**Public Comment on the**

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

# The NAAQS Ozone Science Review Process is Broken and Not Credible:

# EPA Should Start Over


**COMMENT BY:**

**H. Christopher Frey, Ph.D.**

**Glenn E. and Phyllis J. Futrell Distinguished University Professor**

**Department of Civil, Construction, and Environmental Engineering**

**North Carolina State University**


**SUBMITTED TO**

**Clean Air Scientific Advisory Committee**

**U.S. Environmental Protection Agency**

**Washington, DC**

**DATE**

**December 5, 2019**

# Contents

**Biosketch**

Dr. H. Christopher Frey
Glenn E. Futrell Distinguished University Professor
Department of Civil, Construction, and Environmental Engineering
North Carolina State University

Dr. H. Christopher Frey is the Glenn E. Futrell Distinguished University Professor of Environmental Engineering in the Department of Civil, Construction, and Environmental Engineering at North Carolina State University. Dr. Frey's research includes quantification of uncertainty in engineering process technologies and emission factors, probabilistic methods for exposure assessment, measurement and modeling of human exposure to air pollution, and measurement and modeling of vehicle emissions. He teaches courses on air pollution control, environmental exposure and risk assessment, and sustainable infrastructure. Dr. Frey is an adjunct professor in the Division of the Environment and Sustainability at the Hong Kong University of Science and Technology, where he has taught a course on urban air quality and is part of a large team developing an exposure model for Hong Kong.

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 Statement 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 150$^{th}$ 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. I also attended CASAC's teleconference on the ozone Integrated Review Plan on November 29, 2018 at which I submitted a public comment[10] and at which 18 of my colleagues and I from the former CASAC Ozone Review Panel, which I chaired from 2012 to 2014, submitted a written statement. The written statement included a 24 page letter with 7 major findings and 30 recommendations for CASAC.[11] Members of the former CASAC Ozone Review Panel also submitted a written

---

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

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+from+Chris+Frey+191024.pdf

10 Frey, H.C., "Public Comment on the CASAC Review of EPA's Integrated Review Plan for Ozone (External Review Draft – October 2018)," Presented orally on November 29, 2018, Meeting of the EPA Clean Air Scientific Advisory Committee, via teleconference.

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

statement regarding the CASAC review of the draft ISA and draft PA.[12] I also submitted an oral and written statement regarding the former CASAC Ozone Review Panel's letter.[13]

**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.[14,15,16,17,18,19] EPA should not make *ad hoc* changes to the NAAQS review process. 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.[20]

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;

---

[12] Frey, H.C., A.V. Diez Roux, G. Allen, E.L. Avol, J. Brain, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, S.R. Kleeberger, F.J. Miller, H.S. Neufeld, A.G. Russell, J.S. Ultman, K.C. Weathers, P.B. Woodbury, and R. Wyzga, Advice from the former U.S. EPA Clean Air Scientific Advisory Committee Ozone Review Panel on EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft – September 2019), and EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019), Letter to EPA Administrator Andrew Wheeler from members of the former Clean Air Scientific Advisory Committee Ozone Review Panel (2009-2015), December 2, 2019

[13] Frey, H.C., The NAAQS Review Process for Ozone Should be Suspended Until Process Deficiencies are Corrected, Oral and Written Statement to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, December 4, 2019

[14] 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

[15] 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

[16] 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

[17] 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

[18] 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

[19] 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

[20] 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.

(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) refusing to form a CASAC Ozone Review Panel even though nominations had been solicited for such a panel;

(7) 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;

(8) compressing the scientific review into a timeframe that reduces transparency by reducing opportunities for public comment;

(9) doing away with revised external review drafts of complex scientific documents;

(10) doing away with planning for the risk and exposure assessments;

(11) doing away with separate risk and exposure assessment documents for external review; and

(12) 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 ozone should be suspended until these deficiencies are corrected.

EPA should appoint members to CASAC and its review panels based on the need for breath, 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 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. 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 ozone 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 in October 2018 to not appoint a CASAC Ozone Review Panel even though nominations for such a panel had already been solicited in July 2018.

### 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 commend 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.[21] 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

---

[21] 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

review cycle. A key factor that increases the duration of CASAC's involvement in a review cycle is delay in EPA providing CASAC with assessment documents for review. Furthermore, the memorandum omits any discussion of the more salient factors that have led to delays in the NAAQS review process related to decisions made by the EPA, not CASAC, as detailed below. EPA should not impose a reduced duration schedule for the scientific review that compromises the scope and quality of the scientific review. The duration of a review cycle is dependent on the following:

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

(2) EPA decides the allocation of resources for development of assessment reports by EPA staff that are part of the scientific review process;

(3) EPA decides when to release a draft document for CASAC review;

(4) EPA has been responsible for delays in providing draft assessments to the CASAC for review;

(5) Whether a draft EPA document requires further iteration depends on its initial scientific quality; and

(6) EPA has control over the timing of the NAAQS review process from the time that it receives closure on advice from CASAC until it promulgates a final decision.

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

The late 2020 deadline for completing the ozone 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.

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,[16,22,23] 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 ozone 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

---

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

[23] 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

submitting a first draft of the PA for CASAC review. However, in this review, there is no separate REA. The content of the REA has been incorporated into the draft PA. This is not appropriate since there are important scientific issues pertaining to the REA that should be reviewed and vetted prior to 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 ozone 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 ozone 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):[24]

> *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):[25]

> *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):[26]

> *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*

---

[24] 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

[25] 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

[26] 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):[27]

*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):[28]

*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).[29]

---

[27] 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.

[28] 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.

[29] 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):[30] "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):[31]

> *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"[32] 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.[33] CASAC called for EPA to provide a third draft of the ISA to address numerous other issues.

---

[30] 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

[31] 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

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

[33] 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).[34] 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).[35] 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).[36] 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).[37]

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).[38] 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).[39]

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

---

[34] 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.

[35] 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

[36] 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

[37] 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

[38] 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

[39] 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, Preable to the Integrated Science Assessments (EPA, 2015).[40] The framework is also described in a journal publication by Owens et al. (2017).[41]

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).[42] The CASAC review of the 2nd draft of the ISA for oxides of sulfur found that the causal determinations were appropriate (Diex Roux, 2017).[43] 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.

[40] 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

[41] 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.

[42] 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

[43] 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 Ozone NAAQS Review**

The current 7-member CASAC does not have the breadth, depth, or diversity of expertise and experience needed for the ozone 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.[44,45] 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

---

[44] 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

[45] 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 ozone NAAQS. Thus, CASAC should be properly augmented, consistent with its charter with the U.S. Congress,[46] by appointment of a CASAC Ozone 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 regarding the draft PM PA, made an argument that CASAC can usefully offer advice that it is qualified to give. Such arguments are also implicit in CASAC's meeting this week on the ozone draft ISA and draft PA. 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 ozone 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 an Ozone 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 Ozone 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. A CASAC Ozone Review Panel should be appointed 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.

### 3.3 CASAC Should Acknowledge that it Lacks Breadth, Depth, and Diversity of Expertise and Experience Needed for the Ozone NAAQS Review

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.

---

[46] 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

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 Ozone NAAQS;
- It especially lacks expertise in epidemiology, but also lacks diversity of expertise and experience in toxicology and controlled human studies, and does not have adequate scientific domains to address the secondary ozone standards.
- A CASAC Ozone Review Panel should be appointed;
- CASAC will be able to develop and offer advice after such time that it is augmented with a CASAC Ozone Review Panel and has had sufficient opportunity to engage in public deliberations with such a Panel;
- CASAC, augmented with a CASAC Ozone Review Panel, will need to conduct a review of a second external review draft of the PM ISA; and
- CASAC, augmented with a CASAC Ozone 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 ozone 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 the 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."[47] 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.[48] 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

---

[47] 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

[48] 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 and from not forming an Ozone 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 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.[49] 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 regarding the draft PM PA. Two of the consultants co-authored a paper with a CASAC member that addresses policy issues related to the ozone NAAQS review.[50] One of the consultants is an area editor of a journal for which the chair is the editor, and has recently written a review of a

[49] 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.

[50] 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).

book written by the chair.[51] 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.

[51] 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: Refusal to form an Ozone Review Panel is Inconsistent with Four Decades of Precedent

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

**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 | P,S | 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 | P,S | 1994 to 1996 | 6 | 15 | 21 |
| PM Review Panel | P,S | 2001 to 2006 | 7 | 15 | 22 |
| PM Review Panel | P,S | 2008 to 2010 | 7 | 15 | 22 |
| PM Review Panel | P,S | 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 |

*[a]All 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 |

*[a]All 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 Refused to form a CASAC Ozone 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 7-member chartered CASAC does not have the breadth, depth, and diversity of expertise and experience required for a review of the ozone 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 July 27, 2018, EPA issued a Federal Register notice on "Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel." In a press release on October 10, 2018, followed by emails on October 11, 2018 to nominees for the ozone review panel, EPA stated that a panel would not be formed but gave no sensible rationale for this specious, arbitrary, and capricious decision that undermines the process. This was done without advance notice and without prior consultation with the panel or the CASAC.

Compared to the chartered CASAC, the previous CASAC Ozone Review had more experts, covers more scientific disciplines, and had multiple experts who provide diversity of perspectives in many key disciplines, such as epidemiology, toxicology, human clinical studies, and welfare effects, among others.

### 5.3 Administrator Wheeler's Talking Points Regarding Not Forming an Ozone 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 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: 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 ozone, the key scientific domains include, but are not limited to, epidemiology, controlled human studies, toxicology, and effects on plants and vegetation. 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 and welfare rather than placing an undue burden of proof that is beyond that required by statute.

## Part 7: The Role of Expert Judgment in Scientific Review of the NAAQS

In the current review process the Administrator has arbitrarily and capriciously refused to form a CASAC Ozone 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.[3.52,53] 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.[54,55] Given that this CASAC lacks experts in the appropriate scientific domains, it is unqualified to offer such judgments.

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 would have had such a group in the form of a CASAC Ozone Review Panel and yet arbitrarily and capriciously refused to form such a panel.

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

---

[52] 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

[53] 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

[54] 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

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

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 Ozone Review Panel from this review cycle, 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 refusing to form a CASAC Ozone 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 8: '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.

### 8.1 "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 regarding the draft PM PA 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. Presumably, the same talking point will be applied to the ozone review. CASAC's draft letter on the draft PM PA 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. It is correct in being "exceptional" since prior CASAC reviews have generally been based on a balanced, not denialist, review of the scientific evidence. 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.[56] 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, 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.[57]
- 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.[58]

---

[56] 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.

[57] 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.

[58] U.S. EPA to eliminate all mammal testing by 2035, Science, Sep. 10, 2019.

- 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.[59] EPA did not engage the SAB at all with regard to the phased animal testing ban.
- 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."[60] 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 PM ISA, I recommended that CASAC ask the EPA Office of General Counsel (OGC) to explain to CASAC what the NAAQS decision context is.[61] 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. This is the same CASAC that is developing advice on the ozone NAAQS.

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

---

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

[60] 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

[61] 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
See also an article published December 14, 2018 by InsideEPA, "Former CASAC Chairman Warns 'Joke' Review Hurts PM NAAQS Assessment"

(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."

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 PM 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 – or refuse to form an expert panel, such as a CASAC Ozone 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 and refusing to form an Ozone 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 subject to cherry-picking.

### 8.2 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.[62]

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”.[63] 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.” [64] 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.”[65]

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 administrator, 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.”[66]

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.[67] 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

---

62 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

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

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

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

66 Dillon, L., C. Sellers, V. Underhill, N. Shapiro, J.L. Ohayon, M. Sullivant, 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).

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

"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 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:[68]

> "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."

Given that CASAC lacks epidemiologists, it is unqualified to offer fully-informed advice regarding epidemiology.

Note that 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.
- 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.

The strategy of the CASAC majority of redefining the assessment problem in a manner that is inconsistent with mainstream science, 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:

---

[68] Hannson, S., "Science denial as a form of pseudoscience," *Studies in History and Philosophy of Science*, 63(2017):39-47.

> "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 in public comments on CASAC's draft letter on the draft PM PA, there are numerous examples of quote-mining by CASAC.[69,70] Quote-mining undermines CASAC's credibility.

69 https://yosemite.epa.gov/sab/sabproduct.nsf//B9165A397FBF2659852584C50073D8C1/$File/Written+Statement+H+Christopher+Frey+CASAC+PM+Draft+PA+191203+Submitted.pdf

70 https://yosemite.epa.gov/sab/sabproduct.nsf//147C2AAF33D4613A852584C500437CBF/$File/SheppardPAreportCommentsSubmitted.pdf