

December 2, 2019

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

Ref: Draft Integrated Science Assessment: Docket ID No. EPA-HQ-ORD-2018-0274
Draft Policy Assessment: Docket ID No. EPA-HQ-OAR-2018-0279

Subject: 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).

Dear Administrator Wheeler:

We were members of the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel from the 2009 to 2015 review of the primary and secondary National Ambient Air Quality Standards (NAAQS) for ozone. We also include two former chairs and ten former members of the chartered CASAC. This letter represents our consensus.

We reaffirm the findings and recommendations communicated to EPA in our November 26, 2018 letter to the CASAC regarding the EPA's Integrated Review Plan for the Ozone National Ambient Air Quality Standards (External Review Draft).¹ In our November 26, 2018 letter: (1) we reviewed the statutory requirements for scientific review of NAAQS; (2) described our role and experience in the previous NAAQS review; and (3) advised the CASAC of lessons learned from the many scientific reviews that we conducted. In addition, we provided our advice regarding: (1) the impacts of recent changes to the criteria for membership on the CASAC and to the NAAQS review process; (2) the decision not to form an ozone review panel for the current review of the primary and secondary ozone standards; and (3) the Integrated Review Plan for the current review. In this letter, we augment our previous comments and advice.

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

EPA has made numerous *ad hoc* changes to the NAAQS review process since 2017.^{2,3,4,5,6,7} EPA should not make *ad hoc* changes to the NAAQS review process in the middle of a review, as it has been doing in the case of the particulate matter review and is doing here in the case of the ozone review. Changes in the NAAQS review process since 2017 have led to a situation in which standards will not reflect air quality criteria. Air quality criteria must “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” (CAA section 108(a)(2)). As a result of changes since 2017, 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 regarding proposed changes.⁸

We unanimously find that myriad unwarranted changes have been made to the NAAQS review process and to the composition of the CASAC since 2017. 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. The following sections provide details regarding these findings and recommendations. These changes should be reversed. The NAAQS review for ozone should be suspended until these deficiencies are corrected.

Failure to Engage EPA Career Staff in Revisions to the NAAQS Review Process

EPA leadership did not engage EPA career staff involved with the Integrated Science Assessment (ISA) or Policy Assessment (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 not to form an ozone review panel, even though nominations for such a panel had already been solicited.⁹

² 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>

³ 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>

⁴ 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>

⁵ 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>

⁶ 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>

⁷ 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>

⁸ 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.

⁹ 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>

Role of EPA Staff in Preparing Draft Documents

We find that the EPA career staff in the Office of Research and Development have undertaken a good faith effort to produce a first draft of the ISA. We likewise find that the 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 PA. However, both of these draft documents were produced under trying and unprecedented constraints. We commend the staff for this effort. However, it is inappropriate for EPA leadership to rush the scientific and policy assessments and to commingle them such that they were developed in parallel and are being reviewed by CASAC and the public at the same time. It undermines the integrity of the review 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.

Chartered CASAC:

The current seven-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 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.”

The current 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.

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 perceived 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.^{10,11} 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.

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.

¹⁰ 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>

¹¹ 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>

The current CASAC (or any CASAC, with only seven members, that is not augmented with a panel of experts) does not have adequate breadth, depth, and diversity of scientific expertise and experience needed to conduct thorough reviews 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,¹² by appointment of a CASAC Ozone Review Panel for the Ozone NAAQS Review.⁹

Augmentation of CASAC with Experts

It has been long-standing practice, for four decades, to augment the seven-member CASAC with review panels comprised of additional independent experts in the scientific disciplines and subject matter domains needed for a particular pollutant.¹³ Such augmentation is essential to a review process that addresses requirements under the Clean Air Act to have a thorough and accurate review of the criteria. Augmenting CASAC with review panels has been, and is, fully consistent with CASAC's charter with the U.S. Congress. Per this charter, it has always been the seven-member chartered CASAC that approves the content of letter reports and attachments transmitted from CASAC to the Administrator, not its augmented panels.

Contrary to implications of statements made by the Administrator to justify why the PM Review Panel was disbanded and why an ozone review panel was not formed, panels do not slow down or in any way hamper CASAC's role in the NAAQS review process because they work collaboratively and in parallel with the chartered CASAC. Moreover, engagement of panels is essential to CASAC having the breadth, depth, and diversity of expertise and experience needed for these complex scientific reviews.

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."⁹ In a press release on October 10, 2018,⁴ 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.

Although a smaller "pool" of consultants was recently appointed to support the CASAC,⁷ the pool is not focused on ozone in that there is not adequate breadth, depth, and diversity of scientific expertise and experience needed for the ozone review, interacts with the CASAC only in writing, and is not allowed to deliberate with the CASAC; therefore, the pool does not adequately or appropriately substitute for an Ozone Review Panel. An Ozone Review Panel should be reappointed to provide CASAC with the expertise it needs.

EPA should continue to follow the successful practice, proven for four decades, of augmenting CASAC with the expertise it needs via qualified review panels that deliberate, interactively, with members of the chartered CASAC. The current review of the ozone NAAQS should be suspended until CASAC is appropriately and properly augmented with an Ozone Review Panel.

¹² United States Environmental Protection Agency Charter, Clean Air Scientific Advisory Committee, Filed with Congress, June 5, 2019, [https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/\\$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf)

¹³ See individual comments from Dr. H. Christopher Frey that are in Frey, H.C., A.V. Diez Roux, J. Balmes, J.C. Chow, D.W. Dockery, J.R. Harkema, J. Kaufman, D.M. Kenski, M. Kleinman, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and S. Vedal, "CASAC Review of EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018)," 34 page letter and 100 pages of attachments submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA–HQ–ORD–2014-0859, December 10, 2018. [https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/\\$File/PMRP+Letter+to+CA+SAC+181210+Final+181210.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CA+SAC+181210+Final+181210.pdf)

Accelerated Time Frame

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. This would be true 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 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 creates a less transparent NAAQS scientific review process.

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,^{8,14,15} 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. We concur with the October 22, 2019 report of the Independent Particulate Matter Review Panel (IPMRP) (formerly the CASAC PM Review Panel) 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.”¹⁶ We agree with the IPMRP that “to do otherwise puts the cart before the horse.”

¹⁴ Peacock, M., “Modifications to Process for Reviewing National Ambient Air Quality Standards,” Memorandum, U.S. Environmental Protection Agency, Washington, DC, April 17, 2007

¹⁵ 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>

¹⁶ 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

Furthermore, we agree and advise that “EPA should not introduce policy considerations until the scientific issues have been adequately settled.”

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 2015 review. More important, however, is that these deficiencies be corrected.

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

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.

Partial Review is Not Adequate

Some members of the chartered CASAC asserted, during October 24-25, 2019 deliberations on the particulate matter NAAQS review, that CASAC should offer whatever advice it can. However, 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.

Time Period for Public Comment on the Draft Policy Assessment Should be Extended

EPA has given only a 45 day public comment period for the 926 page draft PA. The draft PA incorporates content related to human health exposure and risk (Appendix 3) and welfare exposure and risk (Appendix 4). This content is extensive. Such content normally would have been published separately, prior to release of a draft PA, as a draft Health Risk and Exposure Assessment (HREA) and a Welfare Risk and Exposure Assessment (WREA). In the previous ozone review, the HREA and WREA were separate documents.^{17,18} In the last review cycle, the first external review drafts of the HREA and WREA were released and reviewed by CASAC and the public prior to the release of the first external review draft of the draft Policy Assessment. Thus, the current draft PA covers the same scope as three assessment documents did in the prior review cycle. Combining assessment steps in this manner such that they are reviewed concurrently and without sequencing or iteration undermines the integrity of the review process. Given the critical importance of the HREA in the standard setting process for the ozone primary standard, see, e.g. 80 FR at 80343, 80345-46, 80354, 80358, 80361, 80363-365 (Oct. 26, 2015), this truncation is especially deficient. Given that the last two iterations of a secondary standard have failed to survive judicial review, lack of a WREA is heading inexorably to a third such judicial drubbing.

Forty-five days is an insufficient amount of time for development of properly informed comments on the 926 page draft PA and its embedded exposure and risk assessments, especially since this period overlaps with the review of the 1,411 page draft ISA. The short public comment period does not allow for commenters to adequately take into account deliberations of CASAC at its December 3-6, 2019 meeting, nor a chance to comment on CASAC’s draft recommendations.

The lack of a finalized peer-reviewed ISA makes the process of reviewing the draft PA difficult, since the underlying scientific foundation of the PA is subject to revisions. The EPA review schedule inappropriately requires that the PA go directly from draft to final without a second external review draft. This is procedurally unacceptable. The draft PA should undergo external review after comments on the draft ISA have been addressed. Therefore, we recommend the following: (a) EPA should provide a revised ISA prior to releasing the next draft of the PA; (b) a second draft of the PA must be released for external review after the ISA has been finalized so

¹⁷ U.S. Environmental Protection Agency. (2012). Health Risk and Exposure Assessment for Ozone, First External Review Draft, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA 452/P-12-001.

¹⁸ U.S. Environmental Protection Agency. (2012). Welfare Risk and Exposure Assessment for Ozone, First External Review Draft. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA- 452/P-12-004.

that the public has the opportunity to see how changes to the ISA will be incorporated into changes in the PA; (c) the public comment period for the current draft of the PA and its embedded exposure and risk assessments should be extended by at least 45 days so that the comment period is at least 90 days; and (d) the public comment period on the second external review draft of the PA, sequenced to be released after the draft ISA is finalized, should be at least 90 days.

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. We concur with this choice.

Closing

Since 2017, EPA has made the following changes to the NAAQS review process and to the chartered CASAC, all of which have undermined and compromised the process: (1) CASAC appointment criteria emphasize geographic location and not scientific expertise; (2) CASAC appointment criteria emphasize government affiliation and not scientific expertise; (3) CASAC appointment criteria ban nongovernmental but not governmental recipients of EPA scientific research grants; (4) complete turn-over of CASAC membership; (5) the CASAC PM Review Panel was disbanded; (6) there was refusal to form an Ozone Review Panel for which nominations had already been solicited; (7) a “pool” of consultants was formed with serious shortcomings of expertise and an inability to deliberate; (8) compressed the scientific review into a timeframe that results in lack of transparency, in part, by reducing opportunities for public comment; (9) eliminated revised external review drafts of complex scientific documents; (10) eliminated planning for the risk and exposure assessments; (11) eliminated separate risk and exposure assessment documents for external review; (12) commingled policy with science by producing and reviewing policy and science assessments concurrently; and (13) provided an unrealistically short time period for public review and comment on the draft ozone Policy Assessment.

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. The NAAQS review for ozone should be suspended until these deficiencies are corrected.

Sincerely,

/signed/

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

Chartered CASAC: Member 2008-2012, Chair 2012-2015
CASAC PM Review Panel: Member 2007-2010, 2015-2018
CASAC Ozone Review Panel: Member 2009-2012, Chair, 2012-2014
CASAC Sulfur Oxides Review Panel: Member 2008-2009, 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2008-2009, Chair 2013-2015,

Member 2015-2017
CASAC Lead Review Panel: Chair 2011-2013
SO_x/NO_x Secondary Standard Review Panel: Member 2009-2011
CASAC Carbon Monoxide Review Panel: Member 2008-2010

/signed/

Ana V. Diez Roux, MD, PhD, MPH
Dean and Distinguished University Professor of Epidemiology
Dean's Office, Epidemiology and Biostatistics, Urban Health Collaborative
Dornsife School of Public Health
Drexel University
Philadelphia, PA
Chartered CASAC: Member 2012-2015, Chair 2015-2017
CASAC Ozone Review Panel: Member 2012-2014
CASAC Sulfur Oxides Review Panel: Chair 2013-2017
CASAC PM Review Panel: Chair 2015-2018

/signed/

George Allen
Chief Scientist
Northeast States for Coordinated Air Use Management
Boston, MA
Chartered CASAC: Member 2010-2016
CASAC Ozone Review Panel: Member 2009-2014
CASAC Sulfur Oxides Review Panel: Member 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2013-2017
CASAC Lead Review Panel: Member 2011-2013
CASAC Ambient Air Monitoring and Methods Subcommittee: Member, 2005-2010,
Chair, 2011-2014

/signed/

Edward Lawrence Avol, MS
Professor of Clinical Preventive Medicine
Acting Chief, Environmental Health Division
Keck School of Medicine of USC
Health Sciences Campus
University of Southern California
Los Angeles, CA
CASAC Ozone Review Panel: Member 2009-2014
CASAC PM Review Panel: Member 2007-2010
CASAC Oxides of Nitrogen Review Panel: Member 2007-2009
CASAC Sulfur Oxides Review Panel: Member 2007-2009

/signed/

Joseph Brain, Sc.D.
Cecil K. and Philip Drinker Professor of Environmental Physiology
Department of Environmental Health
Harvard T.H. Chan School of Public Health
Boston, MA
Chartered CASAC: Member 2008-2011
CASAC Carbon Monoxide Review Panel: Chair 2009-2010
CASAC Ozone Review Panel: Member 2009-2014
CASAC Sulfur Oxides Review Panel: Member 2010
CASAC Particulate Matter Review Panel: Member 2007-2010
CASAC Oxides of Nitrogen Review Panel: Member 2009

/signed/

David P. Chock, Ph.D.
Adjunct Research Scientist
Research Center for Group Dynamics
University of Michigan
CASAC Ozone Review Panel: Member 2009-2014

/signed/

David A. Grantz, Ph.D.
Plant Physiologist and Cooperative Extension Air Quality Specialist
University of California at Riverside
Kearney Agricultural Research and Extension Center
Parlier, CA
CASAC Ozone Review Panel: Member 2009-2014
CASAC PM Review Panel: Member 2007-2010
Contributor and Reviewer, Air Quality Criteria for Ozone and Related Photochemical
Oxidants, Criteria Document released February 2006
Principal Author, Air Quality Criteria for Particulate Matter, Criteria Document released
October 2004

/signed/

Jack R. Harkema, DVM, PhD, Dipl ACVP, ATSF
University Distinguished Professor of Pathobiology & Diagnostic Investigation
The Albert C. and Lois E. Dehn Endowed Chair in Veterinary Medicine
Institute for Integrative Toxicology
College of Veterinary Medicine
Michigan State University
East Lansing, MI 48864

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

/signed/

Daniel J. Jacob, Ph.D.
Vasco McCoy Family Professor of Atmospheric Chemistry and Environmental Engineering
Harvard University
Cambridge, MA

CASAC Ozone Review Panel: Member 2009-2014
CASAC Sulfur Oxides Review Panel: Member 2013-2017

/signed/

Donna M. Kenski, Ph.D.
Adjunct Associate Professor
University of Illinois at Chicago
School of Public Health
Chicago, IL

Chartered CASAC: Member 2016-2017, 2007-2010
CASAC Ozone Review Panel: Member 2009-2010
CASAC Sulfur Oxides Review Panel: Member 2016-2018, 2007-2008
CASAC Secondary SO_x/NO_x/PM Review Panel: Member 2016-2018
CASAC Secondary SO_x/NO_x Review Panel: Member 2007-2010
CASAC Lead Review Panel: Member 2007
CASAC PM Review Panel: Member 2007-2010
CASAC Oxides of Nitrogen Review Panel: Member 2008-2009
CASAC Ambient Air Monitoring and Methods Subcommittee: Pb FRM, Ozone monitoring consultations

/signed/

Steven R. Kleeberger, PhD

Chapel Hill, NC

CASAC Ozone Review Panel: Member 2009-2014

CASAC Sulfur Oxides Review Panel: Member 2007-2010

CASAC Oxides of Nitrogen Review Panel: Member 2007-2010

/signed/

Frederick J. Miller, Ph.D., Fellow ATS

Independent Consultant

Fred J. Miller and Associates, LLC

Cary, NC

Ad hoc Professor, Duke University Medical Center

Chartered CASAC: Member 2000-2006

CASAC Ozone Review Panel 2009-2014

CASAC PM Review Panel 2007-2010

/signed/

Howard S. Neufeld, Ph.D.

Professor, Department of Biology

Chair, AppalAIR (Appalachian Atmospheric Interdisciplinary Research Group)

Appalachian State University

Boone, NC

CASAC Ozone Review Panel: Member 2009-2014

/signed/

Armistead G. Russell, Ph.D.

Howard T. Tellepsen Chair & Regents' Professor

Environmental Engineering

Georgia Institute of Technology

Atlanta, GA

Chartered CASAC: Member 2007-2012

CASAC Ozone Review Panel: Member 2006-2008, 2009-2014

CASAC NO_x-SO_x, Secondary NAAQS Review Panel: Chair 2008-2010

CASAC Oxides of Nitrogen Review Panel: Member 2007-2009

CASAC PM Review Panel: Member 2007-2010

CASAC Sulfur Oxides Review Panel: 2007-2010

CASAC Ambient Air Monitoring and Methods Subcommittee: Chair 2009-2011

/signed/

James S. Ultman, Ph.D.
Professor Emeritus, Departments of Chemical Engineering and Biomedical Engineering
Pennsylvania State University
University Park, PA
CASAC Ozone Review Panel: Member 2005-2008, 2009-2014
CASAC Oxides of Nitrogen Review Panel: Member 2007-2009
CASAC Sulfur Oxides Review Panel: Member 2007-2009, 2013-2018

/signed/

Kathleen C. Weathers, Ph.D.
G. Evelyn Hutchinson Chair in Ecology
Cary Institute of Ecosystem Studies
Millbrook, New York
Chartered CASAC: Member 2009-2016
CASAC Ozone Review Panel 2009-2014
CASAC NO_x-SO_x Secondary Review Panel 2008-2010, 2016-2018

/signed/

Peter B. Woodbury, Ph.D.
Senior Research Associate
Section of Soil and Crop Sciences, School of Integrative Plant Science
College of Agriculture and Life Sciences
Cornell University
Ithaca, NY
CASAC Ozone Review Panel: Member 2009-2014
Contributor and Reviewer, Air Quality Criteria for Ozone and Related Photochemical
Oxidants, Criteria Document released February 2006
EPA SAB Biogenic Carbon Emissions Panel Member: 2011-2012, 2015-2018

/signed/

Ron Wyzga, Sc.D.

Retired, Electric Power Research Institute

Palo Alto, CA

Member, Independent Particulate Matter Review Panel

Chartered CASAC: Member 2012-2017

CASAC Ozone Review Panel: Member 2009-2014

CASAC Sulfur Oxides Review Panel: Member 2013-2018

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

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

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

Docket ID No. EPA-HQ-ORD-2018-0274

Docket ID No. EPA-HQ-OAR-2018-0279

www.regulations.gov