March 27, 2019

Louis Anthony (Tony) Cox, Jr., Ph.D.
President, Cox Associates
Denver, CO 82018
and
Chair, Clean Air Scientific Advisory Committee
U.S. Environmental Protection Agency
Washington, DC 20460

Subject: 03-07-19 Draft 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) and its augmented panels, including the Particulate Matter Review Panel that was dismissed without notice by press release on October 10, 2018. This letter represents our consensus. This letter is a follow-on to two previous letters submitted to CASAC, one submitted by members of the former CASAC Ozone Review Panel on November 26, 2018 and one submitted by members of the disbanded CASAC Particulate Matter Review Panel on December 10, 2018.[1],[2] Each of these prior letters included key findings and recommendations. In this letter, we restate and reaffirm key findings and recommendations of the prior letters. In addition, we provide findings and recommendations regarding the current review by CASAC of EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018). Hereafter, we refer to the EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018) as the "Draft ISA."

We restate and reaffirm the key findings in Table 1, as given in Table 1 of the December 10, 2018 letter, and we restate and reaffirm the key recommendations in Table 2, as given in Table 2 of the December 10, 2018 letter. Detailed explanations of the basis for each finding and

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

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

Table 1. Major Findings from December 10, 2018 Letter from Members of the Disbanded CASAC PM Review Panel to CASAC.[3]

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.

(CONTINUED ON NEXT PAGE)

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

Table 1. Continued.

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 from December 10, 2018 Letter from Members of the Disbanded CASAC PM Review Panel to CASAC.[4]

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 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 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.

Continued on next page

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

Table 2. Recommendations, Continued

Recommendation 7: We remind the 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.

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 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.

Continued on next page

Table 2. Recommendations, Continued

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.

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.

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Table 2. Recommendations, Continued

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.

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.

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Table 2. Recommendations, Continued

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

Recommendation 29: The causal framework as stated in the Preamble to the ISAs should be retained in this review cycle because the current state of the science of causal inference methodology needs further development before it can be used to modify or replace the ISA's approach to making causal determinations, or for differently weighting studies used in the causal determinations based on new criteria.

Recommendation 30: The existing causal framework should be consistently and transparently applied.

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.

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Table 2. Recommendations, Continued

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.

recommendation can be found in the December 10, 2018 letter. We recommend that the CASAC incorporate these Key Findings and Key Recommendations into their letter to the Administrator regarding CASAC's Review of the Draft ISA. We find that neither the EPA nor CASAC has adequately addressed the key findings and recommendations from these prior letters, and that both EPA and CASAC have ignored many of the key findings and recommendations. The key findings and recommendations constitute a public record that both EPA and CASAC have been apprised of deficiencies created by recent changes to the NAAQS review process and to the CASAC itself. Adoption of these recommendations is critical to restoring the quality, credibility, and integrity of the National Ambient Air Quality Standard (NAAQS) scientific review process and of the CASAC as an advisory body.

In addition to the key findings and recommendations provided to EPA and CASAC on December 10, 2018, we have the following key findings that are based on the December 12-13, 2018 public meeting of CASAC, minutes of that meeting, and CASAC's draft letter to the Administrator released for public review on March 7, 2019. We organize these findings and recommendations into "process issues" and "science issues."

With regard to process issues:

- Procedurally, CASAC reviewed and agreed to the plan for how the Draft ISA should be developed in 2016 when it reviewed the Integrated Review Plan for the current review cycle. Thus, CASAC has already signed off on the methodological approach for elements of the Draft ISA such as literature review, causal determination, assessment of at risk populations and life stages. It is inappropriate for CASAC to attempt to change the ground rules after-the-fact.
- The Clean Air Act specifically states that EPA must address "air pollution which may reasonably be anticipated to endanger public health or welfare" when setting a NAAQS. This means that neither EPA nor CASAC require complete scientific certainty to offer judgments regarding such effects. The policy and decision context of the science review is set forth by Congress in the Clean Air Act, as interpreted by Federal courts, and is not amenable to ad hoc redefinition by CASAC or its chair. It is not appropriate for the chair or others on CASAC to attempt to redefine the decision and policy context.
- CASAC must deliberate publicly on all points that it wants to include in its letter and consensus response. Simply because one member may have mentioned a point at a public meeting does not constitute deliberation of that point. Points not mentioned public are not allowable in the letter. Points that are not a consensus of the CASAC should not be implied to represent unanimous agreement of the entire CASAC.
- Despite extensive public comments and CASAC's own admissions, the CASAC continues to lack the breadth, depth, and diversity of expertise needed to review the Draft ISA. Thus, CASAC is not qualified to conduct a comprehensive review.
- The disbanding of the CASAC PM Review panel by then Acting Administrator Wheeler was arbitrary and capricious. Based on four decades of precedent and its charter with

Congress, CASAC may be augmented by expert review panels. Contrary to implications of claims by EPA administrative officials, the use of augmented expert review panels is not contrary to the Clean Air Act. The panels have always reported via the CASAC, not directly to the EPA, as per CASAC's Charter with Congress. EPA should reinstate the disbanded CASAC PM Review Panel.

- Because of excessive turnover, the current CASAC is inexperienced. Two of its members were appointed in 2017 and five were appointed in 2018. None have prior experience on the chartered CASAC, including the chair. As a result of inexperience, this CASAC has demonstrated numerous deficiencies, such as lack of familiarity with the statutory mandate and context of the review, earlier steps in the review process, and proper operation of a FACA committee.
- All members of CASAC should read the Integrated Review Plan for the current review cycle. All members of CASAC should read Sections 108 and 109 of the Clean Air Act. CASAC should obtain advice from EPA's Office of General Counsel regarding implications of this statutory language for the scope of CASAC's work and the policy-relevant decision context of the review.
- The science review process in prior EPA documents and CASAC reports has demonstrably been based on thorough systematic reviews of relevant scientific literature. Furthermore, such reviews have been proven to be relevant because they have informed policy decisions that have survived judicial review. Criteria (ground rules) for the reviews have been clearly stated taking into account operational practicality and that the ISA deals with a broad range of scientific disciplines and heterogeneity in the characteristics of policy-relevant studies. There is an explicit role for expert judgment in this process.
- These and other procedural points are also addressed in individual comments submitted separately by members of this group.

Science Issues

- The framework for causal determination, including terminology, and the overall plan for development of the ISA, was reviewed by CASAC in 2016.
- While there may be some opportunities to clarify or refine definitions of some terminology, it is simply not the case, as stated in CASAC's draft letter, that the Draft ISA lacks explicitly stated principles for drawing conclusions or lacks operational definitions. For example, the various considerations in developing causal determinations are explained in the Preamble to the ISAs and have been considered already in CASAC's review of the Draft Integrated Review Plan. The terminology for this framework has existed for many years and has been widely vetted and applied operationally for many years. While there may be opportunities for EPA staff to improve the clarity and transparency of the explanations of the inferences it makes and the conclusions it draws, this is not a fundamental limitation of the underlying framework but rather a

matter of routine scientific review and iteration to improve the clarity and transparency of the final document.

- Many of the statements in CASAC's draft letter are factually incorrect. For example, it is simply not true that the ISA is not a scientific document, nor is it true that all of the key references cited by the ISA are not scientific.
- The current CASAC is unqualified to deliberate on interpretation of epidemiologic studies given that it lacks adequate depth and diversity of epidemiologic expertise. The CASAC PM Review Panel that contained this and other relevant expertise was arbitrarily and capriciously disbanded. The language in CASAC's draft letter about potential concerns regarding the use of experts was not deliberated and thus does not belong in the letter, but is ironic given that CASAC had access to a much larger group of experts as embodied by the CASAC PM Review Panel.
- While systematic review is relatively well-developed in fields that are based on controlled studies, such as toxicology, its application to fields that are based on observational studies, as is the case in air pollution epidemiology, is evolving and not fully mature. It would be premature to impose scoring systems for study quality and strict rules for how studies should be interpreted given that observational studies typically have various strengths and limitations that derive from their study design, time periods, study populations, averaging times, lag times, confounders, effect modifiers, and so on. Whether a particular study is informative or not also depends on its context relative to other studies (i.e. a given study may address deficiencies that are characteristic of other studies, although itself may have other deficiencies).
- Prior CASACs and CASAC review panels have looked at the overall body of evidence, including discordant and apparently contradictory studies. However, it is inappropriate to over-emphasize or exclusively focus on discordant results and ignore the overall preponderance of the evidence when making inferences.
- There is an explicit role for expert judgment in CASAC as implied by language in the Clean Air Act (i.e. to address "air pollution which may reasonably be anticipated to endanger public health or welfare"). Claims that some methodologies are "objective" and others are "subjective" are based on a false dichotomy. The choice of what data sets to analyze, the choice of what analysis methods to use, and how to make inferences all require judgment.
- A Draft ISA that reviews 2,800 references, most new since the 2009 ISA, can hardly be described as not comprehensive. CASAC's draft letter implies that EPA overlooked 14 HEI accountability studies and perhaps a "dozen" studies on inflammasomes. Even if true, this hardly indicates that EPA staff did not conduct a comprehensive review. CASAC has failed to establish that the omitted studies are policy relevant (per the ground rules of the Integrated Review Plan and the Preamble to the ISAs) and, even if policy-relevant, that they are "important." This and other language in CASAC's draft letter is inaccurate and not based on consensus from public deliberations.

- These and other scientific points are also addressed in individual comments submitted separately by members of this group.

We commend EPA staff for development of an excellent first draft of the ISA that provides comprehensive and systematic assessment of the available science relevant to understanding the health impacts of exposure to particulate matter. We recognize that the 1800+ page Draft ISA cites over 2,800 references, most of them new since the last review cycle. The Draft ISA follows methods previously reviewed by CASAC, including the approach to literature review, the causal determination framework, the framework for assessing at risk populations and life stages, and assessment of concentration-response functions, consistent with the Preamble to the ISAs and the 2016 Integrated Review Plan for the current review cycle. However, as with any first draft, revisions are appropriate. For example, we recommend that EPA staff consider a list of accountability studies recently provided by HEI with respect to policy-relevance appropriateness for inclusion in the iSA and, if policy relevant and appropriate, assess their importance.

We find that EPA staff have followed the framework for causal determination that has been developed over the last decade. This framework is similar to that from other agencies and has been reviewed by over 60 experts on CASAC and its review panels. This is a well-established, accepted, and appropriate practical approach that is based on integrative consideration of evidence across various disciplines such as toxicology, controlled human studies, and epidemiology. There is explicitly a role for expert judgment in this process. Given the important role of expert judgment, it is also important that the ISA explain as clearly and transparently as possible the basis for judgments regarding causal determination. As an example, more transparency is needed regarding the causal determination for UFPs and central nervous system effects.

We note that the ISA takes into account poverty, temperature, and season, including lags related to temperature, and makes inferences regarding whether ambient PM concentration independently causes adverse effects and whether concentration and response relationships are either confounded or modified by other variables. Some of these inferences could be explained more clearly or in more detail.

At its December 2018 meeting, CASAC received extensive public comments regarding the decision by EPA to disband the CASAC PM Review Panel just days before the Draft ISA was released for review by CASAC. For four decades, and consistent with its Charter, CASAC has been augmented with additional experts in the form of review panels. These panels report through the chartered CASAC. Thus, CASAC is the body, as mandated by statute, that provides advice to EPA, not any of its panels. Nonetheless, the panels are critical to providing CASAC with the breadth and depth of expertise, and diversity of perspectives, required to meet the statutory mandate of the Clean Air Act for a review that "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" for pollutants that "cause or contribute to air pollution which may

reasonably be anticipated to endanger public health or welfare." Therefore, we recommend that the CASAC PM Review Panel be re-instated in time for the panel to augment CASAC for the review of the Second External Review Draft of the ISA and subsequent documents in this review cycle.

Consistent with the statutory mandate of the Clean Air Act, the EPA and the CASAC must consider the wide ranging kind and extent of possible health effects that may accrue from exposure to criteria air pollutants. Although a portion of the scientific evidence can be established with a high degree of confidence and certainty, in other cases the Clean Air Act asks EPA and CASAC to make judgments for situations in which the science is incomplete. Thus, inevitably, portions of the Draft ISA rest on expert judgments. Such judgments should be explained so that scientific readers can understand the scientific evidence and inferences from which EPA staff reach their conclusions, as clearly and transparently as reasonably possible. CASAC is currently poorly positioned to provide expert judgment because it has been deprived of the CASAC PM Review Panel. A key tenet of development of scientific expert judgment is to share information among a diverse group of experts across disciplines and to have diversity of opinion of multiple experts in key disciplines. Thus, EPA should reinstate the CASAC PM Review Panel.

We recommend development of a Second Draft ISA for CASAC review. CASAC should be augmented with additional experts by reinstating the disbanded CASAC PM Review Panel prior to reviewing the Second External Review Draft of the ISA and prior to reviewing any other EPA assessment documents in this review cycle.

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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Chartered CASAC: Member 2008-2012, Chair 2012-2015
CASAC PM Review Panel: Member 2007-2010, 2015-2018
CASAC Ozone Review Panel: Member 2009-2012, Chair, 2012-2014
CASAC Sulfur Oxides Review Panel: Member 2008-2009, 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2008-2009, Chair 2013-2015, Member 2015-2017
CASAC Lead Review Panel: Chair 2011-2013
SO_x/NO_x Secondary Standard Review Panel: Member 2009-2011

CASAC Carbon Monoxide Review Panel: Member 2008-2010

/signed/

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Chartered CASAC: Member 2011-14, Chair 2015-17
CASAC PM Panel: Chair 2015-17

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Chartered CASAC: Member 2010-2016
CASAC PM Review Panel: Member 2015-2018
CASAC Ozone Review Panel: Member 2009-2014
CASAC Sulfur Oxides Review Panel: Member 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2013-2017
CASAC Lead Review Panel: Member 2011-2013
CASAC Ambient Air Monitoring and Methods Subcommittee: Member, 2005-2010, Chair, 2011-2014

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CASAC PM Review Panel: Member 2015-2018
CASAC Ozone Review Panel: Member 2006-2008
CASAC Sulfur Oxides Review Panel: Member 2007-2009, 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2008-2009

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Chartered CASAC: Member 2015-2018
CASAC PM Review Panel: Member 2015-2018
CASAC Secondary NAAQS for Oxides of Nitrogen and Sulfur Review Panel: Member 2015-2017
CASAC Sulfur Oxides Review Panel: Member 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2016-2018
CASAC Ambient Air Monitoring and Methods Subcommittee: Member 2004-2010
CASAC Ambient Air Monitoring and Measurements Subcommittee: Member 2011-2018

/signed/

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CASAC Oxides of Nitrogen Review Panel: Member 2013-2017

/signed/

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College of Veterinary Medicine
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East Lansing, MI 48864

Chartered CASAC: Member 2012-2018
CASAC PM Review Panel: Member 2015-2018
CASAC Ozone Review Panel: Member 2009-2014
CASAC Sulfur Oxides Review Panel: Member 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2013-2017

/signed/

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Professor
Departments of Environmental & Occupational Health Sciences, Medicine, and Epidemiology
University of Washington

CASAC PM Review Panel: Member 2015-2018
CASAC CO Review Panel: Member 2009 - 2010
CASAC Oxides of Nitrogen Review Panel: Member 2013 - 2017

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Donna M. Kenski, Ph.D.
Adjunct Associate Professor
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CASAC Member: 2016-2017, 2007-2010
CASAC PM Review Panel: Member 2007-2010, 2016-2017
CASAC Sulfur Oxides Review Panel: Member 2016-2018, 2007-2008
CASAC Secondary SOx/NOx/PM Review Panel: Member 2016-2018
CASAC Secondary SOx/NOx Review Panel: Member 2007-2010
CASAC Lead Review Panel: Member 2007
CASAC Oxides of Nitrogen Review Panel: Member 2008-2009
CASAC Ambient Air Monitoring and Methods Subcommittee: Pb FRM, Ozone monitoring consultations

/signed/

Michael Kleinman, Ph.D.
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CASAC PM Review Panel: Member 2007-2010, 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2013-2015
CASAC Carbon Monoxide Review Panel: Member 2008-2010

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University of Southern California
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CASAC PM Review Panel: Member 2015-2018

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Richard L. Poirot, B.A.
Consultant (formerly Air Quality Planner/ Planning Chief, Air Quality and Climate Division, Department of Environmental Conservation, VT Agency of Natural Resources, 1978-2015).

Chartered CASAC: Member2002-2007
CASAC PM Review Panels: Member 2001-2006, 2008-2012, 2015-2018
CASAC Ozone Review Panel: 2005-2008, 2010
CASAC Lead Review Panels: Member 2006-2008, 2008-2013
CASAC SO_x/NO_x Secondary Review Panels: Member 2008-2011, 2015-present
CASAC Ambient Air Monitoring and Methods Subcommittee: Member 2004-2010

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CASAC PM Review Panel: Member 2016-2018
CASAC Oxides of Nitrogen Review Panel: Member 2013-2015

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Seattle, WA

Chartered CASAC: Member 2015-2018
CASAC PM Review Panel: Member 2015-2018
CASAC Ozone Review Panel: Member 2005-2008, 2010, 2011
CASAC Sulfur Oxides Review Panel: Member 2007-2010, 2014-2018
CASAC Oxides of Nitrogen Review Panel: Member 2007-2010, 2013-2017, Chair 2016-2017

/signed/

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University of North Carolina at Chapel Hill

CASAC PM Review Panel: Member 2015-2018

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CASAC member: 1997-2003
CASAC PM and ozone panels: 2004-2018