

Public Comment on the

**CASAC Review of EPA's Policy Assessment for the Review of the
National Ambient Air Quality Standards for Particulate Matter
(External Review Draft – September 2019)**

**The NAAQS PM Science Review Process is
Broken and Not Credible:
EPA Should Start Over**

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Biosketch

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Dr. Frey served as a member (2008-2012) and chair (2012-2015) of the U.S. Environmental Protection Agency's Clean Air Scientific Advisory Committee (CASAC), has chaired CASAC Review Panels on Lead, Nitrogen Dioxide, and Ozone, and has served on CASAC Review Panels for all criteria pollutants include Lead, Nitrogen Dioxide, Ozone, Carbon Monoxide, Particulate Matter, and Sulfur Oxides. He served on the U.S. EPA Science Advisory Board from 2012 to 2018. For the National Greenhouse Gas Inventory Program of the Intergovernmental Panel on Climate Change (IPCC), he served as an expert and Lead Author for the chapter on uncertainties for the 2006 IPCC Guidelines on National Greenhouse Gas Emission Inventories, and in 2016 was an invited expert regarding updates to the 2006 Guidelines. Additionally, he was a technical contributor to the U.S. Department of Transportation's 2010 Report to Congress regarding Transportation's Role in Reducing U.S. Greenhouse Gas Emissions. He served on a World Health Organization working group that developed guidance on uncertainty in exposure assessment (2006). He served on two National Research Council (NRC) committees and was a member (2009-2012) of the NRC Board of Environmental Studies and Toxicology. He currently serves on the MOVES Model Review Work Group of the Mobile Sources Technical Review Subcommittee of the EPA Clean Air Act Advisory Committee (CAAAC).

In the last two years, Dr. Frey has been the principal investigator of research grants and research contracts at North Carolina State University sponsored by the North Carolina Department of Transportation, the U.S. Environmental Protection Agency via the Health Effects Institute and Eastern Research Group, and the Urban Air Initiative. Dr. Frey's research work at HKUST is funded by the HSBC 150th Anniversary Charity Programme. Dr. Frey has also conducted work for the Hong Kong Environmental Protection Department. Dr. Frey's current affiliations include serving as a member of the Transportation and Air Quality (ADC20) Committee of the Transportation Research Board, and as a member of the Publications Committee and the Critical Review Committee of the Air & Waste Management Association (A&WMA)

Dr. Frey is a Fellow of the Air & Waste Management Association (A&WMA) and of the Society for Risk Analysis (SRA), served on the A&WMA Board of Directors (2015-2018), and was President of SRA in 2006. He received the Chauncey Starr Award from SRA in 1999, the Lyman A. Ripperton Award from A&WMA in 2012, and the Frank A. Chambers Award from A&WMA in 2019. He has a B.S. in mechanical engineering from the University of Virginia, a master of engineering in mechanical engineering from Carnegie Mellon University, and Ph.D. in engineering and public policy from Carnegie Mellon.

Introduction

I was a member of the chartered CASAC during 2008-2012 and chair of CASAC during 2012-2015. I served on the CASAC PM Review Panel as a member during 2007-2010 in the review cycle that culminated in the 2012 revision of the PM National Ambient Air Quality Standard (NAAQS). I served on the CASAC PM Review Panel that was appointed in 2015 for the current review cycle but arbitrarily and capriciously disbanded by EPA Administrator Wheeler on October 10, 2018, just five days before the draft Integrated Science Assessment (ISA) for particulate matter was released for external review.

I was a member of the CASAC Ozone Review Panel during 2009-2012 and chair of that panel during 2012-2014. I served as a member of CASAC Sulfur Oxides Review Panels during 2008-2009 and 2015-2018. I was a member of the CASAC Oxides of Nitrogen Review Panels during 2008-2009 and 2015-2017, and chaired the most recent panel during 2013-2015. I was chair of the CASAC Lead Review Panel during 2011-2013. I served as a member of the SO_x/NO_x Secondary Standard Review Panel during 2009-2011. I served as a member of the CASAC Carbon Monoxide Review Panel during 2008-2010. Thus, I have extensive experience with CASAC, CASAC's augmented review panels and the NAAQS review process.

I was closely involved in the current PM NAAQS review as a member of the now-disbanded CASAC PM Review Panel, and, since the panel was disbanded, as an observer of the EPA CASAC, as a public reviewer of the draft Integrated Science Assessment and draft Policy Assessments in this review cycle, as a member of the Independent Particulate Matter Review Panel formed by members of the disbanded CASAC PM Review Panel, and as chair of the IPMRP during its recent October 10-11, 2019 and October 18, 2019 meetings.

As a member of the CASAC PM Review Panel in the current review cycle, I participated in public meetings on May 23, 2016, and August 9, 2016 of the CASAC and the CASAC PM Review Panel to develop advice on the Integrated Review Plan for Particulate Matter.¹

I attended, in person, the December 12-13, 2018 meeting of the chartered CASAC in Crystal City, VA regarding the draft Integrated Science Assessment (ISA) for particulate matter. This meeting occurred after CASAC was stripped of the CASAC PM Review Panel. I delivered written and oral comments on behalf of myself and on behalf of the Independent Particulate Matter Review Panel, which was formed by members of the disbanded CASAC PM Review Panel.^{2,3} I delivered written and oral public comments at the March 28, 2019 meeting of the

¹ Diez Roux, A., CASAC Review of the EPA's Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016), EPA-CASAC-16-003, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, August 31, 2016.

² Frey, H.C., "[Public Comment on the CASAC Review of EPA's Integrated Science Assessment for Particulate Matter \(External Review Draft – October 2018\)](#)," Presented orally on December 12, 2018, Meeting of the EPA Clean Air Scientific Advisory Committee, Crystal City, VA

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.

chartered CASAC regarding its quality review of its draft letter to EPA on the draft ISA,^{4,5} and also delivered comments on behalf of the IPRPM.⁶ At CASAC's October 22, 2019 teleconference, I delivered the written October 22, 2019 report of the IPMRP on EPA's draft Policy Assessment (PA) for particulate matter and oral comments based on the IPMRP's report.^{7,8} I attended, in person, CASAC's meeting on October 24, 2019 in Cary, NC regarding EPA's draft PA, where I delivered oral comments.⁹ I attended CASAC's meeting on October 25, 2019 by teleconference. Thus, I have personally witnessed CASAC's deliberations at each of its meetings in the current particulate matter review cycle.

⁴ Frey, H.C., "[Public Comment: Deficiencies of Procedure and Expertise Must Be Corrected.](#)" [Written Comment to the Clean Air Scientific Advisory Committee](#)," Submitted to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, March 26, 2018

⁵ Frey, H.C., "[Public Comment: Reinstate the CASAC PM Review Panel](#)," Written Transcript of Oral Comment Presented to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, March 28, 2018

⁶ Frey, H.C., A.V. Diez Roux, P. Adams, G. Allen, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R. McConnell, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, "[03-07-19 Draft CASAC Review of EPA's Integrated Science Assessment \(ISA\) for Particulate Matter \(External Review Draft – October 2018\)](#)," 19 page letter submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, March 27, 2019.

⁷ Frey, H.C., P. Adams, J.L. Adgate, G. Allen, J. Balmes, K. Boyle, J.C. Chow, D.W. Dockery, H. Felton, T. Gordon, J.R. Harkema, J. Kaufman, P. Kinney, M. Kleinman, R. McConnell, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and R. Wyzga, "[Advice from the Independent Particulate Matter Review Panel \(formerly EPA CASAC Particulate Matter Review Panel\) on EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter \(External Review Draft – September 2019\)](#)," 11 page letter and 192 pages of attachments submitted to Hon. Andrew Wheeler, Administrator, Docket ID No. EPA-HQ-OAR-2015-0072, and Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, October 22, 2019

[https://yosemite.epa.gov/sab/sabproduct.nsf/81DF85B5460CC14F8525849B0043144B/\\$File/Independent+Particulate+Matter+Review+Panel+Letter+on+Draft+PA.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/81DF85B5460CC14F8525849B0043144B/$File/Independent+Particulate+Matter+Review+Panel+Letter+on+Draft+PA.pdf)

⁸ Frey, H.C., "[Advice from the Independent Particulate Matter Review Panel \(formerly the EPA CASAC Particulate Matter Review Panel\) on EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter \(External Review Draft – September 2019\)](#)," Written Statement to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, October 22, 2019.

⁹ Frey, H.C., "The Clean Air Act, Not CASAC, Defines the Decision Context of the National Ambient Air Quality Standards," Public Comment to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, at its public meeting on Thursday, October 24, 2019 in Cary, NC.
[https://yosemite.epa.gov/sab/sabproduct.nsf/A784C7989417F8C5852584AC00602A11/\\$File/Oral+Statement+fro m+Chris+Frey+191024.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/A784C7989417F8C5852584AC00602A11/$File/Oral+Statement+fro m+Chris+Frey+191024.pdf)

Part 1: EPA Has Made Numerous Ad Hoc and Inappropriate Changes to NAAQS Review

EPA has made numerous *ad hoc* changes to the NAAQS review process since 2017.^{10,11,12,13,14,15} EPA should not make *ad hoc* changes to the NAAQS review process in the middle of a review, as it has been doing in the case of the particulate matter review and is doing here in the case of the particulate matter review. Changes in the NAAQS review process since 2017 have led to a situation in which standards will not reflect air quality criteria — an “accurat[e] reflect[ion] [of] the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the present of [the] pollutant in the ambient air” (CAA section 108 (a)(2)) — since the CASAC and the process under which it is operating is incapable of properly assessing what that science is. If EPA wishes to make changes to the NAAQS review process, EPA should do so in a systematic manner similar to that employed in 2006, when EPA staff, CASAC, and others had an opportunity to provide input.¹⁶

Since 2017, EPA has made the following changes to the NAAQS review process and to the chartered CASAC:

- (1) new CASAC appointment criteria that emphasize geographic location;
- (2) new CASAC appointment criteria that emphasize government affiliation;
- (3) new CASAC appointment criteria ban nongovernmental but not governmental recipients of EPA scientific research grants;
- (4) complete turn-over of CASAC membership;
- (5) disbanding the CASAC PM Review Panel;
- (6) forming an *ad hoc* “pool” of consultants that fails to address shortcomings of expertise and experience introduced by doing away with panels, while introducing new shortcomings related to inability to deliberate;

¹⁰ Pruitt, E.S., “Strengthening and Improving Membership on EPA Federal Advisory Committees,” Memorandum, U.S. Environmental Protection Agency, October 31, 2017. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>

¹¹ Pruitt, S.E., “Back to Basics Process for Reviewing National Ambient Air Quality Standards,” Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 9, 2018. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>

¹² EPA, “Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee Tasks Chartered Panel to Lead Review of Ozone & Particulate Matter Standards Under Reformed Process,” News Release, U.S. Environmental Protection Agency, Washington, DC, October 10, 2018, <https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee>

¹³ GAO, EPA Advisory Committees: Improvements Needed for the Member Appointment Process, GAO-19-280, General Accountability Office, Washington, DC. <https://www.gao.gov/assets/710/700171.pdf>

¹⁴ EPA, “Request for Nominations of Consultants To Support the Clean Air Scientific Advisory Committee (CASAC) for the Particulate Matter and Ozone Reviews,” *Federal Register*, 84(152):38625 (August 7, 2019). <https://www.govinfo.gov/content/pkg/FR-2019-08-07/pdf/2019-16913.pdf>

¹⁵ EPA, “Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts,” News Release, U.S. Environmental Protection Agency, Washington, DC, September 13, 2019. <https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts>

¹⁶ Peacock, M., “Process for Reviewing National Ambient Air Quality Standards,” Memorandum to George Gray and Bill Wehrum, U.S. Environmental Protection Agency, Washington, DC, December 7, 2006.

- (7) compressing the scientific review into a timeframe that reduces transparency by reducing opportunities for public comment;
- (8) doing away with revised external review drafts of complex scientific documents;
- (9) doing away with planning for the risk and exposure assessments;
- (10) doing away with separate risk and exposure assessment documents for external review; and
- (11) commingling policy with science by producing and reviewing policy and science assessments concurrently.

Myriad unwarranted changes have been made to the NAAQS review process and to the composition of the CASAC since 2017. These changes ignore decades of precedent and were undertaken without consultation with or input from EPA career staff, the chartered CASAC or its then existing review panels, and the public. These changes ignore statutory requirements for a thorough and accurate review of scientific criteria. Statutory deadlines are not an excuse for deficiencies in the review process. These changes are collectively harmful to the quality, credibility, and integrity of EPA's scientific review process and to CASAC as an advisory body. These changes have been made without advance notice to, or input from, the CASAC, cognizant EPA staff, or the public. These changes should be reversed. The NAAQS review for particulate matter should be suspended until these deficiencies are corrected.

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

1.1 EPA Failed to Engage EPA Career Staff in Revisions to NAAQS Review

EPA leadership did not engage EPA career staff involved with the ISA or PA, CASAC, or the public prior to developing *ad hoc* revisions since 2017 to the NAAQS review process generally and to the particulate matter review process specifically. Nor did EPA leadership engage the EPA career staff, CASAC, or the public prior to changing criteria since 2017 for appointing members to the CASAC or prior to the decision to disband the CASAC PM Review Panel.

1.2 Role of EPA Staff in Preparing Draft Documents

EPA career staff in the Office of Research and Development have undertaken a good faith effort to produce a first draft of the Integrated Science Assessment (ISA). EPA career staff in the Office of Air Quality Planning and Standards have undertaken a good faith effort to produce a first draft of the Policy Assessment (PA). However, both of these draft documents were produced under extenuating, unprecedented, and inappropriate constraints. The staff should be commended for this effort. However, it is inappropriate for EPA leadership to rush the scientific and policy assessments and to commingle them such that the draft PA is being reviewed before the ISA is finalized. It is inappropriate that EPA leadership made these decisions without input from career staff, without regard to the precedent of a well-designed and well-executed review process that had been in place prior to this review, and without regard to the need for a thorough and accurate review required by the Clean Air Act.

1.3 Accelerated Time Frame

Former EPA Administrator Pruitt signed a memorandum on May 9, 2018 that made major changes to the scientific review process for the NAAQS.¹⁷ The memo is replete with cherry-picking and quote-mining of incomplete information that fails to accurately characterize the established NAAQS review process, including its strengths. The memorandum emphasizes that the Clean Air Act requires that NAAQS be reviewed every five years, but fails to emphasize the statutory mandate for a thorough and accurate scientific review. Statutory deadlines do not excuse substantive deficiencies created by a rushed and truncated review process. For those NAAQS reviews for which EPA entered into a consent decree or was under court order to complete a review, the court-supervised schedules have taken into account the need for EPA staff to develop assessment documents and for CASAC to review the documents and advise the Administrator. Thus, the memorandum fails to acknowledge that courts have recognized that the time needed for a thorough and accurate scientific review can be taken into account in setting schedules that go beyond the five year time frame. Instead, EPA is self-imposing a schedule that compromises the quality, credibility, and integrity of the scientific review and is doing so in a manner beyond what courts have historically imposed.

The memorandum gives the misleading impression that delays in the review process are attributed to CASAC. Based on analysis that I submitted as part of my individual member comments attached to the IPMRP's December 10, 2018 letter to CASAC,³ I showed that the duration of CASAC activities in a NAAQS review cycle is far less than the total duration of the review cycle. A key factor that increases the duration of CASAC's involvement in a review cycle is delay in EPA providing CASAC with assessment documents for review. Furthermore, the memorandum omits any discussion of the more salient factors that have led to delays in the NAAQS review process related to decisions made by the EPA, not CASAC, as detailed below. EPA should not impose a reduced duration schedule for the scientific review that compromises the scope and quality of the scientific review. The duration of a review cycle is dependent on the following:

- (1) EPA controls the duration of time between the conclusion of a prior review cycle and the initiation of the subsequent review cycle;

¹⁷ Pruitt, S.E., "Back to Basics Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 9, 2018. <https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf>

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

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

The late 2020 deadline for completing the particulate matter review given in the May 9, 2018 memorandum is contrary to EPA’s own final Integrated Review Plan for the PM NAAQS review¹⁸

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. Thus, EPA is ignoring statutory requirements for the need for a thorough and accurate scientific review of the NAAQS in setting a review schedule. Statutory deadlines are not an excuse for deficiencies in the review process.

EPA should develop NAAQS review schedules that allow for the likelihood that complex scientific and policy documents, such as an Integrated Science Assessment, a Risk and Exposure Assessment (REA), and a Policy Assessment, may need substantial revision and re-review. EPA should better manage the timing of key milestones in the NAAQS review process so as not to selectively take time away from CASAC as a means to compensate for delays created by EPA elsewhere in the review.

Truncating the scientific review schedule by deleting key steps in the review process, such as by deleting assessment documents (i.e. Risk and Exposure Assessment Planning Document, Health Risk and Exposure Assessment, Welfare Risk and Exposure Assessment) and deleting revised external review drafts of assessment documents, leads to fewer CASAC public meetings and, therefore, fewer opportunities for public comment. Fewer opportunities for public comment create a less transparent NAAQS scientific review process.

¹⁸ EPA, “Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter,” EPA-452/R-16-005, U.S. Environmental Protection Agency, Research Triangle Park, NC, December 2016. <https://www3.epa.gov/ttn/naaqs/standards/pm/data/201612-final-integrated-review-plan.pdf>

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

1.4 Scientific Issues Need to be Settled Before Formulating the Policy Assessment

It has been typical practice that CASAC has had the opportunity to review a draft Policy Assessment *after* it has completed reviews of draft ISAs and after the ISA has been finalized. This sequence was by design. A key principle of the 2006 revisions to the NAAQS review process, which were modified in part in 2007 and 2009,^{16,19,20} is that the scientific foundation of the review must be established before addressing policy issues. Failure to do this risks commingling policy issues prematurely before the science issues are adequately vetted and settled, which in turn creates the potential for policy choices to be made irrespective of the science. Thus, the integrity of the process is harmed when policy issues are addressed before the science issues are adequately settled.

The Pruitt May 9, 2018 memorandum,³ and the concurrent drafts of the ISA and PA in this review, inappropriately commingle science and policy considerations. The October 22, 2019 report of the Independent Particulate Matter Review Panel (IPMRP) (formerly the CASAC PM Review Panel) stated that "EPA should not be producing a Policy Assessment in advance of first finally determining what the science being assessed is – i.e. prior to finalizing the ISA."⁷ As the IPMRP stated, "to do otherwise puts the cart before the horse." Furthermore, "EPA should not introduce policy considerations until the scientific issues have been adequately settled."

1.5 Sequencing of the ISA, REA, and PA

Chapter 1 of the draft PA fails to document the *ad hoc* changes to the NAAQS review process and to the CASAC that have been made compared to the previous particulate matter review. The following steps have been omitted in the current review: (1) no REA planning document(s); (2) no second external review draft of the ISA; (3) no external review drafts of the REAs; (4) no provision for a second external review draft of the PA; (5) no final REA as a separate document; and (6) no final ISA until after CASAC has completed its review of the draft PA. The chapter should enumerate all of the changes to the NAAQS review process and the CASAC since the last review. However, more importantly, these deficiencies should be corrected.

Transparency of the review process, and clear distinction of science and policy issues, is enhanced by obtaining CASAC's advice on the Risk and Exposure Assessment (REA) before submitting a first draft of the PA for CASAC review. However, in this review, there is no separate REA. The content of the REA has been incorporated into the draft PA. This is not appropriate

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

²⁰ Jackson, L., "Process for Reviewing National Ambient Air Quality Standards," Memorandum, U.S. Environmental Protection Agency, Washington, DC, May 21, 2009.
<https://www3.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf>

since there are important scientific issues pertaining to the REA that should be reviewed and vetted prior to their use in the draft PA.

The first draft of the PA should not be released until the ISA has been finalized. Scientific issues in the draft ISA should be resolved prior to development and review of a draft PA. Given that the ISA in this review is intended to go directly from first draft to final, but as of now has not been finalized, it is unclear what changes are pending for the final ISA and whether or how they will affect the content of the final PA. This is an unacceptable process deficiency that commingles policy considerations prior to finalization of the science assessment. This 'puts the cart before the horse.'

A second external review draft of the ISA should be made available to CASAC, augmented with a properly and appropriately constituted particulate matter review panel, and to the public. The second draft of the ISA should be reviewed, and finalized, prior to release of a second draft of the Policy Assessment. The second draft of the Policy Assessment should be reviewed by CASAC, augmented with a properly and appropriately constituted particulate matter review panel, and by the public only after the ISA has been finalized.

1.6 Eliminated Revised External Review Drafts

EPA is reducing the number of drafts of documents for CASAC review irrespective of whether substantial revision of scientific content is needed. Complex scientific documents often require more than one iteration of peer review and revisions to arrive at a final document that adequately and appropriately addresses deficiencies. However, peer review also requires that an appropriate group of experts is engaged in the review process. Such a group must have the breadth, depth, and diversity of expertise and experience commensurate with the draft document to be reviewed.

EPA should not combine assessment documents in a review unless doing so is scientifically justifiable. An assessment that doing so is scientifically justifiable requires concurrence from a properly constituted CASAC augmented with a properly constituted review panel.

Part 2: Causality Determination Framework

The draft ISA and PA have retained the causality determination framework for health effects attributed to exposures of varying durations to particular indicators, and retained the causality framework for at-risk populations. This is an appropriate choice.

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, 2008a):²¹

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).²¹

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):²²

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):²³

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

²¹ Henderson, R., 2008a, Clean Air Scientific Advisory Committee's (CASAC) Peer Review of EPA's Integrated Science Assessment (ISA) for Oxides of Nitrogen – Health Criteria (Second External Review Draft) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2008; Report No.: EPA-CASAC-08-015

²² Henderson, R., 2008b, Clean Air Scientific Advisory Committee's (CASAC) Peer Review of EPA's Integrated Science Assessment (ISA) for Sulfur Oxides – Health Criteria (First External Review Draft, September 2007) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2008; Report No.: EPA-CASAC-08-005

²³ Henderson, R., 2008c, Clean Air Scientific Advisory Committee's (CASAC) Peer Review of EPA's Integrated Science Assessment (ISA) for Sulfur Oxides – Health Criteria (Second External Review Draft, May 2008) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2008; Report No.: EPA-CASAC-08-017

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):²⁴

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):²⁴ “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):²⁵

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).²⁶

²⁴ Samet, J., 2009a, Review of EPA’s Integrated Science Assessment for Particulate Matter (First External Review Draft, December 2008) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2009; Report No.: EPA-CASAC-09-008.

²⁵ Samet J., 2009b, Review of Integrated Science Assessment for Particulate Matter (Second External Review Draft, July 2009). Washington, DC: EPA Clean Air Scientific Advisory Committee, 2009; Report No.: EPA-CASAC-10-001.

²⁶ Brain, J.D., and J.M. Samet, 2009, Review of EPA’s Integrated Science Assessment for Carbon Monoxide (First External Review Draft), Washington, DC: EPA Clean Air Scientific Advisory Committee, 2009; Report No.: EPA-CASAC-09-011

In 2010, the CASAC CO Review Panel found that (Brain and Samet, 2010):²⁷ “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):²⁸

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”²⁹ 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.³⁰ CASAC called for EPA to provide a third draft of the ISA to address numerous other issues.

²⁷ Brain, J.D., and J.M. Samet, 2010, Review of EPA’s Integrated Science Assessment for Carbon Monoxide (Second External Review Draft), Washington, DC: EPA Clean Air Scientific Advisory Committee, 2010; Report No.: EPA-CASAC-10-005

²⁸ Samet, J., 2011, CASAC comments on EPA’s Integrated Science Assessment for Ozone and Related Photochemical Oxidants (March 2011), Washington, DC: EPA Clean Air Scientific Advisory Committee, 2011; Report No.: EPA-CASAC-11-009

²⁹ Hill AB, 1965. The environment and disease: Association or causation? Proceedings of the Royal Society of Medicine, 1965; 58:295–300.

³⁰ Samet, J., 2012, CASAC Review of the EPA’s Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Second External Review Draft – September 2011) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2012; Report No.: EPA-CASAC-12-004.

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).³¹ 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).³² 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).³³ 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).³⁴

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).³⁵ 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).³⁶

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

³¹ Frey, H.C., and J.M. Samet, 2011, CASAC Review of the EPA’s Integrated Science Assessment for Lead (First External Review Draft – May 2011) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2011; Report No.: EPA-CASAC-12-002.

³² Samet, J. and H.C. Frey, 2012, CASAC Review of the EPA’s Integrated Science Assessment for Lead (Second External Review Draft – February 2012) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2012; Report No.: EPA-CASAC-12-005

³³ Frey, H.C., 2013, CASAC Review of the EPA’s Integrated Science Assessment for Lead (Third External Review Draft – November 2012) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2013; Report No.: EPA-CASAC-13-004

³⁴ Frey, H.C. and J.M. Samet, 2013, CASAC Review of the EPA’s Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Third External Review Draft – June 2012) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2012; Report No.: EPA-CASAC-13-001

³⁵ Frey, H.C., 2014, CASAC Review of the EPA’s Integrated Science Assessment for Oxides of Nitrogen – Health Criteria (First External Review Draft – November 2013) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2014; Report No.: EPA-CASAC-14-002

³⁶ Diex Roux, A., and H.C. Frey, 2015, CASAC Review of the EPA’s Integrated Science Assessment for Oxides of Nitrogen – Health Criteria (Second External Review Draft – January 2015) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2015; Report No.: EPA-CASAC-15-001

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).³⁷ The framework is also described in a journal publication by Owens et al. (2017).³⁸

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).³⁹ The CASAC review of the 2nd draft of the ISA for oxides of sulfur found that the causal determinations were appropriate (Diex Roux, 2017).⁴⁰ 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.

³⁷ EPA, 2015, Preamble to the Integrated Science Assessments, Research Triangle Park, NC: U.S. Environmental Protection Agency, 2015; Report No.: EPA/600/R-15/067

³⁸ Owens, E.O., M.M. Patel, E. Kirrane, T.C. Long, J. Brown, I. Cote, M.A. Ross, S.J. Dutton, "Framework for assessing causality of air pollution-related health effects for reviews of the National Ambient Air Quality Standards," *Regulatory Toxicology and Pharmacology* 88 (2017) 332-337.

³⁹ Diex Roux, A., 2016, CASAC Review of the EPA's Integrated Science Assessment for Sulfur Oxides – Health Criteria (External Review Draft – November 2016) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2016; Report No.: EPA-CASAC-16-002

⁴⁰ Diex Roux, A., 2017, CASAC Review of the EPA's Integrated Science Assessment for Sulfur Oxides – Health Criteria (Second External Review Draft – December 2016) Washington, DC: EPA Clean Air Scientific Advisory Committee, 2017; Report No.: EPA-CASAC-17-003.

Part 3: Chartered CASAC Lacks Breadth, Depth, and Diversity of Expertise and Experience Needed for the Particulate Matter NAAQS Review

The current 7-member CASAC does not have the breadth, depth, or diversity of expertise and experience needed for the particulate matter review, nor could any group of this size cover the needed scientific disciplines.

CASAC has transitioned from a committee of nationally and internationally recognized researchers at the leading edge of their fields to a committee composed predominantly of stakeholders chosen based on geographic location and affiliation with state and local government, rather than scientific expertise first and foremost.

CASAC is chartered to be a scientific advisory committee, not a stakeholder committee. Membership criteria for CASAC and its augmented panels should emphasize scientific expertise, not geographic location and government affiliation other than to meet the statutory requirement under Section 109 of the Clean Air Act that there be “one person representing State air pollution control agencies.”

Nongovernmental recipients of EPA scientific research grants have been barred since 2017 from serving on EPA advisory committees. However, governmental recipients of EPA scientific research grants are not barred, which proves that the ban is not about any putative conflict of interest. The ban on nongovernmental EPA scientific research grant recipients is in direct conflict with 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.^{41,42} EPA should allow leading nongovernmental researchers who hold EPA scientific research grants to serve on CASAC and its augmented panels, consistent with existing Federal peer review guidance. The Pruitt memorandum does not acknowledge that persons with financial or professional ties to regulated industries have, at the very least, the appearance of conflict of interest.

Between 2017 and 2018, there was an unprecedented complete turn-over of all members of the seven-member chartered CASAC, such that as of October 2018 no member had served for more than one year. This has led to substantial loss of experienced members and loss of institutional memory among the members of the chartered CASAC. EPA should not have changed the prior practice of appointment of CASAC members to staggered overlapping terms. The prior practice promoted institutional memory and continuity. The new policy to enhance member turnover fails to acknowledge that there are benefits of continuity and knowledge provided by having some previous members continue to serve. Under this new policy, **well-qualified scientists have been “rotated” off of the CASAC, in favor of new members without needed subject matter expertise and without prior experience** on CASAC or CASAC review panels, selected instead for their affiliation or geographic location. CASAC is now the most inexperienced and unqualified that it has been in its history.

The current CASAC (or any CASAC, with only seven members, that is not augmented with a panel of experts) does not have adequate breadth, depth, and diversity of scientific expertise

⁴¹ Office of Management and Budget, “Final Information Quality Bulletin for Peer Review,” *Federal Register*, 70(10):2664-2677 (January 14, 2005), <https://www.govinfo.gov/content/pkg/FR-2005-01-14/pdf/05-769.pdf>

⁴² EPA, “EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees,” Report No. 13-P-0387, Office of Inspector General, U.S. Environmental Protection Agency, Washington, DC, September 11, 2013. <https://www.epa.gov/sites/production/files/2015-09/documents/20130911-13-p-0387.pdf>

and experience needed to conduct thorough reviews of the draft ISA and draft PA based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to the particulate matter NAAQS. Thus, CASAC should be properly augmented, consistent with its charter with the U.S. Congress,⁴³ by reappointment of the disbanded CASAC Particulate Matter Review Panel.⁹

3.1 Partial Review is Not Adequate

Members of CASAC have, on multiple occasions including during the October 24-25, 2019 deliberations of CASAC, made an argument that CASAC can usefully offer advice that it is qualified to give. These statements were typically in response to criticisms from public commenters, and some of CASAC's own members, that CASAC lacks the breadth, depth, and diversity of expertise and experience needed for the particulate matter review. However, despite my own advice to CASAC several times via public comment to carefully consider the language of the Clean Air Act for the decision context of this review, which has been ignored to date by all members of the CASAC, providing partial advice is not the role of the CASAC.

It is simply not adequate for CASAC to offer the advice that it is requested to give when CASAC lacks the breadth, depth, and diversity of expertise and experience necessary to fully consider the full range of salient issues. The Clean Air Act does not specify that the NAAQS review may be partial or incomplete. It requires that "Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." This is why, for four decades, CASAC has been augmented with expert review panels, such that it would have the breadth, depth, and diversity of expertise and experience to fulfill the statutory requirement for the scope of scientific assessment. CASAC must be augmented with a Particulate Matter Review Panel to be able to discharge its duties under the law.

3.2 The Chartered CASAC is Not Qualified to Offer the Judgments and Advice that it Attempts to Provide

Given that CASAC has been populated with members appointed based on geographic location and government affiliation, and that CASAC has been deprived of a duly appointed CASAC PM Review Panel, CASAC is not qualified to advise the EPA in a manner that accurately reflects that latest scientific knowledge of the kind and extent of salient issues that must be considered.

CASAC has already admitted, explicitly, that it is not qualified to offer these judgments, because it lacks the breadth, depth, and diversity of expertise and experience for review of the PM NAAQS.⁴⁴ Therefore, the CASAC PM Review Panel should be reappointed to augment CASAC during this review cycle before CASAC is asked to offer advice that it is not qualified to give.

It is not credible for scientists to provide advice on matters outside of their domains of expertise. Doing so is not technically sound nor consistent with professional conduct. Yet, repeatedly, the

⁴³ United States Environmental Protection Agency Charter, Clean Air Scientific Advisory Committee, Filed with Congress, June 5, 2019, [https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/\\$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf)

⁴⁴ Cox, L.A. (2019), "CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)," EPA-CASAC-19-002, Letter to A. Wheeler, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, April 11, 2019. [https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf)

chartered CASAC, which lacks epidemiologists and was deprived of the ability to deliberate with epidemiologists who were on the disbanded CASAC PM Review Panel, is centering its key arguments on issues related to epidemiology. In many cases, as other commenters have noted, the chartered CASAC mischaracterizes and misunderstands key issues, leading to poorly or inappropriately founded advice.

3.3 It is Technically Unsound and Inappropriate for CASAC to Fail to Acknowledge Its Lack of Breadth, Depth, and Diversity of Expertise and Experience Needed for the PM NAAQS Review

In its undated draft letter posted during November 2019, the CASAC omits discussion of its own lack of expertise. I attended the October 24-25, 2019 meeting of the CASAC in person on Oct 24, and by telephone on Oct 25. I recall numerous times when a CASAC member made the point that CASAC did not have the right experts at the table, especially with regard to epidemiology.

CASAC should acknowledge that it lacks the breadth, depth, and diversity of expertise and experience to conduct this review. It is not credible to offer advice on topics for which the committee does not have the requisite breath, depth, and diversity of expertise and experience.

CASAC should clearly state that:

- It lacks the breadth, depth, and diversity of expertise and experience needed to develop technically sound advice to the EPA regarding the PM NAAQS;
- It especially lacks expertise in epidemiology;
- The disbanded CASAC PM Review Panel should be reappointed;
- CASAC is unable to offer advice at this time regarding the draft PA for the PM NAAQS;
- CASAC will be able to develop and offer advice after such time that it is augmented with the CASAC PM Review Panel and has had sufficient opportunity to engage in public deliberations with the reinstated Panel;
- CASAC, augmented with the CASAC PM Review Panel, will need to conduct a review of a second external review draft of the PM ISA; and
- CASAC, augmented with the CASAC PM Review Panel, will conduct a review of the second external review draft of the Policy Assessment only after the final ISA is made available.

In lieu of a properly constituted CASAC augmented with a properly constituted PM review panel, if CASAC proceeds to provide advice that it is unqualified to give, the EPA and the Federal courts are urged to disregard the advice of CASAC, because EPA Administrators have taken actions since 2017 that render CASAC, and the NAAQS review process itself, incapable of providing the advice required under Sections 108 and 109 of the Clean Air Act based on a thorough review of the criteria.

Part 4: The Unprecedented Ad Hoc Creation of a Pool of Consultants

In this part, the unprecedented approach of appointing an ad hoc pool of consultants to interact with the chartered CASAC only via a writing-based firewall is described and assessed.

4.1 In April, CASAC Asks for Expertise. In July, the EPA Administrator Responds by Playing Games: Ad Hoc Pool of Consultants

After receiving public comments at its December 2018 and March 2019 public meetings to the effect that CASAC lacked the expertise to conduct this PM NAAQS review, the CASAC stated in its April 11, 2019 letter to the EPA Administrator that “the breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members, or indeed of any seven individuals.”⁴⁴ Furthermore, the CASAC recommended that “the EPA reappoint the previous CASAC PM panel or appoint a panel with similar expertise.” The disbanding of the PM Review Panel on October 10, 2017 deprived CASAC of the needed expertise. Compared to the CASAC, the twenty-strong panel has more experts, covers more scientific disciplines, and has multiple experts who provide diversity of perspectives in key disciplines, such as epidemiology, toxicology, and controlled human studies, among others

The EPA Administrator responded in a letter dated July 25, 2019 that disregarded CASAC’s advice to reappoint the disbanded panel or form a new panel. The Administrator did not directly address any rationale for why he did not reappoint the disbanded panel or form a similar panel. The Administrator stated that he would instead “create a pool of subject matter experts.”⁴⁵ In addition, he rejected the CASAC request for the augmented committee to review a revised draft of the ISA. On August 7, 2019, EPA issued a Federal Register notice to request nominations for consultants to support CASAC reviews of particulate matter and ozone.¹⁴

The Administrator announced a “pool” of 12 subject matter experts in an EPA press release on September 13, 2019.¹⁵ The pool of 12 are intended to respond to written questions from the chartered CASAC for both the PM and ozone NAAQS reviews. In contrast, the disbanded PM review panel had 20 experts in addition to the chartered CASAC. At the same time that the Administrator disbanded the CASAC PM Review Panel on October 10, 2018, he also announced that he would not form a CASAC Ozone Review Panel. This was despite the fact that EPA had requested nominations for a CASAC Ozone Review Panel in a Federal Register notice on July 27, 2018.⁴⁶ In the prior ozone NAAQS review, which was completed in 2015, the CASAC was augmented with 15 additional experts to form an ozone review panel. Thus, **the total number of augmented experts for the prior ozone review and the current PM review through 2018 was 35. Twelve people is not an adequate number to cover the breadth, depth, and diversity of scientific expertise and experience needed for review of both ozone and PM.**

The use of a “pool of subject matter experts” rather than a review panel to augment the chartered CASAC is unprecedented. Review panels augment and report through the chartered CASAC, working in parallel and in collaboration with the members of the chartered CASAC. Members of review panels are nominated by the public and the nominations are subject to

⁴⁵ Wheeler, A.R. (2019), Letter to L.A. Cox, EPA Clean Air Scientific Advisory Committee, from Administrator, U.S. Environmental Protection Agency, Washington, DC, July 25, 2019, [https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002_Response.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002_Response.pdf)

⁴⁶ EPA, “Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel,” *Federal Register*, 83(145): 35635- 35636 (July 27, 2018). <https://www.govinfo.gov/content/pkg/FR-2018-07-27/pdf/2018-16116.pdf>

public comment. The SAB staff office reviews, vets, and appoints members of review panels. Members of review panels participate in meetings with members of the chartered CASAC, and deliberate interactively with members of the chartered CASAC on complex subject matter. The chartered CASAC is ultimately responsible for the content of advice sent to the Administrator, but the formulation of that advice is informed based on deliberations with panelists who provide the breadth, depth, and diversity of needed scientific expertise and experience.

In contrast, **there was no opportunity for public comment on the nominees for the pool of subject matter experts.** The decision regarding appointments of ad hoc consultants to serve as subject matter experts was made by the Administrator, not by the SAB Staff Office. The General Accountability Office has documented irregularities in the process since 2017 by which appointments have been made to EPA advisory committees, including the CASAC.¹³

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

As noted by the Independent Particulate Matter Review Panel, the appointment of an ad hoc pool of consultants does not substitute for a properly constituted and appointed review panel. The pool of consultants cannot deliberate with each other or with CASAC, was not involved in reviewing the scientific criteria for this topic, and was appointed under unusual circumstances subject to cherry-picking.

4.2 Ad Hoc Pool of Consultants is Not Independent of the CASAC Majority or Regulated Special Interests

The process by which EPA Administrator Wheeler has appointed members to the ad hoc pool of consultants has not been transparent. Recently, Politico obtained the list of nominees for the ad hoc pool of consultants via a Freedom of Information Act request.⁴⁷ The two members of the ad hoc pool who were nominated by the CASAC chair were the only consultants who were mentioned by name in CASAC's draft consensus responses to EPA charge questions. Two of the consultants co-authored a paper with a CASAC member that addresses policy issues related to NAAQS review.⁴⁸ One of the consultants is an area editor of a journal for which the

⁴⁷ The List of Nominees for CASAC PM and Ozone Consultants – August 2019, obtained by Politico via a FOIA request to EPA, is at this link: <https://static.politico.com/d6/f8/9456f6b547669eea2e692e79eef5/epa-hq-2019-008347-record.pdf>. See also “Wheeler's air advisers pool favored industry over academics,” by Alex Guillén in POLITICO Pro Energy on December 2, 2019.

⁴⁸ Goodman, J.E., S.N. Sax, S. Lange, and L.R. Rhomberg, “Are the elements of the proposed ozone National Ambient Air Quality Standards informed by the best available science?,” *Regulatory Toxicology and Pharmacology*, 72(1):134-140 (2015).

chair is the editor, and has recently written a review of a book written by the chair.⁴⁹ Several consultants were nominated by organizations that represent regulated industries.

The ad hoc pool of consultants was appointed by the EPA Administrator. However, the circumstances and details of the decision-making process for the appointments is not known and, therefore, is not transparent.

⁴⁹ North, D.W., "Mega-Review: Causality Books," *Risk Analysis*, 39(7):1647-1654 (2019).
<https://onlinelibrary.wiley.com/doi/abs/10.1111/risa.13295>

Part 5: Disbanding the CASAC PM Review Panel

This part provides analysis, comment, and advice regarding CASAC review panels and their proper role in the NAAQS science review process.

5.1 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.

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.

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 reviewing 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 reviewing CASAC reports posted online.

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.**

5.2 EPA Arbitrarily and Capriciously Disbanded the CASAC PM Review Panel

The core statutory obligation of the EPA Clean Air Scientific Advisory Committee (CASAC) is incorporated into CASAC's charter with Congress.⁴³ Under that charter, CASAC may be augmented with experts. Specifically, the charter states:

“EPA, or CASAC with the Agency's approval, may form subcommittees or workgroups for any purpose consistent with this charter. Such subcommittees or workgroups may not work independently of the chartered committee and must report their recommendations and advice to the chartered CASAC for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered committee, nor can they report directly to the EPA.”

Augmentation of CASAC with additional experts for the review of criteria and standards has been a routine practice for four decades. Additional experts have been appointed to review panels that interact with members of the chartered CASAC for all reviews since the late 1970s. Over time, the chartered CASAC has typically been augmented with 12 or more additional experts in a given review cycle for a given criteria pollutant. The average number of experts among 20 such panels for which membership data is available is 14, and the average size of the review panels is 20 members, inclusive of participating CASAC members.

The previous four particulate matter review panels have been comprised of members of the chartered CASAC augmented with additional experts. CASAC was augmented with additional experts for the joint review of the criteria and standards for particulate matter and sulfur oxides in the early 1980s.⁵⁰ The CASAC Subcommittee on Health Effects of Particulate Matter and Sulfur Oxides included six experts in addition to members of the chartered CASAC. The CASAC Subcommittee on Welfare Effects of Particulate Matter and Sulfur Oxides included five additional experts in addition to members of the chartered CASAC. In total, there were 11 additional experts who augmented the chartered CASAC for this review cycle. For the 1994 to 1996 PM review, there were 6 members of the chartered CASAC and 15 additional experts on the review panel.⁵¹ 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.^{52,53} From 2015 to 2018, the CASAC Particulate Review Panel had 6 members of the chartered CASAC and 20 additional experts.¹ Thus, the use of augmented review panels specifically for particulate matter dates back 37 years.

⁵⁰ EPA, Air Quality Criteria for Particulate Matter and Sulfur Oxides, Volume 1, EPA-600/8-82-029a, U.S. Environmental Protection Agency, Research Triangle Park, NC, December 1982.
http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=459608

⁵¹ Wolff, G.T., “Closure by the Clean Air Scientific Advisory Committee (CASAC) on the Staff Paper for Particulate Matter,” Letter to Carol M. Browner, EPA-SAB-CASAC-LTR-96-008, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, June 13, 1996.
[https://yosemite.epa.gov/sab/sabproduct.nsf/C146C65BA26865A2852571AA00530007/\\$File/casl9608.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/C146C65BA26865A2852571AA00530007/$File/casl9608.pdf)

⁵² Henderson, R. “Clean Air Scientific Advisory Committee Recommendations Concerning the Proposed National Ambient Air Quality Standards for Particulate Matter,” EPA-CASAC-LTR-06-002, Letter to Stephen L. Johnson, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, March 21, 2006, [https://yosemite.epa.gov/sab/sabproduct.nsf/CD706C976DAC62B3852571390081CC21/\\$File/casac-ltr-06-002.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/CD706C976DAC62B3852571390081CC21/$File/casac-ltr-06-002.pdf)

⁵³ Samet, J.M., “CASAC Review of Policy Assessment for the Review of the PM NAAQS – Second External Review Draft (June 2010),” EPA-CASAC-10-015, Letter to Lisa P. Jackson, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, September 10, 2010, [https://yosemite.epa.gov/sab/sabproduct.nsf/CCF9F4C0500C500F8525779D0073C593/\\$File/EPA-CASAC-10-015-unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/CCF9F4C0500C500F8525779D0073C593/$File/EPA-CASAC-10-015-unsigned.pdf)

The 7-member chartered CASAC does not have the breadth, depth, and diversity of expertise and experience required for a review of the particulate matter criteria and standards that meets the requirements of the Clean Air Act for a “thorough review” that “shall accurately reflect the latest scientific knowledge” of the “extent and kind of ... effects.”³ The only credible way to provide a “thorough review” that “shall accurately reflect the latest scientific knowledge” is to engage scientists who are active at the leading edge of scientific work in disciplines and areas related to the subject matter of a review, as described in the February 4, 2015 Federal Register request for nominations, and as illustrated by the history of CASAC Review Panels.

On February 4, 2015, the EPA Science Advisory Board (SAB) staff office issued a “Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel.”⁵⁴ 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.”

The notice also stated:

“Selection criteria to be used for panel membership include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; (e) skills working in committees, subcommittees and advisory panels; and, (f) for the panel as a whole, diversity of expertise and viewpoints.”

On November 17, 2015, a memorandum from Aaron Yeow to Chris Zarba in the EPA Science Advisory Board office established the CASAC PM Review Panel.⁵⁵ 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.”

⁵⁴ EPA, “Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel,” *Federal Register*, 80(23):6086-6089 (February 4, 2015). <https://www.govinfo.gov/content/pkg/FR-2015-02-04/pdf/2015-02265.pdf>

⁵⁵ Yeow, A., Formation of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel, Memorandum to C. Zarba, Science Advisory Board Staff Office, U.S. Environmental Protection Agency, Washington, DC, November 17, 2015, [https://yosemite.epa.gov/sab/sabproduct.nsf/0/EB862B233FBD0CDE85257DDA004FCB8C/\\$File/Determination%20memo-CASAC%20PM.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0/EB862B233FBD0CDE85257DDA004FCB8C/$File/Determination%20memo-CASAC%20PM.pdf)

In the case of particulate matter, for which there are health effects data from multiple scientific disciplines, including epidemiology, toxicology, and controlled human studies, it has been common practice to have multiple experts in each of these disciplines to assure breadth and depth of expertise. The CASAC PM Review Panel was comprised of leading scientists recognized nationally and internationally for their expertise in multiple scientific disciplines, including air quality, exposure assessment, dosimetry, toxicology, epidemiology, medicine, risk assessment methodology, uncertainty analysis, and related fields.

The CASAC Particulate Matter Panel held teleconference meetings on May 23, 2016, and August 9, 2016, to peer review the EPA's Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016).¹

On October 10, 2018, then acting EPA Administrator Wheeler eliminated the CASAC PM Review Panel by press release,¹² with a follow-up email from the SAB staff office on October 11, 2018. This was done without advance notice and without prior consultation with the panel or the CASAC. There is no precedent for disbanding a review panel in the middle of a review cycle.

The EPA released the external review draft of the Integrated Science Assessment (ISA) on October 15, 2018, five days after disbanding the CASAC PM Review Panel.⁵⁶ The Federal Register notice announcing that the draft ISA was available for public review was dated October 16, 2018 and published on October 23, 2018.⁵⁷

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

5.3 Administrator Wheeler's Talking Points Regarding Disbanding the CASAC PM Review Panel are Specious

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

The talking point that only CASAC should advise the Administrator is specious because in fact it has only been the CASAC that has advised the Administrator throughout the history of CASAC. Per CASAC's charter with the U.S. Congress:⁴³

“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

⁵⁶ EPA, “Integrated Science Assessment for Particulate Matter (External Review Draft),” EPA/600/R-18/179, U.S. Environmental Protection Agency, Research Triangle Park, NC, October 2018. [https://yosemite.epa.gov/sab/sabproduct.nsf/0/932D1DF8C2A9043F852581000048170D/\\$File/PM-1STERD-OCT2018.PDF](https://yosemite.epa.gov/sab/sabproduct.nsf/0/932D1DF8C2A9043F852581000048170D/$File/PM-1STERD-OCT2018.PDF)

⁵⁷ EPA, “Integrated Science Assessment for Particulate Matter (External Review Draft),” *Federal Register*, 83(205):53471-53472 (October 23, 2019). <https://www.govinfo.gov/content/pkg/FR-2018-10-23/pdf/2018-23125.pdf>

make decisions on behalf of the chartered committee, nor can they report directly to the EPA.”

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

The talking point that panels must be eliminated to streamline the review process is specious because, without the panels, CASAC does not have the breadth, depth, and diversity of expertise and experience to conduct scientific review consistent with the Clean Air Act requirements for being accurate and thorough. Thus, the panels are essential. Secondly, the panels do not slow down CASAC’s review time. They work in parallel and concurrently with the chartered CASAC.

Part 6: The Disbanded CASAC PM Review Panel Reconvenes as the Independent Particulate Matter Review Panel

Members of the disbanded CASAC PM Review Panel formed the Independent Particulate Matter Review Panel (IPMRP). Like the disbanded CASAC PM Review Panel, the IPMRP is committed to providing “public service” “in protecting public health and safeguarding our nation’s air,” as described in the Nov 20, 2015 appointment letters from the EPA SAB staff office to panelists. The panel does not require affiliation with EPA to carry on its mission. Although no longer affiliated with the U.S. EPA, the IPMRP continues as a group of independent science advisors recognized for their national leadership in policy-relevant science pertaining to the particulate matter NAAQS.

The mission of this Panel is three-fold: (1) to provide independent advice regarding technical and policy assessments pertaining to the EPA’s review of the National Ambient Air Quality Standard (NAAQS); (2) objectively observe and assess modifications to the NAAQS Review Process and their implications; and (3) educate the public about the public health and public welfare objectives of the NAAQS, the NAAQS review process, and scientific issues pertaining to the NAAQS. Given the process under which this group was originally formed as the CASAC PM Review Panel, the Panel is recognized for its expertise and independence.

On December 10, 2018, the IPMRP submitted public comments to the CASAC pertaining to the EPA’s Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018).³ The IPMRP subsequently submitted comments to the CASAC on March 27, 2019 with additional comments on the draft ISA.⁶ These letters contain detail on the statutory requirements for the review of the NAAQS, history of the CASAC PM Review Panel and the IPMRP, and specific findings and recommendations related to the CASAC, NAAQS review process, and draft ISA.

In early September of 2019, EPA released an external review draft of the Policy Assessment (PA) for the PM NAAQS review.⁵⁸ A Federal Register notice published on September 11, 2019 indicated availability of the draft PA for public comment through November 12, 2019.⁵⁹ The chartered CASAC held a public teleconference on October 22, 2019 to receive public comments to consider in their peer review of the EPA’s Policy Assessment for Particulate Matter on October 24-25, 2019.⁶⁰ The chartered CASAC held a public meeting in North Carolina on October 24-25, 2019 for the purpose of conducting a peer review of EPA’s Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019).⁶¹

⁵⁸ EPA (2019), Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter, External Review Draft, EPA-452/P-19-001, U.S. Environmental Protection Agency, Research Triangle Park, NC, September 2019. https://www.epa.gov/sites/production/files/2019-09/documents/draft_policy_assessment_for_pm_naaqs_09-05-2019.pdf

⁵⁹ EPA, “Release of a Draft Document Related to the Review of the National Ambient Air Quality Standards for Particulate Matter,” *Federal Register*, 84(176):47944-47945 (September 11, 2019). <https://www.govinfo.gov/content/pkg/FR-2019-09-11/pdf/2019-19627.pdf>

⁶⁰ Public Teleconference of the Chartered Clean Air Scientific Advisory Committee (CASAC) on Particulate Matter, 10/22/2019, 12:00 PM - 04:00 PM. <https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCalCASAC/A2DF51609E3DFC9C85258473006CF120?OpenDocument>

⁶¹ Public Meeting of the Chartered Clean Air Scientific Advisory Committee (CASAC) on Particulate Matter, 10/24/2019 to 10/25/2019. <https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCalCASAC/49FAF8892AD2D38285258473006D1F4A?OpenDocument>

6.1 October 10-11, 2019 Meeting of the Independent Particulate Matter Review Panel

Because EPA did not correct the deficiencies created by disbanding the CASAC PM Review Panel, the IPMRP decided to reconvene in October 2019 to continue to provide its expert advice, based on the breadth, depth, and diversity of its expertise and experience, and based on interactive deliberation among its members.

Video and audio of the full October 10-11, 2019 meeting of the Independent Particulate Matter Review Panel is available on YouTube:

Day 1: <https://www.youtube.com/watch?v=wpodC23hJnQ>

Day 2: <https://www.youtube.com/watch?v=Y4LHvEAllrk>

More details of the meeting, which was hosted by the Union of Concerned Scientists, are at <http://www.ucsusa.org/pmpanel>. These details include:

- [Agenda](#)⁶²
- [Memo from Panel Chair](#)⁶³
- [Independent Particulate Matter Review Panel Biosketches](#)⁶⁴
- [Overarching Context for Review of the Particulate Matter National Ambient Air Quality Standards](#)⁶⁵
- [Background on the Independent Particulate Matter Review Panel](#)⁶⁶
- [Eligibility for Membership in the Independent Particulate Matter Review Panel](#)⁶⁷
- [Administrative Procedures for the Meeting](#)⁶⁸
- [Charge Questions for Panel on the EPA Particulate Matter Policy Assessment](#)⁶⁹

Individual members of the Panel submitted pre-meeting written comments which were posted publicly. Public comments were invited. Written public comments were received from 12 individuals. An opportunity was provided at the meeting for oral public comments.

IPMRP members were subject to a good faith ethics review by the former director of the EPA Science Advisory Board Staff Office. The IPMRP meeting was conducted according to the same procedures as a CASAC meeting. Panelists were reimbursed by the Union of Concerned Scientists for travel to attend the October 10-11, 2019 meeting but did not accept honoraria or other compensation. The content of the meetings, this letter, and attachments were determined exclusively by the Panel, and reflect exclusively the Panel's deliberations.

The [Panel's report](#) is available at the EPA CASAC website⁷ and has been submitted to Docket ID No. EPA-HQ-OAR-2015-0072.

⁶² <https://ucs-documents.s3.amazonaws.com/science-and-democracy/pm-panel-meeting-docs/ipmrp-agenda.pdf>

⁶³ <https://ucs-documents.s3.amazonaws.com/science-and-democracy/pm-panel-meeting-docs/1-memo-to-independent-pm-review-panel.pdf>

⁶⁴ <https://ucs-documents.s3.amazonaws.com/science-and-democracy/pm-panel-meeting-docs/2-ipmrp-biosketches.pdf>

⁶⁵ <https://ucs-documents.s3.amazonaws.com/science-and-democracy/pm-panel-meeting-docs/3-overview.pdf>

⁶⁶ <https://ucs-documents.s3.amazonaws.com/science-and-democracy/pm-panel-meeting-docs/4-ipmrp-history.pdf>

⁶⁷ <https://ucs-documents.s3.amazonaws.com/science-and-democracy/pm-panel-meeting-docs/5-eligibility.pdf>

⁶⁸ <https://ucs-documents.s3.amazonaws.com/science-and-democracy/pm-panel-meeting-docs/6-procedures.pdf>

⁶⁹ <https://ucs-documents.s3.amazonaws.com/science-and-democracy/pm-panel-meeting-docs/7-ipmrp-charge-questions.pdf>

6.2 EPA and Federal Courts Should Defer to the Independent Particulate Matter Review Panel, not CASAC

In contrast, the disbanded CASAC PM Review Panel, which reconvened as the Independent Particulate Matter Review Panel, has the breadth, depth, and diversity of expertise and experience necessary to conduct a proper review of the criteria and to develop advice for the EPA Administrator. Compared to the CASAC, the twenty-strong panel has more experts, covers more scientific disciplines, and has multiple experts who provide diversity of perspectives in key disciplines, such as epidemiology, toxicology, and controlled human studies, among others. All of the members of the Panel were originally appointed by EPA to the CASAC PM Review Panel. The Panel has developed its advice in accordance with the same FACA procedures it would have been subject to had it not been arbitrarily and capriciously disbanded in the middle of a review cycle. EPA should defer to the advice of the scientifically authoritative and appropriately constituted Panel, rather than the smaller and inappropriately constituted CASAC that is unqualified to offer advice in these matters.

6.3 Credible Advice on the Draft Integrated Science Assessment from the Independent Particulate Matter Review Panel

In its December 10, 2018 letter to CASAC and the EPA docket for the draft Integrated Science Assessment, the Independent Particulate Matter Review Panel offered consensus advice on numerous issues related to the draft ISA.³ The failure of EPA to provide a second external review draft of the ISA compromises the credibility and integrity of the NAAQS review process. This is because there were many important scientific issues raised regarding the first external review draft that require revision and iteration prior to their application in risk and exposure assessment and prior to their interpretation in the policy assessment. Although the IPMRP found that the draft ISA was a comprehensive scientific document, the IPMRP identified numerous areas for which refinement or revision was needed as detailed in its December 10, 2018 letter to CASAC. These areas include low cost sensors, air quality, contrasts between PM_{2.5} and UFP, coarse PM, PM components, onroad and near-road microenvironments, mixtures and copollutants, study selection, transparent application of the causal framework, more in-depth treatment of specific issues related to PM_{2.5} and mortality, more explanation and possible reconsideration of the causal determination for short-term exposure to coarse PM and respiratory adverse effects, more explanation and possible reconsideration of the causal determination for long-term exposure to UFP and central nervous system effects, and reconsideration of the at-risk causal finding for populations with pre-existing cardiovascular or respiratory disease. Members of the IPMRP also provided extensive individual comments that were attached to the December 10, 2018 letter from the panel.

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

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

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

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

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

6.4 Credible Advice on the Draft Policy Assessment from the Independent Particulate Matter Review Panel

Based on scientific evidence, as detailed in Attachment B of the Panel's letter,⁷ the Independent Particulate Matter Review Panel, formerly the CASAC PM Review Panel, finds that the current suite of primary fine particle (PM_{2.5}) annual and 24-hour standards are not protective of public health. Both of these standards should be revised to new levels, while retaining their current indicators, averaging times, and forms. The annual standard should be revised to a range of 10 µg/m³ to 8 µg/m³. The 24-hour standard should be revised to a range of 30 µg/m³ to 25 µg/m³. These scientific findings are based on consistent epidemiological evidence from multiple multi-city studies, augmented with evidence from single-city studies, at policy-relevant ambient concentrations in areas with design values at and below the levels of the current standards, and are supported by research from experimental models in animals and humans and by accountability studies.

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

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

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

The Panel finds that background PM_{2.5} levels are substantially below the levels of current and recommended alternative standards. Specific recommendations for areas of new research are provided.

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

for the disbanded CASAC PM Review Panel. The CASAC PM Review Panel should be reappointed to provide CASAC with the expertise it needs.

The detailed findings and recommendations of the Independent Particulate Matter Review Panel have been transmitted to the EPA Administrator, the docket for the draft Particulate Matter Policy Assessment, and to the CASAC.

Details on the Panel, including background materials and videos of the October 10-11, 2019 meeting of the Panel, are available via www.ucsusa.org/pmpanel. Comments Regarding CASAC's "Consensus" Statements

Part 7: Decision Context for NAAQS Review May Not Be Redefined by CASAC

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

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

“Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities.” and “any known or anticipated adverse effects on welfare”

And from Section 109:

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

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

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

Federal courts have found that the language of the Clean Air Act is intended to address uncertainties – meaning that standards can be set to protect public health even if there are uncertainties in the scientific evidence. Stated another way, the CAA does not require absolute certainty of adverse effects as the basis for setting a NAAQS. The courts have found that the CAA requires a reasonable degree of protection not just to the general public, but to subpopulations that are at greater risk than the general public. Such groups are characterized in the draft ISA, as they have been in ISA’s for other criteria pollutants in recent review cycles, as “at-risk” populations. The CAA does not require that there be zero risk nor does it require any ‘brightline’ definition of ‘acceptable risk.’

Historically, and as demonstrated by the regulatory record, the NAAQS are typically set at levels that have been found to be associated with, or that are anticipated to be associated with, adverse effects to public health and public welfare. Scientific advice regarding the indicator, level, averaging time, and form of a NAAQS can and should be based on reasoned scientific judgment based on the overall weight of evidence. Scientific judgment must be based on the judgment of scientists with the appropriate competence relevant to the domain(s) of the review. In the case of particulate matter, the key scientific domains include, but are not limited to, epidemiology, controlled human studies, and toxicology. The CASAC lacks any epidemiologists, and the appointment of an ad hoc pool of consultants that cannot deliberate with the CASAC interactively, and who were not involved in review of the scientific criteria in the draft ISA, does not correct this deficiency. It is not sufficient or appropriate for CASAC to offer advice based on

its limited scope of scientific competence, and given that it lacks breadth, depth, and diversity of expertise and experience necessary to the PM NAAQS review.

Moreover, it is not appropriate for CASAC to impose a normative decision-making context given that the Clean Air Act expressed the intent of Congress regarding how the NAAQS should be set. If Congress had wanted to impose a highly risk-seeking decision framework that would emphasize a very high burden of evidence based on exclusive focus on true positive findings established with complete certainty, or near-certainty, while ignoring the overall weight of evidence, then surely Congress would have so specified such a context in the Clean Air Act. Congress did not do this. Instead, Congress specified a decision context based on concepts of public health, protecting public health, and doing so with an adequate margin of safety. These phrases in the Clean Air Act are well understood to take a protective view of how the standards should be set: that is, if there are uncertainties, the standards should err on the side of protecting public health rather than placing an undue burden of proof that is beyond that required by statute.

Part 8: The Role of Expert Judgment in Scientific Review of the NAAQS

In the current review process the Administrator has arbitrarily and capriciously done away with the CASAC PM Review Panel. Given the important role of expert judgment in CASAC's work, it is essential that CASAC be augmented with additional experts in the multiple scientific disciplines needed for this review. Furthermore, there must be multiple experts in key areas, such as air quality physics and chemistry, exposure assessment, toxicology, controlled human studies, epidemiology, and others, to have a diversity of perspectives to assure that judgment is based on the large body of relevant scientific evidence using accepted inference methods. For four decades, CASAC has been augmented with expert panels as documented by Frey et al. (2018) and others.^{3,70,71} Augmented panels advise the CASAC and supplement it with the expertise it needs. Absent such augmented expertise, the chartered CASAC is scientifically unqualified to conduct a review consistent with language in the Clean Air Act.

Expert judgment requires judgment by domain experts.^{72,73} Given that this CASAC lacks experts in the appropriate scientific domains, it is unqualified to offer such judgments. Given that this CASAC lacks expertise in many key disciplinary areas, especially epidemiology, and that EPA arbitrarily and capriciously disbanded the CASAC PM Review Panel a few days before the Draft ISA was released, thereby depriving CASAC of the needed expertise, this CASAC is not in a credible position to offer judgments regarding causal determinations.

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

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

The CASAC chair has, on several occasions during the PM NAAQS review, made comments regarding biases in elicitation of expert judgment. The comments focused on limitations that appeared aimed at discrediting expert judgment, without acknowledgment that knowledge of

⁷⁰ Bloomer, L., and J. Goffman, "The Legal Consequences of EPA's Disruption of the NAAQS Process," Environmental and Energy Law Program, Harvard Law School," undated, <http://eelp.law.harvard.edu/wp-content/uploads/Legal-Consequences-of-NAAQS-Changes.pdf>, accessed 10/7/19

⁷¹ Bachmann, J., "Written Statement for the Public Meeting of the EPA Chartered Science Advisory Board, Re: 5/31 SAB Discussions about EPA Planned Actions and their Supporting Science," Environmental Protection Network, May 29, 2018, <http://www.scientificintegrityinstitute.org/EPATransBachmann052918.pdf>

⁷² EPA, Expert Elicitation Task Force White Paper, Science and Technology Policy Council, U.S. Environmental Protection Agency, Washington, DC, August 2011. https://www.fwspubs.org/doi/suppl/10.3996/052017-JFWM-041/suppl_file/10.3996052017-jfwm-041.s7.pdf

⁷³ Morgan, M.G., and M. Henrion, *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press, 1990.

heuristics and other biases involved in eliciting judgments can be used to design better processes for inferring such judgments.

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

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

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

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

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

Part 9: ‘Sound Science’, CASAC, and Science Denial

As detailed in this section, the deliberations and draft written recommendations of the CASAC are self-described as being based on ‘sound science.’ The characteristics of so-called ‘sound

science,' as evident by CASAC's own words, are described here. Well-known characteristics of science denial are reviewed based on recent literature. These characteristics are evident in the positions taken by CASAC. The espousal of 'sound science' in a denialism context renders CASAC as not credible.

9.1 "Sound Science" – Raising the Burden of Proof Beyond/Despite Statutory Requirements

The chair of CASAC made statements during CASAC's October 24-25, 2019 public meeting to the effect that both the EPA Administrator and the CASAC chair share the same view of "sound science" and will apply it to the review of the PM NAAQS. CASAC's draft letter contains the claim that "the Administrator's and CASAC's explicit emphasis on sound science throughout the review process, including critically reexamining long-standing practices and assumptions in light of recent data and methods" is an example of the "exceptional nature of the current CASAC and NAAQS review process." This is a political, not scientific, statement. The CASAC is engaging in science denial, as further discussed below. Based on statements and actions of the EPA Administrator, it is very clear that "sound science" entails ignoring science so as to provide more freedom for the application of an ideological regulatory roll-back agenda. The term "sound science" is often an ideological statement to require a higher burden of proof than is required by the statute.⁷⁴ In the case of the CASAC chair, 'sound science' is used to raise the burden of proof beyond that required by statute.

Examples of statements and actions by the Administrator that reveal his contempt for, and denial of, science include but are not limited to the following:

- Numerous changes to the NAAQS review process during the middle of the PM NAAQS review, as detailed elsewhere in these comments.
- Pending release of a "supplemental" for the so-called "transparency" rule, which is clearly aimed at undermining the use of scientific studies that are based on human subject data and, therefore, would have the effect of eliminating valid scientific studies from use in developing regulations.⁷⁵
- A suddenly-announced policy to phase out animal testing, which will have the effect of preventing the development of toxicological evidence based on animal models. Such evidence is often the basis for inferring causal modes of action with regard to how exposure to contaminants in the environment lead to health effects. There is not an adequate substitute inference method for this type of finding. Thus, EPA is proposing to do away with a key tool without having a replacement tool readily available.⁷⁶
- Proposing science policy initiatives, such as the so-called "transparency" rule and the phased in ban on animal testing, without engaging scientists. As required by law under ERDDAA, EPA failed to notify the Science Advisory Board of the proposed so-called "transparency" rule, and has slow-walked its limited engagement with the SAB.⁷⁷ EPA did not engage the SAB at all with regard to the phased animal testing ban.

⁷⁴ An example of a discussion of the meaning of "sound science" in the context of environmental regulation is given by Ruden and Hansson (2008) in "Evidence-Based Toxicology: "Sound Science" in New Disguise," *International Journal of Occupational and Environmental Health*, October 2008, 299-306.

⁷⁵ H. Holden Thorp, Magdalena Skipper, Veronique Kiermer, May Berenbaum, Deborah Sweet, Richard Horton, Joint statement on EPA proposed rule and public availability of data (2019), *Science*, 26 Nov 2019.

⁷⁶ U.S. EPA to eliminate all mammal testing by 2035, *Science*, Sep. 10, 2019.

⁷⁷ Frey, H.C., EPA Has a Statutory Responsibility to Use Properly Developed and Reviewed Science, Written Public Comment to the U.S. EPA Science Advisory Board, Washington, DC, June 5, 2019.

- At the EPA Science Advisory Board meeting in June 2019, the Administrator stated that “I’ve believed for a long time that federal research would be more accepted by the public if you used the double-blind standard for everything.”⁷⁸ This type of study design is used in clinical trials of pharmaceuticals. It is irrelevant to the study of the effect of contaminants in the environment to real people. Espousing that double-blind should be a standard for everything would create a situation in which nothing could be inferred about real-world exposures to real-world contaminants and their effects on real-world people. In short, the Administrator’s statement is a stunning example of breath-taking ignorance of the types of health effects problems that EPA routinely must address.

These are not actions consistent with improving the scientific knowledge basis for making informed regulatory decisions. They are actions aimed at undermining, censoring, and truncating scientific activity and studies.

In December 2018, during clarifying public oral comments at CASAC’s public meeting on the draft ISA, I recommended that CASAC ask the EPA Office of General Counsel (OGC) to explain to CASAC what the NAAQS decision context is.⁷⁹ When I chaired CASAC and CASAC review panels, I asked for this. However, neither the chair nor any member of CASAC asked OGC for this input.

On October 24, 2019, I delivered an oral public comment that again recommended that CASAC ask OGC for this input.⁹ The statutory requirements are given in the Clean Air Act. Section 109 of the Clean Air Act states:

“National primary ambient air quality standards, prescribed under subsection (a) shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.” The phrase “such criteria” refers to Section 108 of the Clean Air Act, which specifies that “[a]ir quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on--(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant; (B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and (C) any known or anticipated adverse effects on welfare.”

[https://yosemite.epa.gov/sab/sabproduct.nsf/E7E9BB166E07DB7885258415005F0FD8/\\$File/Written+statement+from+Christopher+Frey+to+SAB+190605.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/E7E9BB166E07DB7885258415005F0FD8/$File/Written+statement+from+Christopher+Frey+to+SAB+190605.pdf)

⁷⁸ Goldman, G., “Wheeler’s Breathtaking Ignorance of Science, in One Comment,” Union of Concerned Scientists, June 6, 2019. <https://blog.ucsusa.org/gretchen-goldman/wheelers-breathtaking-ignorance-of-science-in-one-comment>

⁷⁹ Frey, H.C. “Clarifying Oral Comment,” to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Crystal City, VA, December 13, 2018. [https://yosemite.epa.gov/sab/sabproduct.nsf/0471352D965DF693852583620007AEA3/\\$File/List+of+speakers-121218-clarifying+comments.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0471352D965DF693852583620007AEA3/$File/List+of+speakers-121218-clarifying+comments.pdf)

See also an article published December 14, 2018 by InsideEPA, “Former CASAC Chairman Warns ‘Joke’ Review Hurts PM NAAQS Assessment”

The language of Sections 108 and 109 have been interpreted by Federal courts, including the U.S. Supreme Court. This language is understood to allow for protection of public health even when there are uncertainties, and to allow for protection of at risk populations in addition to the general population. Protection does not, however, require zero risk. The level of protection required under the Clean Air Act does not require scientific certainty as a basis for setting a standard.

On October 25, 2019, shortly after the CASAC meeting reconvened for a second day, Dr. Cox referenced and partially responded to my remark above regarding “sound science”. In his remarks, Dr. Cox did not address the key point in my comment that members of this CASAC are imposing a burden of proof beyond that required by the statute in formulating their advice on whether to retain or revise existing PM NAAQS. In addressing my comment about “sound science” in his opening remarks on Oct 25, Dr. Cox: (1) did not state that he would ask the EPA Office of General Counsel for an explanation of the decision context of the NAAQS review; (2) did not ask any of the other members of CASAC if they would like to hear from the EPA Office of General Counsel regarding the decision context for the NAAQS review; (3) did not acknowledge my advice to ask the EPA Office of General Counsel for an explanation of the decision context of the NAAQS review; (4) did not explain why CASAC has not asked for such an explanation nor provide any rationale for why CASAC will not seek such input; and (5) did not summarize his or the CASAC’s understanding of the decision context as set forth in Sections 108 and 109 of the Clean Air Act and as interpreted by Federal courts. Especially at this stage of NAAQS review, during which CASAC is deliberating on a draft Policy Assessment, it has been common, in my experience (having served on 10 CASAC review panels and chaired three of them), to provide a few minutes for the EPA Office of General Counsel to share their perspective on these matters and answer clarifying questions from members of the cognizant CASAC review panel.

I further note that CASAC’s undated draft letter on the draft PA, posted during November 2019, does not reference Sections 108 or 109 of the Clean Air Act, does not explain what CASAC’s understanding is of these sections of the Act, and does not explain whether or in what why the CASAC has taken the statutory requirements of the NAAQS into account, including their interpretation by authoritative courts, in considering the appropriate burden of proof that should be the foundation for advice. Furthermore, I note the following:

- The Clean Air Act requires that standards protect not just the general population, but also “at-risk” groups, taking into account uncertainties. At-risk groups include those exposed to elevated levels of air pollution due to social disparities. In contrast, other than a very brief mention, without elaboration, of the term “sensitive subpopulation,” CASAC does not mention, much less take into consideration, at-risk groups.
- Environmental justice is mentioned zero times in the 297 pages of CASAC’s draft report.
- The three times higher hazard ratio faced by African-Americans compared to the general public is completely ignored by CASAC.

Examples of “sound science” tactics include, but are not limited to, the following:

- Insistence on re-definition of widely accepted terminology.
- Claiming and insisting that existing inference methods are “technically unsound” while positing that only a new method or group of methods, not actually demonstrated in the subject matter domain, must be used to arrive at valid inferences.
- Demanding that each and every study be subject to highly restrictive “study selection” and “study evaluation” criteria, which would have the effect of throwing out each study

one by one, after which a claim would be made that there are few/no acceptable studies and, hence, nothing new and no need to make any changes to existing regulations. This is in contrast to a more balanced approach in which studies are considered with regard to their strengths and limitations, recognizing that shortcomings of one study might be addressed by other studies and that, collectively, they provide a body of evidence useful for making inferences.

- Repeatedly citing one’s own work.
- Over-emphasizing/exaggerating uncertainties.

Other examples of “sound science” tactics go beyond claims about the science itself to process issues. For example, if one wanted to design a “science review” process that would lead to a predetermined outcome – in this case that there should be no change to the annual average PM NAAQS – one would likely do the following (this list is illustrative, not exhaustive):

- Get rid of actual experts. Actual experts are a threat to a predetermined agenda because they will follow the science. Thus: (1) disband an expert panel, such as the CASAC PM Review Panel, that has the breadth, depth, and diversity of expertise and experience to conduct a review; and (2) completely replace all of the existing members of the statutory advisory body, CASAC, using new criteria based on geographic location and governmental affiliation, rather than scientific expertise. Add to this a ban on nongovernmental recipients of EPA research grants.
- Require EPA staff to create assessment documents on an accelerated schedule.
- Not allow second external review drafts of the assessment documents, even if scientific revisions are warranted.
- Delete key assessment documents, such as the Risk and Exposure Assessment planning document and the first and second external review drafts of the Risk and Exposure Assessment.
- Release and review a draft PA before the draft ISA has been finalized, thereby commingling policy and science issues.
- Reduce the number of public meetings of the CASAC, which reduces opportunities for public comment and leads to a less transparent process.
- After criticism for disbanding the CASAC PM Review Panel, appoint an ad hoc pool of consultants by the politically appointed EPA Administrator rather than the SAB Staff Office, including consultants nominated by the CASAC Chair whose advice is cherry-picked in CASAC’s draft letter to the Administrator.

9.2 Skepticism versus Denialism

A skeptic is a person inclined to question or doubt all accepted opinions. The scientific method, which entails attempting to falsify hypotheses, is rooted in a form of skepticism as part of a search for truth. For example, a pro-science skeptic could have honest questions about climate change. In contrast, climate “skeptics” appear to be motivated primarily by ideology, and do not base their views on evidence. The terms “skeptic” and “denier” are used nearly interchangeably in some cases. The term “contrarian” may be more accurate than “skeptic”. In the extreme, a skeptic is a person who denies the possibility of knowledge, or even rational belief, in some sphere.⁸⁰

⁸⁰ Whitmarsh, L., 2011. Scepticism and uncertainty about climate change: Dimensions, determinants and change over time. *Global Environmental Change, Special Issue on The Politics and Policy of Carbon Capture and Storage* 21, 690–700. doi:10.1016/j.gloenvcha.2011.01.016

In contrast, a denialist is a person who refuses to admit the truth of a concept or proposition that is supported by the majority of scientific or historical evidence. The application of denialism to science-based issues is often traced to the famous 1969 memorandum to Brown and Williamson regarding the health effects of tobacco that stated “doubt” is the “product”.⁸¹ According to Bjornberg et al., science denial is the “unwillingness to believe in the existing scientific evidence” and “[d]isseminating doubt about valid scientific data and results is at the very heart of science denial.”⁸² Bjornberg et al. find that “the strategies employed by those who actively deny climate science are also employed in other environmental policy fields.” Karlsson more recently found that “science denial commonly occurs also in the field of chemicals assessment and policy, but the research on this topic is scarce.”⁸³

Bjornberg et al. find that “a small minority of scientists actively deny the evidence of environmental problems” and that such scientists “are typically not part of the established community of researchers working in the field in question.” Many, although not all, “of the denialists are not affiliated with any academic institution.”

Governments can be captured by denialist special interests. For example, based on an extensive literature review, Bjornberg et al. found that “[s]everal articles identify the former George W. Bush administration as a significant actor in the “war on science” and that “this presidency institutionalized climate science denial throughout the most powerful branch of the U.S. government, allowing representatives of fossil fuel industries and conservative think tanks to undermine climate science and policy from within the administration. The new Trump administration seems possibly second to none in this context.” Based on changes at EPA during the first six months of the Trump administration, Dillon et al. (2018) found that “new EPA leadership has thus far aimed at deconstructing, rather than reconstructing, the agency by comprehensively undermining many of the agency’s rules, programs, and policies while also severely undercutting its budget, work capacity, internal operations, and morale.”⁸⁴

Diethelm and McKee identified five characteristics of science denial, including conspiracy theories, reliance on fake experts, selectivity in picking papers that in isolation seem to support their claims (cherry-picking), impossible expectations of what research can deliver, and misrepresentation and outright logical fallacies.⁸⁵ Karlsson observes that the characteristics of chemicals denial share these characteristics “including reliance on fake experts, cherry-picked facts... with a key aspect being the questioning of causal relationships.” The latter includes “insistence on impossible causal certainty” and leads to ‘causality-denial’ claims. Karlsson further points out that:

“[d]eniers commonly have unreasonable expectations on what research can deliver and often argue for placing the burden of proof on those who claim the existence of risks or problems, arguing that such an order applies ‘sound science’. However, as the question of where to place the burden of proof is

⁸¹ <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=psdw0147>, see top of page 4.

⁸² Bjornberg, K.E., M. Karlsson, M. Gilek, and S.O. Hansson, “Climate and environmental science denial: A review of the scientific literature published in 1990-2015,” *Journal of Cleaner Production*, 167(2017):229-241.

⁸³ Karlsson, M., “Chemicals Denial – A Challenge to Science and Policy,” *Sustainability*, 2019, 11, 4785.

⁸⁴ Dillon, L., C. Sellers, V. Underhill, N. Shapiro, J.L. Ohayon, M. Sullivan, P. Brown, et al., “The Environmental Protection Agency in the Early Trump Administration: Prelude to Regulatory Capture,” Editorial, *American Journal of Public Health* (AJPH), 8, Vol 108, No. S2, S89-S94 (2018).

⁸⁵ Diethelm, P., M. McKee, “Denialism: What is it and how should scientists respond?,” *Eur. J. Public Health*, 19(1):2-4 (2009).

normative, this argumentation is a naturalistic fallacy (and ‘sound science’ is tautological) that serves to delay decision making.”

The denialist tactic of raising the burden of proof is pervasive. For example, Hansson notes that:⁸⁶

“scientific hirelings of the tobacco industry have argued epidemiological evidence should be systematically disregarded unless it presents very high odds ratios or relative risks... The same requirements has also been raised by industry-affiliated pseudoscientists lobbying against reductions in human exposure to other toxic substances... These and other re-interpretations of science by the tobacco industry would make many health risks with a considerable death toll, including passive smoking, immune against risk reduction measures.”

An example of raising the burden of proof beyond that required by statute is evident in the position of the majority of the current CASAC, including Drs. Cox, Lange, Packham, and Macusa, who appear to be arguing that each and every epidemiologic study should be subject to quantitative causal tests, and that current standards should be revised only if there is a very high level of certainty (or absolute certainty) of the outcome of these posited quantitative causal tests, applied to each study one by one. The denialism here is that the CASAC majority is setting aside the ground rules of the scientific review, established in the Integrated Review Plan and as set forth in the Preamble to the Integrated Science Assessments, and in so doing is ignoring the overall weight of evidence. Findings based on the overall weight of evidence are given by the Independent Particulate Matter Review Panel in its October 22, 2019 letter and report to the EPA Administrator.³ The CASAC majority (of four people) is insisting on redefining the science assessment and inference process based on a new set of rules that are not in the policy-relevant particulate matter health effects literature, based on impossible expectations of what science can deliver in this context as they have defined it. The majority appears to be insisting that, in lieu of the application of quantitative causal tests, inferences regarding concentration-response relationships should be disregarded on the premise that they are merely ‘associational.’ However, CASAC has not demonstrated that these associations are spurious artifacts of confounding, or identified other overwhelming threats to validity that undermine the robustness of these associations, in combination with other lines of evidence, for making causal inferences using a judgment-based approach. Admittedly, however, the CASAC is not well-constituted to make such judgments.

Note the entry of denialism into CASAC is possible only because of the myriad of changes to the NAAQS review process:

- By eliminating CASAC review panels, CASAC is not burdened by a breadth, depth, and diversity of expertise and experience that would challenge denialist views.
- By appointing an ad hoc pool of consultants that can only communicate with CASAC in writing, CASAC may cherry-pick. In fact, CASAC has cherry-picked from the consultants. The only consultants whose opinions are mentioned by name in CASAC’s draft so-called ‘consensus’ statements are persons nominated by the CASAC chair who hold views consistent with those of the chair. Consultant viewpoints inconsistent with those of the CASAC majority are ignored.

⁸⁶ Hansson, S., “Science denial as a form of pseudoscience,” *Studies in History and Philosophy of Science*, 63(2017):39-47.

- By placing emphasis on non-scientific criteria, such as geographic location and government affiliation, CASAC can be populated with persons who are not mainstream scientists.
- By banning nongovernmental recipients of EPA research grants from serving, leading researchers are disqualified from serving on CASAC. However, there is no ban on persons with the appearance of conflict of interest, such as consultants whose clients include regulated industries with a vested interest in the outcome of these proceedings.

An editorial in the prestigious journal *Nature* recently stated that CASAC “is deliberately ignoring the weight of evidence from an array of rigorous epidemiological studies, aligned with other sources.”⁸⁷ The position of the CASAC majority is inconsistent with the well-established causality determination inference framework, as set forth in the Preamble to the ISAs³⁷ (and that has been peer-reviewed by many experts over the course of many CASAC reviews for more than a decade), based on the overall weight of evidence that takes into account many factors, including but not limited to consistency in findings of epidemiological studies that represent wide ranges of variability in underlying conditions such as population demographics, socio-economic status, housing types, climatic zones, and so on, and coherence with other line of evidence such as controlled human studies and toxicological studies.

The strategy of the CASAC majority of redefining the assessment problem in a manner that is inconsistent with mainstream science, inconsistent with the Integrated Review Plan for particulate matter, and inconsistent with the Preamble to the ISAs, has the effect of denying the overall weight of evidence.

Hansson notes that “to form a well-considered scientific judgment, it is essential to evaluate the whole body of evidence.”⁸⁶ He goes on to state:

“Arguably, you can prove almost anything you want by cherry-picking the evidence. A classic example is the tobacco industry’s campaigns in the 1990s in which cherry-picking was systematically employed to discredit the evidence showing that passive smoking causes deadly diseases”

Hansson notes that “quote-mining” is a type of cherry-picking that involves “truncation and misrepresentation” of quotes. As detailed later in these comments, there are numerous examples of quote-mining in CASAC’s draft consensus statements.

Hansson notes that “science denialists place excessive emphasis on possible sources of error in evidence supporting the mainstream view, whereas argumentation purportedly supporting the denialist view are taken at face value.” The current CASAC majority has listed many purported sources of doubt in their individual comments and in the draft letter and consensus responses to charge questions. However, as an example of ‘asymmetry of scientific challenge,’ the CASAC makes many of its own judgments about uncertainties, about what methods should be used to infer causality, and that causality should be inferred on an individual study-by-study basis, while claiming as “technically unsound” expert scientific judgment by others. The CASAC does not have the breadth, depth, or diversity of expertise and experience to offer scientific judgments in areas for which it lacks competence, especially with regard to epidemiology, yet this CASAC is engaged in making very strong statements about how epidemiology should be done and applied, both of which are not consistent with mainstream scientific practice.

⁸⁷ “Stop denying air pollution risks: research linking fine particulate pollution and premature deaths is under attack in the United States and other countries,” editorial, *Nature*, 568:433 (25 April 2019).

An example of cherry-picking is near-exclusive focus on doubt-raising as a tactic to obfuscate robust scientific findings in favor of the impression that such findings cannot be reliably known. In reading CASAC's draft letter, and having listened to the deliberations that are only partly reflected in the draft letter, as well as having likewise listened to CASACs prior deliberations and read its prior letter on the draft ISA, it is clear that members of the CASAC majority are focusing with near-exclusivity on doubt-raising. It is very hard to find any statements by this majority regarding anything that is known with a reasonable degree of confidence. There is not a balanced discussion, for example, of what is known and of what can reasonably be inferred. Instead, laundry lists of doubts are posited, as if each listed item might be equally important or sufficient to impugn an overall finding based on the weight of evidence.

A more balanced approach acknowledges and accounts for uncertainty but is not paralyzed by laundry lists of uncertainty unless uncertainties are truly so large as to obscure any positive findings. The latter is not the case with regard to the central issues regarding criteria in this review or reasonable advice that should therefore follow. In fact, the Independent Particulate Matter Review Panel carefully considered key sources of uncertainty in the use of multiple pollutant models in multi-city epidemiological studies and took those into account in arriving at a well-conditioned expert judgment that robust inferences can be made even in the face of such uncertainties.⁷ The Panel could do that because it was comprised of multiple experts in each of the relevant key scientific domains, such that it had the breadth, depth, and diversity of expertise and experience upon which to form such judgments with credibility.

Well-known denialist organizations and their representatives are expressing support for the position of the CASAC majority. Examples include, but are not limited to, "Junkscience.com," "Heartland Institute," and "The Heritage Foundation."

Denialism is based on fallacies. **Examples** of fallacies in CASAC's draft letter include but are not limited to:

- Appeal to authority: e.g., self-citations and references to papers outside of the domain of literature of policy-relevant science.
- Argument from repetition: repeating the claims that the EPA assessment documents are "technically unsound" does not make them technically unsound.
- False attribution: e.g., quoting out of context.
- False authority: e.g., claiming that a small committee that lacks expertise in epidemiology has any credibility to offer opinions, much less recommendations, regarding epidemiology.
- Fallacy of many questions: e.g., asking many questions, as in the case of diverting CASAC's attention away from EPA charge questions towards questions posed by the chair, does not prove that such questions are salient or that the issues underlying the questions are fatal flaws.
- Proof by verbosity, shotgun argument: e.g., see also the fallacy of many questions. Also illustrated by use of valuable public meeting time by one member of CASAC to lecture fellow members of CASAC on self-selected issues without affording similar opportunities to other members. Also illustrated by offering so many definitions of causality to the point where another CASAC member stated that doing so serves to obfuscate.
- Red herring: repeatedly claiming that the only valid epidemiologic studies are ones that explicitly account for daily min/max temperature, and other such *dicto simplicitor* types of edicts.
- Thought-terminating cliché: e.g., "sound science".

9.3 Other Characteristics of Denialism

Denialism is often described as having five key characteristics, with the identification of the five characteristics attributed to Diethelm and McKee (2009):⁸⁵

- **Conspiracy Theories:** For example, the conspiracy theory that academic recipients of EPA scientific research grants are simply going to rubber stamp whatever the EPA proposes, which is the underlying rationale for why academic EPA scientific research grant recipients are now not allowed to serve on EPA advisory committees. This, by the way, is not true, given that EPA has diverged from CASAC's advice on many occasions and that CASAC has diverged from draft PA's on many occasions.
- **Fake Experts:** "These are individuals who purport to be experts in a particular area but whose views are entirely inconsistent with established knowledge," often coupled with the "marginalization of real experts." Typically, the "fake experts" are well-credentialed, but are offering advice in areas beyond their core competence without sufficient conditioning based on interaction with domain experts. These characteristics are evident in the re-composition of the chartered CASAC and the disbanding of the CASAC PM Review Panel, respectively.
- **Selectivity:** "drawing on isolated papers that challenge the dominant consensus or highlighting the flaws in the weakest papers that support it as a means of discrediting the entire field." This characteristic is also known as "cherry-picking." Numerous examples of cherry-picking are given elsewhere in this comments. These include self-citations, insistence that the draft ISA and draft PA cite references that are not policy-relevant or within the timeframe of the literature review (despite otherwise insisting on strict study selection criteria), highlighting claimed but not proven strengths of advocated methods while ignoring any of their limitations, and developing qualitative laundry lists of doubts and over-emphasized uncertainties about robust scientific findings without critical evaluation of the robustness of the findings to such doubts and uncertainties, and so on.
- **Creation of Impossible Expectations of What Research Can Deliver:** the case in point in this review is claim in CASAC's draft letter that quantitative causal inference methods are readily available and should be applied in this review cycle to the evaluation of each epidemiological study individually, even though such methods have not been adequately demonstrated and vetted in the policy-relevant literature and have significant limitations that preclude their rapid adoption.
- **Misrepresentation and Logical Fallacies:** Examples of misrepresentations are given later regarding, for example, quotes in CASAC's draft consensus responses that are taken out of context in a manner that is misleading while also misrepresenting the main points of the quoted authors. Examples of logical fallacies are given above. Other fallacies include simply ignoring relevant evidence, as in the case of the apparent rationale by which CASAC claims to find that the current annual primary PM_{2.5} standard does not need to be revised.

Part 10: Comments Regarding CASAC's Draft Letter

CASAC's draft letter on EPA's draft Policy Assessment is technically unsound and severely lacking in foundation and credibility. It is predicated on judgments, mainly by a sub-group of four people. This sub-group of four lacks the breadth, depth, and diversity of expertise and experience necessarily to properly condition such judgments on the full weight of evidence. In particular, the subgroup of four, and the chartered CASAC as a whole, lacks expertise in epidemiology, which is the scientific discipline central to the review of the primary PM standards. The selective cherry-picking of written comments of the ad hoc pool of consultants by the CASAC does not correct this deficiency in any substantial way. The CASAC has been arbitrarily and capriciously deprived of the CASAC PM Review Panel. There should have been 26 people, not 6 people, at the table at each of CASAC's meetings since December 2018.

10.1 The Draft Integrated Science Assessment Provides a Comprehensive, Systematic Assessment of Available Policy-Relevant Science

The characterization that the draft Integrated Science Assessment (ISA) for Particulate Matter "does not provide a sufficiently comprehensive, systematic assessment of the available science relevant to understanding the health impacts of exposure to PM" and related text is unsupported by the evidence and is a finding completely at odds with that of a much larger expert group. See comments of the Independent Particulate Matter Review Panel.⁷ The Panel has the breadth, depth, and diversity of expertise and experience needed for this review and that is lacking in the chartered CASAC.

10.2 CASAC's Finding that the Current Primary Annual PM_{2.5} Standard is Adequate is Technically Unsound

The claim by some members of the CASAC that "the Draft PM PA does not establish that new scientific evidence and data reasonably call into question the public health protection afforded by the current 2012 PM_{2.5} annual standard" is not credible. This claimed finding is specious because:

- The chartered CASAC lacks the breadth, depth, and diversity of expertise and experience necessary to make a judgment on this matter.
- The CASAC is ignoring evidence to arrive at this finding.
- During deliberations of the CASAC, CASAC failed to ask clarifying questions of epidemiologists on the EPA staff, demonstrating that CASAC is not interested in hearing from experts who might contradict their own biases.
- CASAC has cherry-picked written opinions most favorable to their majority view from among the ad hoc pool of consultants. For example, the views of Dr. Duncan Thomas were ignored. However, the circumstances under which the pool was appointed, and the inability to have interactive deliberations between the pool and the CASAC, undermines the credibility of the use of an ad hoc pool of consultants as a resource for the CASAC.
- A far more qualified panel, comprised of the breath, depth, and diversity of scientific expertise and experience necessary to these matters, reached a different conclusion based on appropriate use of the scientific inference framework in place for this review as established in the Integrated Review Plan and the Preamble to the ISAs, and based on the policy-relevant scientific evidence.

The CASAC claims as "technically unsound" an inference that regression concentration-response functions are treated as causal. In fact, this is not technically unsound. The causal inference here is not based on quantitative causality tests applied to individual epidemiologic studies. The causal inference here is based on a methodology that has been reviewed by at

least 74 experts over the course of multiple CASAC review panels prior to 2017. This is 70 more experts than in the current CASAC majority of 4 people.

The IRP sets the ground rules for the PM NAAQS review and was itself reviewed by CASAC in 2016. Thus, CASAC is ignoring itself when it attempts to change the ground rules of a review in the middle of a review cycle. This is illogical and inappropriate. Furthermore, four members of the CASAC are attempting to impose new methods and new evaluation criteria that are not adequately demonstrated and vetted in the policy-relevant literature for this review cycle. Moreover, in attempting to impose requirements for the use of new inference methods, this CASAC is attempting to redefine the decision context in a manner that creates a burden of proof in excess of that required by statute.

10.3 CASAC's Finding that the Current Primary Annual PM_{2.5} Standard is Adequate is Technically Unsound

The CASAC's draft statement that "the available evidence does not call into question the adequacy of public health protection afforded by the current 24-hour PM_{2.5} standard" is not supported by the weight of scientific evidence. See the findings and advice of the Independent Particulate Matter Review Panel for an accurate and appropriate interpretation of the available evidence and implications for the need to revise the existing primary 24-hour PM_{2.5} standard to a level between 30 µg/m³ to 25 µg/m³, while retaining the current indicator, averaging time, and form.⁷

10.4 CASAC's Finding that the Current Primary Annual PM₁₀ Standard is Adequate is Technically Unsound

The CASAC spent approximately 10 minutes deliberating on the primary annual PM₁₀ standard. The Independent Particulate Matter Review Panel took this standard more seriously and developed credible advice based on a full consideration of the salient issues.⁷

10.5 CASAC's Finding that the Current Welfare Standard is Adequate is Technically Unsound

The chartered CASAC is not properly constituted to offer advice on the secondary PM standards, since there was no one present at CASAC's meeting with expertise in the key scientific domains and areas pertaining to that topic, including visibility, materials damage, and climate effects. Thus, CASAC was not able to engage in any deliberation or to properly condition its judgments on the needed breadth, depth, and diversity of scientific expertise and experience on these matters. CASAC hardly touched the issue of visibility. In contrast, the Independent Particulate Matter Review Panel provided detailed comments regarding how the draft PA should be revised to more appropriately and fully address the issue of whether the current standard is adequate and how the revised draft PA should provide a framework for consideration of other indicators, forms, averaging times, and levels that are more relevant to welfare effect endpoints.⁷

10.6 Proposed Methodological Changes are Unwarranted

CASAC has failed to establish the viability of proposed "methodological changes in the current CASAC's scientific and technical approach in this review cycle." The four-member majority of CASAC is attempting to substitute methods not adequately demonstrated and vetted in the policy-relevant peer-reviewed literature for a well-established and broadly reviewed weight of evidence framework for causality determination. The adoption of new methodology in a regulatory decision-making context requires that the method be established in the relevant peer-reviewed literature. This is simply not the case with regard to the "formal quantitative causal inference" methods and their application to policy-relevant epidemiologic studies. Moreover,

although the CASAC majority is adept at making laundry lists of uncertainties for other analysis methods, there has not been acknowledgement of any limitations of the methods that are advocated by the CASAC majority for quantitative causality tests of individual epidemiologic studies. See comments, for example, of Dr. Lianne Sheppard, regarding examples of limitations of such methods. Credible science advice should be based on candid acknowledgment of the shortcomings of the advocated new methods, especially if they are not demonstrated in practice in the policy-relevant science.

10.7 Scientific Asymmetry of Making Judgments to Misleadingly Downplay Judgment

In a way, it is understandable that this CASAC would attempt to argue for what appears to be less reliance on “judgment for drawing causal conclusions.” This is because the CASAC lacks the breadth, depth, and diversity of scientific expertise and experience needed to condition on the overall body of evidence and from which to make such inferences. Furthermore, the CASAC is a case study in motivational bias, in that its members have been selected in such a way as to enhance, rather than avoid, biases related to previously stated positions and biases related to conflict of interest. These biases are compounded by a majority of only four members of CASAC who are making statements and judgments about scientific domains for which they do not have adequate breadth, depth, and diversity of expertise and experience. The CASAC has been gerrymandered such that mainstream views are either removed from the deliberations or have been relegated to minority status, in favor of fringe views.

This is not to say that there is not some value and some merit to exploring new ideas, and to giving reasonable consideration to possibilities for new methods and new inference methods. The idea that causal inference methods that have been developed and applied in other fields might be adapted to the evaluation of epidemiological studies is interesting, and is a good area for future research. However, these methods have not matured to the point where they are demonstrated in the **peer-reviewed policy-relevant literature** to be useful nor have their limitations been characterized by this CASAC. It is also not clear that such methods are applicable to observational studies as readily and easily as implied by the CASAC majority.

10.8 Review of Scientific Criteria Must be Based on Peer-Reviewed Policy-Relevant Literature

It has been a well-established ground rule for these NAAQS reviews that the scientific criteria (ISA) is based on established peer-reviewed policy-relevant science. It is not the job of EPA staff to re-analyze existing peer-reviewed policy-relevant studies. Re-analysis would generate a new burden for peer-review – i.e. to publish the new analyses in the peer-reviewed literature before they can be used in the ISA. This is usually not feasible given that the time to conduct such an analysis, prepare it for submission, submit it, have it undergo peer review, and revise and resubmit in response to comments prior to possible acceptance and publication can take up to a year or more, assuming that the EPA has the resources to commit to such an endeavor.

10.9 Inferences Can Be Made Even When There Are Uncertainties

There is value to identifying and explaining key assumptions. In fact, the IPMRP considered this in its own deliberations, particularly with regard to the assumption of linear multipollutant models, in arriving at a well-conditioned expert judgment that, despite uncertainties, such models are useful for making inferences of adverse effects in real-world human populations, including at risk populations. In any policy-relevant context, it is often the case that there are uncertainties in the available scientific evidence. Uncertainty, however, does not mean that no decision can be made. In my own work, I have published numerous peer-reviewed journal papers on uncertainty analysis, and have contributed to a book on probabilistic exposure assessment, and international guidance on the application of uncertainty analysis for emission

inventories and exposure assessment. I am familiar with many quantitative and qualitative methods for uncertainty analysis. While I agree in principle that quantification of uncertainty is desirable, quantification of uncertainty require resources, including expertise, and involves considerable judgment even when employing what are arguably “objective” statistical techniques. There are various approaches to uncertainty characterization that are empirically based, but limited in applicability depending on data availability, or that are based on expert judgment, and thus inherently more subjective. Furthermore, there are qualitative frameworks for identifying and discussing uncertainties. There are also other approaches for taking uncertainties into account, such as sensitivity analysis, scenario analysis, and others. In a time-sensitive regulatory framework such as the NAAQS review, judgments have to made regarding what are the most useful types of analyses given constraints of data, tools/techniques, and time, also taking into account the interpretability of the results and their usefulness. Simply making laundry lists of uncertainty analysis methods, without due regard to priority setting, is not helpful to the EPA, and comes across as being more along the lines of paralysis by analysis.

10.10 Exposures are Estimated

The repeated references to “estimated vs. actual individual exposures” is puzzling. There is very little, if any, expertise on the chartered CASAC in measurement and modeling of individual human exposure. This is an area in which I have done quite a bit of work, including publishing in the peer-reviewed literature. Of course exposures are estimated. There is not a practical way to measure “actual” exposure for every person at all times, especially in studies that have millions of subjects. Exposure estimation methods have inherent uncertainties. However, uncertainty in exposure estimates does not invalidate the exposure estimates, nor does it prove that such uncertainties undermine robust findings regarding concentration-response relationships. The IPMRP noted the performance of exposure estimation approaches in its assessment of the utility of key epidemiological studies.⁷

10.11 Normative Redefinition of the Decision Context is Not Appropriate

Page 3, lines 10-14: Here, CASAC is making a normative statement of the decision context for the NAAQS review, which is not consistent with the statutory mandate for the decision context as set forth in the Clean Air Act. The CAA actually does not require the level of specificity that the CASAC claims is “needed”. For example, it is sufficient to demonstrate, or to infer based on well-conditioned scientific expert judgment, that adverse effects occur to populations at ambient concentrations below the current standard as a basis for finding that the current standard is not adequate to protect public health. Furthermore, it is sufficient to find, based on direct evidence, or based on reasoned scientific inference, that populations, including at-risk populations, are subject to adverse effects at ambient levels below the current standard in recommending a range of levels for alternative standards.

10.12 Quote-Mining

There are numerous quotes given in CASAC’s consensus responses to charge questions and other consensus statements. I encourage readers of this material to be skeptical of the context of these quotes. Dr. Lianne Sheppard, in her written comments to CASAC for the December 3, 2019 meeting of CASAC, has found that the three quotes that she investigated were taken out of context. According to Dr. Sheppard, CASAC’s draft consensus response

“quotes many reputable papers out of context and presents a different perspective than the point being made by the authors and evident from reading the full paper. Examples include quotes from Fuentes et al (2009) (p 7 | 3), Dominici et al (2014) (p 7 | 6), Carone et al (2019) (p 13 | 10).”

Another example of quote-mining is the very misleading use of a quote from IOM, 2018, Chapter 8 on page 4, lines 19-20. The given quote is

“Association, especially association adjusted for potential confounders, is evidence for the causal claim,”

followed by a claim that this is an invalid statement based on a 1963 reference. However, the full sentence states:

“Association, especially association adjusted for potential confounders, is evidence for the causal claim, **but it is not identical to the causal claim.**”
(emphasis added)

The last clause, “but it is not identical to the causal claim” is extremely important to the accurate portrayal and understanding of the message, but was omitted.

10.13 Gaslighting: “Confirmatory Evidence Does Not Justify Revising the Current Standards”

I have read the several passages in CASAC’s draft report that address this topic, and still cannot see any logic to it. I say this as a person who served on the previous CASAC PM Review Panel during 2007 to 2010 whose advice culminated in the 2012 revision of the annual primary PM_{2.5} standard, and as a former member of the CASAC PM Review Panel during 2015 to 2018 in this review cycle until it was disbanded and then reconvened in 2018 as the Independent Particulate Matter Review Panel.

CASAC’s apparent argument here is that, in the last review, CASAC and EPA found that there were “positive C-R associations.” In this review, there is also a finding of a positive C-R association. By some unknown logic, this supposedly means – without logical explanation -- that no revision is needed to the NAAQS.

This makes absolutely no sense, whatsoever, and is another example of cherry-picking. In this case, key information is omitted and ignored.

For the sake of argument, let’s assume that the 2007 to 2010 review and the 2015 to 2019 review both found that the C-R association was approximately numerically the same value. In both reviews, an assumption is made that there is not a population threshold in the concentration-response relationship. The inferred C-R association is predicated on a linear C-R relationship with no threshold. Such assumptions can be clearly stated and then critiqued. Let’s set the critiques aside, momentarily, and acknowledge the similarity of the magnitude of the beta (slope) coefficients. If this is in fact a reasonable interpretation, then this by itself is quite important. The C-R relationships in this review are based on a different selection of studies than in the last review. Thus, if approximately the same beta coefficient is found based on different studies conducted at different times, this implies a remarkable consistency that is worth noting.

In the prior 2007-2010 review, in the judgment of a well-constituted CASAC PM Review Panel that had the breadth, depth, and diversity of expertise and experience needed for such a review, including multiple epidemiologists, the available epidemiological evidence of positive C-R associations at ambient levels below the then-current standard was noted. Furthermore, based on the causality determination from the weight of evidence framework for long-term exposure to PM_{2.5} and premature death, at policy-relevant concentrations, this association was judged to be causal. Given the distribution of estimated exposure concentrations in the key epidemiologic studies at that time, and taking into account relevant uncertainties such as potential threats to validity of the epidemiological studies, the CASAC PM Review Panel judged that there was

sufficient scientific uncertainty of a positive C-R association in the range of ambient annual levels between 11 ug/m³ and 13 ug/m³.⁵³ Note that, at that time, there were NOT epidemiological studies available that showed positive C-R associations at lower concentrations such as, say, 8 ug/m³ and 10 ug/m³. Given the absence of adequately informative empirical observations below approximately 11 ug/m³, a judgment was made that the available evidence was too uncertain to support recommendations of revised standards at levels lower than 11 ug/m³.

However, in the current 2015-2019 review, using similar inference criteria as in the prior review, there are new studies that provide new evidence of positive C-R associations at annual ambient levels at least as low as 8 ug/m³, with additional support from Canadian studies that show consistent results down to 7 ug/m³ or lower. Thus, even if the beta coefficient of the C-R association were identical in the 2007-2010 review and in the 2015-2019 review, **the key difference is the annual levels at which there is observational evidence of a positive association.**

It was **NOT** the case in the 2007-2010 that EPA or CASAC assumed that the positive C-R association found between 11 ug/m³ and 13 ug/m³, and higher, could be extrapolated downward to levels that were outside the range of empirical observation in terms of recommending alternative levels of a standard. This is why CASAC did not recommend levels of standards in the last review down to, say, 10 ug/m³, or 8 ug/m³, or 5 ug/m³, etc. It was not reasonable or justifiable to recommend a level at the low end that was outside the range of the evidence-based observation.

It **IS** the case in the 2015-2019 review that the empirical observational evidence shows positive C-R associations at levels down to 8 ug/m³, which is different than the evidence in the last review. These associations are judged to be causal based on the overall weight of evidence. The report of the Independent Particulate Matter Review Panel goes into detail regarding the recommendation, based on scientific evidence, to revise the annual primary PM_{2.5} standard within a range between 10 ug/m³ to 8 ug/m³.⁷

Perhaps CASAC is making some other unstated judgment in choosing to ignore the fact that positive C-R associations in this review are found at lower annual levels than in the previous PM NAAQS review. CASAC has not explained why it is disregarding this evidence, particularly in light of the decision context set forth by Congress for the NAAQS.

10.14 At Risk Populations

CASAC mentioned “sensitive subpopulations” once, on page 8, line 26, but does not treat this issue substantively. Otherwise, CASAC completely ignores issues related to at risk groups and environmental justice, and fails to note, as the IPMRP did, that the hazard ratio for African-Americans was found to be three times higher than for the general population.⁷ According to legal precedent, the NAAQS must be set to protect not just the general population, but also at-risk populations. The Clean Air Act does not require complete scientific certainty as the basis for setting a health protective standard.

10.15 Doubt

Much of CASAC’s letter and so-called consensus responses focus on doubt-raising, with lengthy qualitative listing of this or that possible source of uncertainty but without any critical evaluation of which uncertainties matter and which are likely to be less important. Moreover, there is hardly any, if any, identification of the strengths of available scientific evidence and robust findings.

10.16 Making Up Data

Figure 1 appears to be based on made-up data. By the “logic” expressed on page 16, as long as there is a positive C-R association no matter at how low of an ambient annual concentration, this CASAC can be relied upon to find no need to revise the standard. This is illogical – see also the section on “Gaslighting.”

10.17 Defer to the Independent Particulate Matter Review Panel

The draft letter and consensus responses of the CASAC lack credibility. EPA is strongly advised to set aside the advice of its gerrymandered CASAC, and instead to accept the credible and properly derived advice of the authoritative and well-constituted Independent Particulate Matter Review Panel, which has the breadth, depth, and diversity of expertise and experience appropriate to this review. See the October 22, 2019 report of the IPMRP for a full treatment of EPA’s charge questions.⁷

10.18 Miscellaneous Comments

On page 2, lines 18-20, there is a statement “Apply a more explicit, systematic and transparent process for selecting, evaluating, summarizing, and interpreting studies.” EPA has already applied a systematic and transparent process for selecting, evaluating, summarizing, and interpreting studies as done in the draft ISA. There may be opportunities to improve the clarity of application of the process, but the process itself has been well-vetted by prior CASAC review panels over the course of many review cycles.

On page 2, lines 37-42. A ground rule of the literature review of the ISA is that it must be based on policy-relevant science within a defined time frame. This is to provide some reasonable boundaries to the scope of the review, which already is quite large. CASAC has been repeatedly asking for inclusion of studies which are either not policy-relevant or not in the time frame of this review.

Page 3, line 5: omitted here is that these studies include ambient air pollution levels that are at or below levels of current standards.

Page 3, 8-10: this is an example of laundry listing possible sources of uncertainty, without a critical evaluation of whether or to what extent these actually matter in the context of the key studies selected as the basis for the evidence-based approach and the risk-based approach in the draft PA.