesis and Chapter 8.

Upgrading the evidence for CNS effects as "likely" to be causal is based largely on the toxicologic evidence, which is very convincing, although what epidemiological evidence that exists on cognitive function is largely supportive. The reports on changes in brain morphology in adults related to PM exposure are particularly notable. However, the characterization of the epidemiologic evidence on cognitive function as "consistent" in the Integrated Synthesis (line 25, p1-28) is a bit of a stretch at this point. See Figures 8.3 and 8.4 (pp. 8-37 through 8-39) for the basis of my hesitancy. The generally negative findings regarding cognitive function in children should also give us pause, although admittedly effects of chronic exposure might only be observable in adults. Again, in the Integrated Synthesis, I would quarrel with the use of "consistently observed" (line, p. 1-29) to characterize the findings from recent studies of long-term exposure to PM_{2.5} during the prenatal period and autism spectrum disorder (ASD). The basis for my point here is found in Section 8.2.7.2; the Guxens 2015 study, a negative study using cohorts, should be weighted more heavily than the case-control studies.

Regarding the evidence on ultrafine PM and CNS effects, again the toxicologic evidence is strong, as it was for PM generally. The one important epidemiologic study (Sunyer 2015), important partly because ultrafine concentrations were measured at the children's schools, provides observational support for the toxicologic results.

Overall, I agree with the causality determination of "likely" for PM/ultrafine PM and nervous system effects based on the strength of the toxicologic evidence, even though it is admittedly unusual to base this determination largely on toxicologic evidence.

Minor points:

Table 8.19 (p. 8-58). Since this is a source or PM component table, all of the descriptions of the studies should identify which components or sources were assessed.

4. PM and overall and cause-specific mortality.

Integrated Synthesis and Chapters 6 and 11.

In light of the emphasis in this round on low concentration effects, as would be expected, it would be helpful to include a section of chapters 6 (CVD) and 11 (mortality), especially, (and a paragraph or so in the Integrated Synthesis, section 1.5.3.2) dedicated solely to studies in which there was an analysis of effects only at concentrations approximately below the current standards, either from studies with restriction of concentrations used in the analyses within a study or from studies in which concentrations were low to begin with.

5. Children as a susceptible population

Integrated Synthesis and Chapters 5 and 12

Children and race were the only factors identified in the ISA for which there was "adequate evidence" of enhanced susceptibility (sections 12.5.1.1 and 12.5.4. I agree with this.

The issue of lung development in children has been a perennial issue for me, however. I had been concerned that spirometric measures of lung function in children did not distinguish between irreversible deficits in lung development or growth and reversible airways effects. I dispute the contention (line 29, p. 5-159) that "lung function measures capture the cumulative effects of pulmonary growth, damage, and repair (Wang et al., 1993). As such, measures of lung function are effective indicators of pulmonary health, and changes in lung function over time are indicative of lung development." An equally credible interpretation of all of the children's spirometric studies summarized in the Table 5-19 and Figure 5-28 is that what are being deemed developmental deficits (and identified as such in the table/figure titles) are in fact reversible airways effects. The animal toxicology studies from Brazil and China (section 5.2.2.1.2) provide some evidence that these effects are actually developmental deficits, but we need to await evidence in humans. Post-bronchodilator studies, for example, would go some way toward addressing this, as would studies of children who move out of more highly polluted areas.

There is an interesting statement in the Integrated Synthesis which I think is correct: "For children, although stratified analyses do not indicate a difference in the risk of PM-related health effects between children and adults, there is strong evidence from studies focusing on children demonstrating health effects that are only observable in growing children" (Integrated Synthesis, p. 1-55). This implies that effects that can only be investigated in a certain population can by itself identify a susceptible population, which I think is largely correct. This also applies to studies of adult CVD and respiratory disease (see issue #6, below).

Regarding asthma, according to the ISA the observational evidence for development of asthma in children has become stronger since the previous ISA, while the evidence for asthma in adults continues to be weak. I agree.

6. Other susceptible populations

Integrated Synthesis and Chapters 5 and 12

In the Integrated Synthesis (p. 1-56) and elsewhere, it is concluded that there is "*suggestive evidence*" that populations with pre-existing cardiovascular (Section 12.3.1) or respiratory (Section 12.3.5) disease are especially susceptible. I find this odd in light of the statement in the third paragraph of #5, above, which would suggest that the evidence with respect to these populations would be "adequate." For example, it is stated that "it is important to note that epidemiologic studies, particularly those studies examining short-term PM_{2.5} exposure and asthma or COPD emergency department visits and hospital admissions report generally consistent positive associations (Section 5.1.2.1 and Section 5.1.4.1), which represent exacerbations that are only possible in people with asthma or COPD" (line 18, p. 1-56). This to me would indicate that these populations should be identified as being more susceptible. The same can be said for populations with underlying CVD for which studies of many endpoints are only possible in those with pre-existing CVD.

On the other hand, I was very pleased to see that evidence regarding "older lifestage" was finally characterized correctly, rather than simply, in a knee jerk manner, repeating the litany of "young children, *the elderly*, pregnant women and those with pre-existing disease" as being susceptible populations. The evidence regarding the elderly being particularly susceptible is now characterized as "inadequate evidence," (Section 12.5.1.2), which I agree with.

Minor points

As a bit of an aside, I am often troubled by the overly liberal use of "consistent" in many sections. At some point, EPA will need to grapple with what level of consistency of findings merits that description, rather than simply aping usage that pervades the literature as a whole. See issue #3, above, for a few examples.

Integrated Synthesis:

Table 1-2. It is not exactly clear what the PM concentration ranges refer to in the epidemiological studies. Are these ranges of mean concentrations across studies? If so, the relevance and utility are questionable.

p. 1-58. It is stated that "due to these radiative effects, the net effect of PM has been to cool the planet over the last century, masking some of the effects of greenhouse gases on warming." I know that in Section 13.3.3 there is discussion of the warming effect of some particles, namely, black carbon. The above statement makes it seem that particles have only a cooling effect. I would add "..., masking some of the effects of greenhouse gases *and of some particles* on warming."