November 26, 2018

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and
Chair, Clean Air Scientific Advisory Committee
U.S. Environmental Protection Agency
Washington, DC 20460

Subject: CASAC Advice on the EPA's Integrated Review Plan for the Ozone National Ambient Air Quality Standards (External Review Draft).

Dear Dr Cox:

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 former chairs and members of the chartered 7-member CASAC. This letter represents our consensus. In this letter: (1) we review the statutory requirements for scientific review of NAAQS; (2) we describe our role and experience in the previous NAAQS review; and (3) based on our experience, we advise the current CASAC of our lessons learned from the many scientific reviews that we conducted.

In addition, we provide our advice regarding: (4) the impacts of recent changes to the criteria for membership on the CASAC and to the NAAQS review process; (5) the recent decision not to form an ozone review panel for the current review of the primary and secondary ozone standards; and (6) the Integrated Review Plan for the current review.

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

Statutory Requirements

Section 108 of the Clean Air Act requires that the Administrator periodically review and update the air quality criteria for an air pollutant so that they "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." Section 109 requires the Administrator to adopt NAAQS that are requisite to protect public health with an adequate margin of safety and to protect the public welfare
(text continues on Page 7)

Table 1. Major Findings

MAJOR FINDING 1:	The myriad of changes to the NAAQS review process are collectively harmful to the quality, credibility, and integrity of the scientific review process and CASAC as an advisory body.
MAJOR FINDING 2:	The current 7-member CASAC does not have the depth or breadth of expertise needed for the ozone review, nor could a group of this size cover the needed scientific disciplines.
MAJOR FINDING 3:	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.
MAJOR FINDING 4:	CASAC has transitioned from a committee of nationally and internationally recognized researchers at the leading edge of their fields toward a committee composed predominantly of stakeholders chosen based on geographic location and affiliation with state government, rather than scientific expertise first and foremost. The statute requires only "one person representing State air pollution control agencies."
MAJOR FINDING 5:	An underlying principle is to maintain distinction between science and policy issues. The Pruitt May 9, 2018 memorandum violates this principle by commingling science and policy considerations.
MAJOR FINDING 6:	In 2014, the CASAC provided advice to the Administrator regarding how CASAC's role in reviewing adverse effects of NAAQS implementation should be structured. This advice has been ignored by EPA.
MAJOR FINDING 7:	There are numerous deficiencies in EPA's Integrated Review Plan related to the above findings. EPA's proposal in the IRP to structure the Ozone ISA with appendices rather than chapters is contrary to the requirement for EPA to thorough review" of the "latest scientific information" of the "kind and extent" of "all identifiable effects" as required by the Clean Air Act.

Table 2. Recommendations

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

> **Recommendation 1**: The CASAC should recommend that the EPA rescind the October 31, 2017 and May 9, 2018 memoranda by former Administrator Scott Pruitt.
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> **Recommendation 2**: CASAC should recommend a wider consideration of approaches to streamlining the NAAQS review process, including opportunity for input from EPA staff in ORD and OAQPS, CASAC, and other stakeholders including the public.
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> **Recommendation 3**: CASAC should advise EPA that, if it wishes to change the criteria for appointments to EPA advisory committees including CASAC, it should provide opportunity for input on such criteria from EPA staff in ORD and OAQPS, the EPA Science and Technology Policy Council, CASAC, and other stakeholders including the public.
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> **Recommendation 4**: CASAC should not agree to changes to the review process or to the schedule proposed by EPA.

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

> **Recommendation 5**: CASAC should acknowledge and advise the current Acting Administrator that it does not have adequate breadth and depth of scientific expertise to conduct thorough reviews based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to either the Ozone or the Particulate Matter NAAQS.
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> **Recommendation 6**: CASAC should remind the current Acting Administrator that it has been long-standing practice to augment the 7-member CASAC with additional independent expert consultants, and this augmentation is essential to a high quality review.
>
> **Recommendation 7**: CASAC should remind the current Acting Administrator that in all past reviews conducted by CASAC, it has always been the 7-member chartered CASAC that approves the content of letter reports and attachments transmitted from CASAC to the Administrator.
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> **Recommendation 8**: CASAC should immediately call for the formation of an Ozone Review Panel and for the reinstatement of the CASAC PM Review Panel.

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Table 2. Recommendations, Continued

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

Recommendation 9: CASAC should reject EPA's proposed accelerated schedule. EPA should allow time for an adequate review by relaxing its 2020 deadline.

Recommendation 10: CASAC should reject EPA's proposal for one draft of an Integrated Science Assessment and one draft of a Policy Assessment.

Recommendation 11: The CASAC should advise the current Acting Administrator that the CASAC, supported by an augmented panel of scientific experts, requires typically three years to conduct this review.

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

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

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

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

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

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

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Table 2. Recommendations, Continued

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

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

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

Recommendation 20: CASAC should affirm that its members should not be dismissed *en masse* or appointed *en masse*, and turnover in a given year should be limited to a minority fraction of the total panel. Members should be eligible for reappointment to a second term especially if such appointments would provide continuity, key scientific expertise, and institutional memory.

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

Recommendation 21: CASAC should reject EPA's proposal to combine the REA into the PA for the Ozone review. Further, the CASAC review of the REA should not be concurrent with the PA for the Ozone review.

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Table 2. Recommendations, Continued

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

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

Recommendation 23: CASAC should consider both adverse and beneficial effects.

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

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

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

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

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

With regard to **MAJOR FINDING 7**: Deficiencies in the Ozone Integrated Review Plan

Recommendation 29: The ISA for the current ozone review should be consistent with the now well-established structure and content of CASAC-reviewed ISAs, such as from the previous ozone review.

Recommendation 30: EPA should 'start over' with the scientific review of the primary and secondary NAAQS for ozone. Specifically, EPA should set aside the current Integrated Review Plan and develop a new Integrated Review Plan that is appropriately formulated to take into account the findings and recommendations provided herein. Given the extensive revisions needed to the IRP, the CASAC and the public should have an opportunity to comment on a new IRP.

based on the scientific knowledge embodied in the air quality criteria. Section 109 requires EPA to conduct a "thorough review" of the air quality criteria and the NAAQS at five-year intervals. As part of this review, Section 109 also requires that the Administrator "appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies." This scientific review committee must review the air quality criteria and the NAAQS, and recommend any "appropriate" revisions to the criteria and the NAAQS, consistent with the obligations of Sections 108 and 109. The scope of scientific issues involved in satisfying Section 108's requirements means that a broad range of scientific expertise is needed to conduct the comprehensive scientific assessments needed for the periodic NAAQS reviews.

For this review to be "thorough", "accurate", and reflect "the latest scientific knowledge … of all identifiable effects", a broad range of scientific expertise is needed. The CASAC charter reflects the need for this breadth of expertise. Thus, the charter states that "[m]embers will be persons who have demonstrated high levels of competence, knowledge, and expertise in scientific/technical field relevant to air pollution and air quality issues". Moreover, for the past four decades, comprising well over 20 reviews, CASAC has recognized that the chartered CASAC requires participation of additional experts, acting as consultants, in order that its review be "accurate" and "thorough". This augmentation of chartered CASAC expertise again is reflected in the CASAC charter, which states "EPA, or CASAC with the Agency's approval, may form subcommittees or workgroups for any purpose consistent with this charter. Such subcommittees or workgroups may not work independently of the chartered committee and must report their recommendations and advice to the chartered CASAC for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered committee, nor can they report directly to the EPA."

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

From a scientific perspective, scientific experts who are qualified to conduct a "thorough review" based on the "latest scientific knowledge" are those who are engaged in peer-reviewed scientific research in pertinent scientific disciplines and areas of study. This is why the SAB Staff Office sought "nominations of nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone" in its July 27, 2018 Federal Register notice on "Request for Nominations of Experts for the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel."

The 2009 to 2015 CASAC Ozone Review Panel

Review panels are comprised of additional scientific experts appointed as special governmental employees to supplement the chartered CASAC. As noted in attached individual comments, CASAC has a long history of being augmented with additional experts to support its review activities. Our panel was comprised of the seven members of the chartered CASAC and 13 additional experts. The augmentation of CASAC with panels has been well-established for four decades, as detailed in attached member comments. This has ensured a multidisciplinary, comprehensive, integrated and thorough review of massive amounts of scientific literature encompassing wide-ranging and complex scientific studies.

Augmentation of the expertise of the chartered CASAC with that of the panel members was critical to the quality, credibility, and integrity of our scientific review process. The panel members provided needed breadth and depth of expertise beyond that of the chartered CASAC. Specifically, as noted in a January 29, 2009 EPA memorandum, our panel was appointed to assure coverage of expertise in atmospheric science, exposure modeling and assessment, dosimetry, toxicology, controlled human exposure, epidemiology, risk assessment and biostatistics, ecological effects, and ecological resource valuation.

The panel met and deliberated in public according to requirements of the Federal Advisory Committee Act. Members of the panel were subject to the same financial disclosures and ethics requirements as members of the chartered CASAC.

In each review activity, the panel deliberated and developed draft advice for the Administrator in public meetings and in an advisory role to the chartered CASAC. The members of the chartered CASAC conducted a "quality review" of each draft CASAC report in public meetings. The quality reviews provided the chartered CASAC with opportunities to modify draft reports prior to a vote by the chartered CASAC to approve the final report for submission to the Administrator. Reports submitted by the chartered CASAC to the Administrator were on behalf of the chartered CASAC, not on behalf of the panel. The formation of a review panel is, therefore, not mutually exclusive with the chartered CASAC being the body that provides comments to the Administrator.

CASAC Activity in the Previous Ozone Review

The chartered CASAC produced reports to the EPA Administrator from 2010 to 2014 regarding:

- Consultation on EPA's Integrated Review Plan (Report No. EPA-CASAC-10-004, dated December 3, 2009);
- Consultation on the Scope and Methods Plan for the health and welfare Risk and Exposure Assessments (REAs) (EPA-CASAC-11-008, June 21, 2011);
- Review of the first draft of the Integrated Science Assessment (ISA) (EPA-CASAC-11-009, August 10, 2011);
- Review of the second draft of the ISA (EPA-CASAC-12-004, March 13, 2012);

- Review of the third draft of the ISA (EPA-CASAC-13-001, November 14, 2012);
- Review of the draft health and welfare REAs (EPA-CASAC-13-002, November 19, 2012);
- Review of the first draft of the Policy Assessment (PA) (EPA-CASAC-13-003, November 19, 2012);
- Review of the second draft of the health REA (EPA-CASAC-14-005, July 1, 2014);
- Review of the second draft of the welfare REA (EPA-CASAC-14-003, June 18, 2014); and
- Review of the second draft of the policy assessment (EPA-CASAC-14-004, June 26, 2014).

For each activity listed above, CASAC held one or more public meetings announced in the Federal Register, during which there was opportunity for public comment.

Timeframe for NAAQS Review

We understand from the historical record and from the last ozone review that the timeframe for NAAQS review cycles usually has taken longer than the statutory mandate for reviews "at five-year intervals." Concern about the length of review cycles was a clear motivating factor for the May 9, 2018 memorandum by Administrator Scott Pruitt regarding "Back to Basics Process for Reviewing National Ambient Air Quality Standards." It is a matter of public record that the review cycle for ozone in the last review took more than five years. It is a matter of public record that nearly all of the NAAQS review cycles for various combinations of criteria pollutants and standards (primary, secondary) since the inception of the NAAQS have taken more than five years.

As noted in attached individual comments, the NAAQS review process was revised in 2006 in large part to shorten the duration of NAAQS review while maintaining or enhancing its scientific rigor and credibility, taking into account key factors such as the need to promote separation between science and policy issues. The duration of NAAQS review has generally decreased in the last decade compared to prior decades. However, challenges clearly remain in achieving the statutory mandate for a five year review.

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

(1) EPA controls the duration of time between the conclusion of a prior review cycle and the initiation of the subsequent review cycle;
(2) EPA decides the allocation of resources for development of assessment reports by EPA staff that are part of the scientific review process;
(3) EPA decides when to release a draft document for CASAC review;
(4) EPA has been responsible for delays in providing draft assessments to the CASAC for review;
(5) Whether a draft EPA document requires further iteration depends on its initial scientific quality; and

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

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

Although the 2009 to 2015 review of the primary and secondary ozone NAAQS clearly took longer than five years, these delays are mainly attributable to actions of the EPA, as detailed below. Our panel reacted in an appropriate and reasonable time frame to all draft reports submitted for our review in terms of developing comments from individual members, conducting public meetings, deliberating in public, and providing our consultations or advice.

Thus, we reject the implication that delays in the NAAQS review process are in any substantial way due to CASAC's role. Delays in the current NAAQS review for ozone cannot be attributed to CASAC. For example, the last ozone review cycle resulted in a final rule on October 26, 2015. EPA did not begin the current NAAQS review cycle until a June 26, 2018 Federal Register notice of a "call for scientific and policy-relevant information." Thus, EPA waited two years and eight months to start the current review cycle. This is more than half of the five year review interval called for in the Clean Air Act. It is unreasonable for EPA to ask its staff in ORD and OAQPS, and CASAC, to sacrifice a reasonable schedule for the scientific aspects of the NAAQS review to compensate for EPA's delay in starting the review.

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

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

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

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

Timeframe for the Last Ozone Review

As noted in individual member comments, the time frame for CASAC's role in the review process has varied, but averages 3.2 years in the most recent cycle of reviews of primary NAAQS for each criteria pollutant. CASAC's involvement for the most recently completed ozone review spanned 4.7 years, which is longer than this recent average. There were several reasons for this, that are provided below.

The call for information for the ozone review was announced in the Federal Register (FR) on September 29, 2008. The FR notice for a workshop to inform development of the Integrated Science Assessment (ISA) was 13 months later, on October 29, 2009. EPA issued its Integrated Review Plan also on October 29, 2009. CASAC provided its consultation on the Integrated Review Plan (IRP) on December 3, 2009.

The first draft of the Integrated Science Assessment (ISA) was not provided to CASAC until March 2011, 15 months after CASAC's consultation on the IRP. CASAC met on May 20, 2011 to review the first external review draft (ERD) of the ISA. CASAC transmitted its advice on the first ERD of the ISA on August 10, 2011. As detailed below, CASAC had extensive concerns with the first ERD of the ISA.

The second ERD of the ISA was received by CASAC on September 2011. Given the need for a thorough review and challenges in scheduling meetings near the holidays, CASAC met on January 9-10, 2012, to review the 2nd ERD of the ISA, and communicated its advice on March 3, 2012. As detailed below, CASAC identified numerous scientific issues that needed to be addressed, and requested a third ERD of the ISA.

EPA responded with the third ERD of the ISA in a timely manner, such that CASAC was able to review it on September 11, 2012 and complete its final advice on the ISA on November 14, 2012. Detailed findings of the CASAC on the third draft of the ISA noted the adequacy of many of the changes compared to the second draft.

The first drafts of the health and welfare REAs were reviewed by CASAC concurrently with the 3rd draft of the ISA. CASAC completed its advice on the first drafts of the REAs in November 2012 (EPA-CASAC-13-002). CASAC found that the "draft HREA and WREA documents are works in progress." The health REA required substantial scientific revisions pertaining to:

- The analysis framework;
- Background ozone;
- Comparison of risk estimates based on lowest measured level (LML) and zero ozone;
- A model-based approach for risk estimates "just meeting" the current standard;
- Performance and validation of the exposure model;
- Relevance and representativeness of human activity data used in the exposure model;
- Consideration of additional sources of uncertainty in exposure assessment;
- Choice of data and models for risk assessment; and

- Discussion of exposure measurement error in the selected epidemiologic studies.

The welfare REA required substantial revisions pertaining to:

- Effects of ozone on competition among species;
- Scaling from tree seedlings to mature trees;
- Impacts on individual sensitive species;
- Regional variability in impacts;
- A model-based approach to estimate risk at ambient levels meeting the current standard; and
- Analysis of crop yield loss.

Given the extent of the needed scientific revisions, it would not have been reasonable for CASAC to concur that these REAs could be finalized by EPA without further review by CASAC.

The second drafts of the health and welfare REAs were provided to CASAC 15 months later, in February 2014. In June 2018, the CASAC found that the revised REAs were substantially improved and that, with some further revisions that did not require further CASAC review, they would be adequate for their intended purpose.

The CASAC was asked to review a first draft of the policy assessment (PA) concurrently with the first draft of the health and welfare REAs. This is not a preferred sequencing because the PA should be developed after the scientific basis pertaining to the health and welfare REAs is well-established based on CASAC input. In its public meeting held from September 11 to 13, 2012, CASAC reviewed the 3rd draft of the ISA first, then the draft REAs, and lastly the draft PA, to sequence the deliberations such that scientific issues were identified before discussing the draft PA.

The draft PA brought to CASAC for deliberation at its September 13, 2012 meeting was characterized both by EPA and CASAC as preliminary. For example, although EPA staff proposed to find that the current standards were not adequate to protect public health and welfare, the EPA staff did not propose alternatives for revised standards, leaving these sections of the draft PA blank. Thus, this was not a 'full' PA. This lack of completeness was appropriate, since CASAC had not yet concluded deliberations on scientific issues for the ISA or the REAs. Hence, it would have been premature for EPA staff to propose alternatives to the existing NAAQS at this early stage in the review process. CASAC stated, "overall, the CASAC finds that the PA needs substantial improvement, reflecting the still very preliminary first draft that was brought to the CASAC."

This experience clearly demonstrates that if a draft PA is provided to CASAC for review before science issues are fully vetted in the ISA and REAs, substantial revisions are very likely to be required. Furthermore, science issues must be resolved in the ISA and REA before reviewing a PA.

The second draft of the PA, provided to CASAC in January 2014, deliberated by CASAC at a face-to-face meeting on March 24 and follow-up teleconferences on May 28, 2014 and June 4, 2014,

was found to be (EPA-CASAC-14-004): "an excellent summary of information needed to judge the adequacy of the current National Ambient Air Quality Standards (NAAQS) for ozone and to consider alternative standards." The second draft of the PA was a substantive and very useful basis for CASAC to deliberate on the formulation of its own recommendations regarding the primary and secondary standards.

Whether by teleconference or in-person, CASAC held public meetings on:

- November 13, 2009 (teleconference);
- May 19-20, 2011 (in person and teleconference);
- July 6, 2011 (teleconference);
- January 9-10, 2012 (in person and teleconference);
- March 9, 2012 (teleconference);
- September 11-13, 2012 (in person and teleconference);
- November 5, 2012 (teleconference);
- March 25-27, 2014 (in person and teleconference);
- May 28, 2014 (teleconference); and
- June 4, 2014 (teleconference).

At each of these public meetings, the public had opportunity to provide comment. The public comment periods were highly valuable to informing the CASAC of scientific and policy matters relevant to CASACs deliberations. For example, there were valuable comments regarding background ozone and regarding the statutory mandate to CASAC regarding the scope of its advisory activities. Public comments provide an opportunity for scientists and stakeholders to provide input to CASAC. CASAC should affirm and advise the EPA of the importance of public comments. However, this clearly does not mean that public comments can substitute for the formation of an augmented review panel.

Some lessons learned from the last ozone review are the following:

(1) Primary and secondary NAAQS for ozone depend on a "thorough review" of the "latest scientific knowledge" in many scientific disciplines regarding 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";
(2) For many of these disciplines, the perspectives of multiple experts are needed as provided by an augmented panel of additional experts in this field of study;
(3) The review must be conducted by scientific experts with the "latest scientific knowledge," which specifically includes active researchers;
(4) Stakeholders and other members of the public provide comments to CASAC that inform CASAC's deliberations;
(5) The number of drafts needed for a given assessment document depends on the scientific completeness and quality of EPA's initial and revised drafts;
(6) The number of drafts of assessment documents necessary for a "thorough review" of the "latest scientific knowledge" is determined by the scientific judgment of the CASAC; and

(7) Policy issues should not be addressed until the underlying science has been adequately vetted by CASAC.

These lessons should be considered in planning the current review of the primary and secondary NAAQS for ozone.

Factors Affecting Review Duration for the Integrated Science Assessment

We are aware of concerns about the amount of time required in the last review cycle for ozone to complete the ISA. There are two factors to consider in the duration of CASAC's review of the ISA in the last review cycle:

(1) The length of time it took EPA to provide CASAC with drafts; and
(2) The need for three drafts.

With regard to the former, the amount of time taken by EPA to provide CASAC with drafts was lengthy for the first draft. However, we have no direct knowledge of factors that might explain the duration for preparation of the ISA, such as budgetary or resource constraints, or other priority setting decisions. With regard to the second factor, there were scientific deficiencies in the first and second drafts of the ISA. Here, we review the public record regarding these factors. Based on this record, we provide advice to CASAC.

Regarding the first draft of the ISA, CASAC found that (EPA-CASAC-11-009):

- "The ISA's coverage of Policy Relevant Background (PRB) ozone concentrations is still a work in progress";
- "characterization of the temporal and spatial variability of ozone could be improved";
- "more description of some of the respiratory effects of ozone, especially on lung structure and host defenses, is needed";
- "The links between this literature [on epidemiological, human clinical, animal toxicological, and mechanistic studies], as it contributes to the biological plausibility of chronic effects, should be strengthened";
- EPA should "deepen and reorganize the discussion of susceptibility to explain how its definition of susceptibility was applied and how the identified susceptibility-determining factors apply specifically to ozone"; and
- "more attention should be given to methane as the only ozone precursor for which control would directly reduce climate forcing."

These are scientific issues that needed to be addressed to meet requirements for a "thorough review" based on the "latest scientific knowledge" and regarding the "kind and extent" of impacts indicated in the Act. Given the extent of the needed scientific revisions, it would not have been reasonable for CASAC to concur that the first ERD of the ISA could be finalized by EPA without further review by CASAC.

Regarding the second ERD of the ISA, CASAC stated (EPA-CASAC-12-004): "The CASAC commends EPA for substantial revisions to the first draft ISA based upon its prior advice

(August 2011). Nevertheless, the CASAC has further recommendations for improving the document and recommends that EPA develop a third draft of the ISA and provide it to the CASAC for a review focused on the key changes called for in this letter."

Both CASAC and EPA understood that this was an exceptional request. However, based on its expert scientific review, CASAC was not able to find that the 2nd ERD of the ISA was adequate for its intended purpose without substantial revisions. It is well established scientific practice that substantial revisions require further review.

Based on its expert scientific review of the 2nd ERD of the ISA, CASAC found that:

- "the discussion of background ozone concentration needs a stronger synthesis of current knowledge along with a quantitative assessment of the related uncertainties";
- "a discussion of long-term ozone exposures should be included";
- "discussions on the results from personal exposure simulations at several different NAAQS level scenarios should be reconsidered or deleted, as the findings of geographic variability in the 8-hour ozone exposures of children are not supported by the data";
- "analysis of population proximity to ozone monitors should be tied to maps of ozone concentrations";
- "findings from exposure studies should be integrated with discussions … related to exposure error, confounding, and highly exposed populations";
- "the connection between dosimetry principles and theoretical or experimental observations of dose distribution and tissue damage should be discussed with greater clarity and detail";
- "EPA should give consideration to the totality of the evidence on cardiovascular effects" in its causal determination;
- "conceptual and definitional issues" need to be further addressed, including for populations at "increased risk"";
- "additional synthesis highlighting the key conclusions" for health effects was needed,"
- revisions are needed to "the reference to "sensing of ozone" by plants, which does not describe the process as currently understood; the lack of clear, unambiguous statements regarding the impact of ozone on root growth; and the lack of emphasis on ambient ozone effects on native vegetation";
- "The consideration of radiative forcing from ozone precursor emissions is inadequate"; and
- "the effect of expected tropospheric ozone changes on UV-B radiation is quite small and provide a quantitative upper limit on the effect."

This extensive list of substantive scientific deficiencies in the 2nd ERD of the ISA is why we called for a third draft. The third draft was necessary to assure the quality, credibility, and adequacy of the ISA for its intended purpose of establishing the scientific foundation for use in the REAs and to inform the PA. Given the extent of the needed scientific revisions, it would not have been reasonable for CASAC to concur that the second ERD of the ISA could be finalized by EPA without further review by CASAC.

We note that it has been common occurrence for there to be two external review drafts of ISAs in all of the recent NAAQS reviews, including particulate matter, carbon monoxide, oxides of nitrogen, and sulfur oxides. In the most recent lead review, a third draft of the ISA was requested by CASAC.

We find that the duration of review time for the ISA was related in large part to the duration of time for EPA to develop the first draft for CASAC review and to scientific deficiencies in draft ISAs that had to be addressed. With regard to the first point, the EPA staff need adequate time to prepare a document of the scope and complexity of an ISA.

Therefore, we advise that adequate time must be allowed for scientific review of the ISA. Although EPA may propose to provide CASAC with only one draft of an ISA, as it has done in the current Integrated Review Plan, this does not obligate CASAC to provide 'closure' on the ISA after reviewing only one draft. Because the ISA is a key component of the scientific review process, the ISA is key foundation for demonstrating that EPA satisfies the statutory mandate for a "thorough review" based on the "latest scientific knowledge" of the "kind and extent" of effects that pertain to the primary and secondary NAAQS for ozone. As a body independent of EPA, CASAC may refuse to concur that a given draft is adequate, and may ask for additional drafts. Thus, it is also in EPA's interest to recognize that a realistic schedule is needed and to take into account the possibility, if not likelihood, of revisions that require further CASAC review. Conversely, if CASAC were to agree in advance to review only one draft of an ISA, this would be an *a priori* judgment that the draft would not require major reviews. Such a judgment cannot be nor ever should be made until the ISA is reviewed.

The Current Integrated Review Plan for Ozone

We have serious concerns and reservations regarding EPA's Integrated Review Plan in addition to the points raised above and other points detailed in attached individual comments. For example, we understand that EPA proposes that the ISA will include prefatory material and integrated synthesis, which is consistent with past ISAs. However, EPA proposes that subsequent parts of the ISA would be treated as appendices rather than chapters, which would be inappropriate.

The May 9, 2018 memorandum by Administrator Pruitt states, without proper context, that "CASAC has frequently identified reducing the length and complexity of the ISA as a key process improvement for streamlining NAAQS reviews." While it is true that, from time to time, various review panels and the CASAC have made comments regarding a preference for more concise documents, the 'as revealed' preference of CASAC, in terms of what it has recommended and agreed with, is clearly for an ISA that provides a thorough review of the latest scientific knowledge of the kind and extent of scientific issues pertaining to a given review cycle.

CASAC has provided 'closure' on ISAs that are lengthy documents. The final ISAs for various review cycles have been 260 pages for Oxides of Nitrogen in 2008, 479 pages for Sulfur Oxides in 2008, 898 pages for Oxides of Nitrogen and Sulfur – Ecological Criteria in 2008, 1,071 pages for Particulate Matter in 2009, 593 pages for CO in 2010, 1,885 pages for lead in 2013, 1,251 pages for Ozone in 2013, 1,148 pages for Oxides of Nitrogen in 2016, and 696 pages for Sulfur Oxides in 2017. A document that is scientifically concise is not necessarily a short document. Moreover, EPA is required to meet the statutory requirements for a "thorough review" of the "latest scientific knowledge" of the "kind and extent" of scientific issues pertaining to a given review cycle.

ISAs were introduced as a result of 2006 revisions to the NAAQS review process. It is not surprising that there was a 'learning curve' by EPA staff and CASAC regarding how to structure and organize these documents that cover a large and complex scope of scientific issues. In the various review cycles alluded to in the previous paragraph, CASAC has repeatedly reviewed and commented on the structure and organization of the ISAs, which has led to ISAs that are comprised of a preface, executive summary, integrative synthesis, and chapters on major scientific issues that support the integrative synthesis. These chapters include, for example, atmospheric chemistry and ambient concentrations, exposure, dosimetry, health effects, and at-risk populations, among others. The scope of chapters is tailored to the particular review. EPA has created a separate Preamble to the ISAs that document general frameworks that are applied to each ISA regarding literature review, causal determination, and characterization of at-risk populations. These frameworks have been reviewed numerous times by CASAC.

Thus, the proposal in the IRP to substantially change the structure and content of the ISA is a substantial deviation from established practice. EPA needs to be more specific regarding this proposal, the extent to which it is based on pertinent and appropriately interpreted CASAC advice in proper context, and the extent to which it supports or compromises a "thorough review" based on the "latest scientific knowledge" of the "kind and extent" of effects that pertain to the primary and secondary NAAQS for ozone.

EPA Plans for the Current Review of the Primary and Secondary NAAQS for Ozone

As detailed in attached individual member comments, we find that the changes to the NAAQS review process called for in the May 9, 2018 memorandum from former Administrator Scott Pruitt were developed in a non-transparent manner without input from CASAC or the public.

EPA's strategy and plans for the current review of the primary and secondary standards for the NAAQS for ozone are indicated in a recent series of documents, including:

- A July 27, 2018 Federal Register notice requesting nominations for a CASAC Ozone Review Panel,
- An EPA press release of October 10, 2018 announcing new appointments and instructions to CASAC,
- An email sent by EPA on October 11, 2018 to candidates for a CASAC Ozone Review Panel informing them that a panel will not be formed,

- A November 7, 2018 "determination" memorandum from the EPA Science Advisory Board office that the chartered CASAC will conduct the ozone review, and
- The Ozone Integrated Review Plan provided by EPA for consultation with CASAC.

These recent documents are based, at least in part, on October 31, 2017 and May 9, 2018 memoranda by former Administrator Scott Pruitt that revised criteria for appointment to EPA Federal Advisory Committees, including CASAC, and the NAAQS review process itself, respectively. The implications of these recent changes are analyzed in detail in the attached member comments.

Based on this collective record, we state the seven major findings given in Table 1. Based on the seven major findings in Table 1, we make 30 recommendations as given in Table 2.

Both EPA and CASAC are required to conduct the scientific review in a manner that meets the statutory requirements of the Clean Air Act.

Sincerely,

/signed/

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Glenn E. Futrell Distinguished University Professor
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Chartered CASAC: Member 2008-2012, Chair 2012-2015
CASAC Ozone Review Panel: Member 2009-2012, Chair, 2012-2014
CASAC PM Review Panel: Member 2007-2010, 2015-2018
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
SOx/NOx Secondary Standard Review Panel: Member 2009-2011
CASAC Carbon Monoxide Review Panel: Member 2008-2010

/signed/

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Chartered CASAC: Member 2006-2008, Chair 2008-2012
CASAC Ozone Review Panel: Chair 2009-2012
CASAC PM Review Panel: Member 2008, Chair 2009-2010
CASAC PM Review Panel: Member 1995-1996

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CASAC Ozone Review Panel: Member 2012-2014
CASAC Sulfur Oxides Review Panel: Chair 2013-2017
CASAC PM Review Panel: Chair 2015-2018

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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/

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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

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CASAC Carbon Monoxide Review Panel: Chair 2009-2010
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CASAC Sulfur Oxides Review Panel: Member 2010
CASAC Particulate Matter Review Panel: Member 2007-2010
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/signed/

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CASAC PM Review Panel: Member 2015-2018
CASAC Sulfur Oxides Review Panel: Member 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2013-2017

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CASAC Ozone Review Panel: Member 2009-2010
CASAC Sulfur Oxides Review Panel: Member 2016-2018, 2007-2008
CASAC Secondary SOx/NOx/PM Review Panel: Member 2016-2018
CASAC Secondary SOx/NOx Review Panel: Member 2007-2010
CASAC Lead Review Panel: Member 2007
CASAC 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/

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CASAC Ozone Review Panel: Member 2009-2014
CASAC Sulfur Oxides Review Panel: Member 2007-2010
CASAC Oxides of Nitrogen Review Panel: Member 2007-2010

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CASAC Ozone Review Panel: Member 2009-2014
CASAC PM Review Panel: Member 2007-2010

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CASAC Ozone Review Panel: Member 2009-2014

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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/

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CASAC Ozone Review Panel: Member 2009-2014
CASAC PM Review Panel: Member 2007-2010

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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

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CASAC Ozone Review Panel: Member 2009-2014
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EPA SAB Biogenic Carbon Emissions Panel Member: 2011-2012, 2015-2018

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Palo Alto, CA

Chartered CASAC: Member 2012-2017
CASAC Ozone Review Panel: Member 2009-2014
CASAC Sulfur Oxides Review Panel: Member 2013-2018
CASAC PM Review Panel: Member 2008-2011, Member 2015-2018
CASAC Oxides of Nitrogen Review Panel: Member 2008-2010, 2013-2017

Attachments

Attachment A: Written Statement from H. Christopher Frey (44 pages)
Attachment B: Written Statement from David A. Grantz (3 pages)
Attachment C: Written Statement from Howard S. Neufeld (2 pages)
Attachment D: Written Statement from James S. Ultman (2 pages)

WRITTEN STATEMENTS FROM

INDIVIDUAL FORMER MEMBERS OF THE

2009-2014 CASAC OZONE REVIEW PANEL

Public Comment on the Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards

Attachment A: Written Statement from H. Christopher Frey (44 pages)

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WRITTEN STATEMENT

Public Comment on the Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards

PREPARED BY:

H. Christopher Frey, Ph.D.

SUBMITTED TO

Clean Air Scientific Advisory Committee

U.S. Environmental Protection Agency

Washington, DC

DATE

November 26, 2018

DISCLAIMER

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

1.0 INTRODUCTION

This written statement is organized as follows:

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

The recommendations are based on information from the comments on the IRP and the Appendices.

Major changes have recently been made to the National Ambient Air Quality Standard (NAAQS) review process based on Administrator memoranda issued on October 31, 2017 regarding "Strengthening and Improving Membership on EPA Federal Advisory Committees," and on May 9, 2018 regarding "Back to Basics Process for Reviewing National Ambient Air Quality Standards." It is not readily apparent to external observers that these changes were based on a deliberative process within EPA that welcomed or considered input from the EPA staff who are tasked with development of this document. It is clear that these changes were based on a secretive process that did not include opportunity for public comment nor any public consultation with CASAC. Thus, this November 29, 2018 meeting of the CASAC to review the IRP for Ozone is the first opportunity for the public to comment on the implementation of the October 31, 2017 and May 9, 2018 memoranda with respect to the NAAQS review process.

2.0 Executive Summary of Major Findings and Recommendations

The **7 Major Findings** and **30 Recommendations** are given in Tables 1 and 2, respectively. These correspond to Tables 1 and 2, respectively of the written statement co-signed by 19 former members of the 2009 to 2014 CASAC Ozone Review Panel. The co-signers include:

- Three former chairs of the chartered CASAC (Samet, Frey, and Diez Roux),
- The two former chairs of the 2009 to 2014 CASAC Ozone Review Panel (Samet and Frey), and
- Eleven former members of the chartered CASAC (Allen, Brain, Diex Roux, Frey, Harkema, Kenski, Miller, Russell, Samet, Suh, Wyzga).

The 19 co-signers have served on an average of more than three CASAC panels each.

Table 1. Major Findings[a]

MAJOR FINDING 1:	The myriad of changes to the NAAQS review process are collectively harmful to the quality, credibility, and integrity of the scientific review process and CASAC as an advisory body.
MAJOR FINDING 2:	The current 7-member CASAC does not have the depth or breadth of expertise needed for the ozone review, nor could a group of this size cover the needed scientific disciplines.
MAJOR FINDING 3:	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.
MAJOR FINDING 4:	CASAC has transitioned from a committee of nationally and internationally recognized researchers at the leading edge of their fields toward a committee composed predominantly of stakeholders chosen based on geographic location and affiliation with state government, rather than scientific expertise first and foremost. The statute requires only "one person representing State air pollution control agencies."
MAJOR FINDING 5:	An underlying principle is to maintain distinction between science and policy issues. The Pruitt May 9, 2018 memorandum violates this principle by commingling science and policy considerations.
MAJOR FINDING 6:	In 2014, the CASAC provided advice to the Administrator regarding how CASAC's role in reviewing adverse effects of NAAQS implementation should be structured. This advice has been ignored by EPA.
MAJOR FINDING 7:	There are numerous deficiencies in EPA's Integrated Review Plan related to the above findings. EPA's proposal in the IRP to structure the Ozone ISA with appendices rather than chapters is contrary to the requirement for EPA to thorough review" of the "latest scientific information" of the "kind and extent" of "all identifiable effects" as required by the Clean Air Act.

[a] These major findings are from Table 1 in Frey, H.C., J.M. Samet, A.V. Diez Roux, G. Allen, E.L. Avol, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, 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)," Letter to L.A. Cox, Clean Air Scientific Advisory Committee, November 26, 2018.

Table 2. Recommendations[b]

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

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

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

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

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

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

Recommendation 5: CASAC should acknowledge and advise the current Acting Administrator that it does not have adequate breadth and depth of scientific expertise to conduct thorough reviews based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to either the Ozone or the Particulate Matter NAAQS.

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

Recommendation 7: CASAC should remind the current Acting Administrator that in all past reviews conducted by CASAC, it has always been the 7-member chartered CASAC that approves the content of letter reports and attachments transmitted from CASAC to the Administrator.

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

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

Recommendation 9: CASAC should reject EPA's proposed accelerated schedule. EPA should allow time for an adequate review by relaxing its 2020 deadline.

Recommendation 10: CASAC should reject EPA's proposal for one draft of an Integrated Science Assessment and one draft of a Policy Assessment.

Recommendation 11: The CASAC should advise the current Acting Administrator that the CASAC, supported by an augmented panel of scientific experts, requires typically three years to conduct this review.

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Table 2. Recommendations, *Continued*

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

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

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

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

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

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

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

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

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

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

Recommendation 20: CASAC should affirm that its members should not be dismissed en masse or appointed en masse, and turnover in a given year should be limited to a minority fraction of the total panel. Members should be eligible for reappointment to a second term especially if such appointments would provide continuity, key scientific expertise, and institutional memory.

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

Recommendation 21: CASAC should reject EPA's proposal to combine the REA into the PA for the Ozone review. Further, the CASAC review of the REA should not be concurrent with the PA for the Ozone review.

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Table 2. Recommendations, *Continued*

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

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

Recommendation 23: CASAC should consider both adverse and beneficial effects.

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

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

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

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

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

With regard to **MAJOR FINDING 7**: Deficiencies in the Ozone Integrated Review Plan

Recommendation 29: The ISA for the current ozone review should be consistent with the now well-established structure and content of CASAC-reviewed ISAs, such as from the previous ozone review.

Recommendation 30: EPA should 'start over' with the scientific review of the primary and secondary NAAQS for ozone. Specifically, EPA should set aside the current Integrated Review Plan and develop a new Integrated Review Plan that is appropriately formulated to take into account the findings and recommendations provided herein. Given the extensive revisions needed to the IRP, the CASAC and the public should have an opportunity to comment on a new IRP.

[b] These major findings are from Table 1 in Frey, H.C., J.M. Samet, A.V. Diez Roux, G. Allen, E.L. Avol, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, 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)," Letter to L.A. Cox, Clean Air Scientific Advisory Committee, November 26, 2018.

3.0 MAJOR FINDINGS AND RECOMMENDATIONS

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

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

> **Recommendation 1: The CASAC should emphasize that the quality, credibility, and integrity of the review process depends on multiple facets of how the review is structured**, including the sequence of documents, the opportunity to review revised drafts, augmentation of the CASAC with additional experts for each review (i.e. for ozone and for PM), opportunity for public input, adequate time in which to conduct the review, engagement of experts based on scientific expertise and not based on geography or affiliation, and engagement of experts with or without EPA research grants based foremost on the relevance of their scientific expertise. **Thus, simply changing one or two of these facets alone will not assure the quality, credibility, and integrity of a "thorough review" based on the "latest scientific knowledge"** as required by Sections 108 and 109 of the Clean Air Act. **The CASAC should recommend that the EPA rescind the October 31, 2017 and May 9, 2018 memoranda by former Administrator Scott Pruitt.**
>
> **Recommendation 2:** In attempting to alter the NAAQS review process, EPA should have followed the kind of open and transparent process undertaken in 2006.[3] Such a process would lead to a better understanding of the key needs and challenges of NAAQS review and perhaps effective ideas for reviews which are more timely. **CASAC should recommend a wider consideration of approaches to streamlining the NAAQS review process, including opportunity for input from EPA staff in ORD and OAQPS, CASAC, and other stakeholders including the public**.
>
> **Recommendation 3:** In revising criteria for membership on EPA Federal Advisory Committees in the October 31, 2017 memorandum[1] from former Administrator Pruitt, EPA should have recognized that such committees may serve different purposes, and should have acknowledged Federal guidance on peer review.[4] The membership criteria for a scientific review committee should not be the same as the membership criteria for a stakeholder committee. **CASAC should advise EPA that, if it wishes to change the criteria for appointments to CASAC, it should provide opportunity for input on such criteria from EPA staff in ORD and OAQPS, the EPA Science and Technology Policy Council, CASAC, and other stakeholders including the public**.
>
> **Recommendation 4**: As a group independent from EPA, **CASAC should not agree to recent changes to the NAAQS review process or to the ozone NAAQS review schedule proposed by EPA**.

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MAJOR FINDING 2: Acting Administrator Andrew Wheeler appointed five members to the CASAC on October 10, 2018.[5] The 7-member CASAC is comprised of four members from state agencies, one member from a Federal agency, a consultant, and an academic researcher. In the same October 10, 2018 press release that announced the new CASAC membership, the Acting Administrator announced that only the 7-member CASAC would conduct reviews of both the ozone and particulate matter standards and that the reviews would be conducted simultaneously on an expedited schedule. On October 11, 2018, members of the CASAC PM Review Panel, which was formed in 2016, were informed that their services were no longer needed, and candidates for the CASAC Ozone Review Panel were informed that a panel would not be formed, even though EPA requested nominations for such a panel in July 2018.[6,7] The 1800+ page Integrated Science Assessment for Particulate Matter was released four days later, on October 15, 2018.[8] **The current 7-member CASAC does not have the depth or breadth of expertise needed for the ozone and particulate matter reviews, nor could a group of this size cover the needed scientific disciplines**.

> **Recommendation 5**: **CASAC should acknowledge and advise the current Acting Administrator that it does not have adequate breadth and depth of scientific expertise to conduct thorough reviews based on the latest scientific knowledge of the kind and extent of scientific issues that pertain to either the Ozone or the Particulate Matter NAAQS**. This is generally true given that CASAC is comprised of only seven members, whereas these reviews require multiple experts in each of many scientific disciplines. This is even more true given that the current CASAC was appointed based primarily on geography and affiliation, and not by scientific discipline, in accordance with the October 31, 2017 memo by former Administrator Pruitt.[1,5] According to November 7, 2018 "determination" memos from the EPA SAB office, the CASAC has no epidemiologists, even though epidemiology is a key scientific discipline related to both the ozone and PM reviews.[9,10] The CASAC lacks adequate coverage of many other disciplines, such as exposure assessment, effect of ozone on climate, and other areas, and lacks depth in areas for which CASAC has historically and necessarily engaged multiple experts, such as toxicology.
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> **Recommendation 6**: **CASAC should remind the current Acting Administrator that it has been long-standing practice to augment the 7-member CASAC with additional independent expert consultants, and this augmentation is essential to a high quality review.** It has been long-standing practice since the 1970s (see Section 6) to augment the 7-member CASAC with additional independent expert consultants, so as to have the breadth and depth of expertise required to conduct a "thorough review" based on the "latest scientific knowledge," consistent with requirements of the Clean Air Act. It is not sufficient, as the Administrator suggested, to state that the 7 member committee meets the minimum requirements of the law.
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> **Recommendation 7**: **CASAC should remind the current Acting Administrator that it has always been the 7-member chartered CASAC that approves the content of letter reports and attachments transmitted from CASAC to the Administrator**. This point is clearly stated in CASAC's charter.[11] CASAC should remind the Administrator that based on long-standing well-established practice, consultants who augment the CASAC to form a review panel provide input and advice that ultimately is considered and vetted by the CASAC, and that it is the CASAC and not its independent consultants who decide on what advice is transmitted to the Administrator. Thus, forming an augmented panel is not mutually exclusive with only the 7-member CASAC providing advice to the Administrator.

<u>Recommendation 8</u>: **CASAC should call for the formation of an Ozone Review Panel and for the reinstatement of the CASAC PM Review Panel** that was disbanded on Oct 11, 2018,[7] only four days before the first draft PM ISA was released on Oct 15, 2018.[8] **CASAC should make these recommendations to the Administrator as soon as possible**.

MAJOR FINDING 3: 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.

<u>Recommendation 9</u>: CASAC should reject EPA's proposed accelerated schedule. EPA should allow time for an adequate review by relaxing its self-imposed deadline of 2020 and instead allow adequate time to complete the ozone NAAQS review process. Given a typical duration of CASAC involvement with NAAQS reviews that have averaged 3 years, and that EPA usually takes another 1 to 2 years to finalize a rule (see Section 5 for details), a more realistic deadline is end of 2023, or five years from now. The actual time to completion could be less but this would depend on interim findings from EPA staff and CASAC in the course of preparing and reviewing the ISA, REA, and PA. To allow adequate time for review, the schedule should be set based on established experience with similar reviews.

<u>Recommendation 10</u>: CASAC should reject EPA's proposal for one draft of an ISA and one draft of a PA. CASAC may decide later that the first draft of either of these documents are adequate for their intended purpose, but CASAC should not feel constrained to review only a single draft of each document, and EPA should provide for the possibility and opportunity for CASAC to review a second draft of either the ISA or the PA.

<u>Recommendation 11</u>: Given that the duration of CASAC's role in the most recent six primary NAAQS reviews focused on public health has been 2.2 years to 4.7 years, with an average of 3.2 years (see Section 5 for details), EPA's proposal for CASAC to execute its role in the current Ozone review in only one year is unprecedented, unrealistic, and infeasible if the CASAC is to conduct a review with adequate quality, credibility, and integrity. **The CASAC should advise the Administrator that the CASAC, supported by an augmented panel of scientific experts, requires typically three years to conduct this review**.

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

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MAJOR FINDING 3: ***Continued*.**

Recommendation 13: The CASAC should note that the duration of time to complete a NAAQS review depends in part on CASAC but also on EPA. In particular, EPA controls the timeline with regard to when a new review is initiated. Lapses of time between the end of a prior review up until the start of a new review are entirely at the discretion of the EPA. In the case of the Ozone review, EPA did not start the review process until June 2018, even though the final rule of the prior review cycle was published in 2015. **The CASAC should affirm that delays in initiation of the review cycle by EPA should not infringe on the adequacy of the time frame needed by CASAC to properly do its job with adequate quality and integrity**.

Recommendation 14: CASAC should affirm the important role of public comments in CASAC's review of the NAAQS, noting that a compressed and curtailed review process leads to fewer public meetings and, therefore, fewer opportunities for CASAC to be informed by public comment. CASAC should further note that the shortened duration for the ozone NAAQS scientific review results in fewer opportunities for public input to CASAC. Therefore, CASAC should advise the Administrator that, to promote transparency of the review and opportunity for public input consistent with long-standing practice, the CASAC should have a longer time frame for its deliberations, consistent with historic practice in the last decade, and should not have the public meeting process truncated to meet shortened deadline that resulted from EPA delays in starting the current review.

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

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

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

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MAJOR FINDING 4: Acting Administrator Andrew Wheeler, in making new appointments to the CASAC on October 10, 2018,[5] has implemented provisions of former Administrator Pruitt's October 31, 2017 memorandum.[1] **CASAC has transitioned from a committee of nationally and internationally recognized researchers at the leading edge of their fields toward a committee composed predominantly of stakeholders chosen based on geographic location and affiliation with state government, rather than scientific expertise first and foremost. The statute requires only "one person representing State air pollution control agencies"**. The appointment of five members at one time is highly unusual, leading to a high degree of turn-over and inexperience on the current CASAC.

> **Recommendation 18**: Scientific expertise for panels should be relevant to the particular review. Different NAAQS reviews require different expertise. CASAC should re-affirm that membership criteria for the chartered CASAC and for its augmented panels should emphasize scientific expertise, not geographic diversity nor affiliation with state, local, and tribal agencies, other than to meet the Clean Air Act requirement for "one person representing State air pollution control agencies." CASAC has always fulfilled this requirement.
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> **Recommendation 19**: **CASAC should affirm that**, per long standing prior practice from the formation of CASAC until October 2017, nationally and internationally prominent researchers who hold peer-reviewed independently managed research grants from the U.S. Environmental Protection Agency are able to offer independent scientific advice to the agency. Per the peer review bulletin of the Office of Management and Budget, for scientists who hold federal research grants, "there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects."[4] Therefore, **receipt of an EPA research grant should not disqualify membership on the CASAC or CASAC review panels**. Further, CASAC should point out that it is illogical to allow persons from state, local, and tribal governments who hold EPA grants to serve on CASAC while preventing persons of other affiliations who hold grants, such as academia, from serving. Moreover, allowing members with funding from regulated industries to serve creates an appearance of lack of impartiality.
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> **Recommendation 20**: **CASAC should affirm that**, while there are benefits to having turnover of membership on the chartered CASAC, there are also significant benefits to continuity and knowledge provided by having some previous members continue to serve for a second term and to have staggered, overlapping terms. Thus, **members should not be dismissed *en masse* or appointed *en masse*, and turnover in a given year should be limited to a minority fraction of the total panel. Members should be eligible for reappointment to a second term especially if such appointments would provide continuity, key scientific expertise, and institutional memory**.

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

> **Recommendation 21**: **CASAC should reject EPA's proposal to combine the REA into the PA for the Ozone review. Further, the CASAC review of the REA should not be concurrent with the PA for the Ozone review**. A decision to combine the REA into the PA is doubly premature. First, the REA should not be prepared until the ISA has been adequately reviewed, since the REA is based on the air quality criteria established by and set forth in the ISA. This means that, at the earliest, the REA cannot be credibly prepared until CASAC review of the first draft of the ISA. If CASAC finds that the scientific basis of the review has changed since the last review such that a separate REA is needed, then EPA should provide CASAC with a draft REA. Second, the REA should be properly reviewed before the first draft of the PA. The PA cannot credibly set forth a policy-relevant summary of the REA without adequate review of the REA to know what elements reliably to highlight. Thus, CASAC should receive a first draft of the REA in a review step prior to receiving a first draft of the PA, such that CASAC's scientific advice on the REA is known, at least in large part, prior to the formulation of the first draft of the PA.

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

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

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

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MAJOR FINDING 6: *Continued*.

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

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

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

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

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

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MAJOR FINDING 7: There are numerous deficiencies in EPA's Integrated Review Plan[17] related to the above findings. EPA's proposal in the IRP to structure the Ozone ISA with appendices rather than chapters is contrary to the requirement for EPA to thorough review" of the "latest scientific information" of the "kind and extent" of "all identifiable effects" as required by the Clean Air Act.

> **Recommendation 29**: **The ISA for the current ozone review should be consistent with the now well-established structure and content of CASAC-reviewed ISAs, such as from the previous ozone review**. Previous ISAs include chapters that pertain to key scientific disciplines (e.g., air quality, exposure, dosimetry, human health effects, at-risk populations, welfare effects). These chapters are critical to demonstration of "thorough review" that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." Such chapters identify, based on a thorough literature review, and a thorough assessment of the literature, the policy relevant science that supports scientific determinations in the integrative synthesis.
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> **Recommendation 30**: **EPA should 'start over' with the scientific review of the primary and secondary NAAQS for ozone. Specifically, EPA should set aside the current Integrated Review Plan and develop a new Integrated Review Plan that is appropriately formulated to take into account the findings and recommendations provided herein. Given the extensive revisions needed to the IRP, the CASAC and the public should have an opportunity to comment on a new IRP**.

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[1] Pruitt, E.S., "Strengthening and Improving Membership on EPA Federal Advisory Committees," Memorandum, U.S. Environmental Protection Agency, October 31, 2017

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[3] 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.

[4] Bolten, J.B., "Issuance of OMB's "Final Information Quality Bulletin for Peer Review," Memorandum, Office of Management and Budget, Executive Office of the President, Washington, DC, December 16, 2004.

[5] EPA, "Acting Administrator Wheeler Announces Science Advisors for Key Clean Air Act Committee," News Release, October 10, 2018. https://www.epa.gov/newsreleases/acting-administrator-wheeler-announces-science-advisors-key-clean-air-act-committee

[6] Khanna, Johnston, "CASAC Ozone Panel Thank you for your interest. Providing an update." Email to Aaron Yeow, U.S. Environmental Protection Agency, October 11, 2018.

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[8] EPA, "Integrated Science Assessment for Particulate Matter (External Review Draft)," EPA/600/R-18/179, U.S. Environmental Protection Agency, Research Triangle Park, NC, October 2018.

[9] Yeow, A., "Determinations Associated with the Clean Air Scientific Advisory Committee (CASAC) Review of the Ozone National Ambient Air Quality Standards (NAAQS)," Memorandum to T.H. Brennan, Science Advisory Board, U.S. Environmental Protection Agency, Washington, DC, November 7, 2018.

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[12] 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

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[14] EPA, "The Benefits and Costs of the Clean Air Act, 1970 to 1990," U.S. Environmental Protection Agency, Washington, DC, October 15, 1997.

[15] EPA, "The Benefits and Costs of the Clean Air Act, 1990 to 2010: First prospective study," U.S. Environmental Protection Agency, Washington, DC, November 15, 1999.

[16] EPA, "The Benefits and Costs of the Clean Air Act, 1990 to 2020: Second prospective study," U.S. Environmental Protection Agency, Washington, DC, March 1, 2011.

[17] EPA, Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards, External Review Draft, EPA-452/P-18-001, U.S. Environmental Protection Agency, Research Triangle Park, NC, October 2018.

4.0 COMMENTS ON THE INTEGRATED REVIEW PLAN FOR OZONE

Page 1-3, lines 14-15: The IRP appropriately notes "Issues that are not relevant to standard setting may be relevant to implementation of the NAAQS once they are established." **The IRP should make clear that when developing recommendations to retain, revise, or develop new NAAQS, it is <u>illegal</u> to consider issues related to cost and technical feasibility of implementation**. Thus, any CASAC role in providing advice regarding effects of implementations should be done separately, and on a different timeline, than the development of CASAC's advice regarding the adequacy of current standards or revision or setting of new standards.

Page 1-4, lines 21-24: The document should make clear that **the Peacock, 2006 memorandum was based on a public process for getting input on the NAAQS review process. The Pruitt, 2018 memo was not**. More details in Section 5 of this statement.

Page 1-5, paragraph of lines 7 to 22 is misleading. While it is true that ISAs have been reviewed in draft form by CASAC, since the revised NAAQS review process from the Peacock, 2006 memorandum, **CASAC has reviewed at least two and sometimes three drafts of the ISA, not merely one draft of the ISA**. While it may be possible that a single draft could be adequate (more details on this point below), it is not reasonable to pre-judge that this will be the case. Ozone is one of the most researched and studied of ambient air pollutants, and the ISA for ozone is sure to be complex with many topics and scientific inferences. The scientific credibility of the review process is compromised if an *a priori* judgment is made that only one draft of the ISA will be adequate. Furthermore, CASAC is not required to concur that an ISA is adequate for its intended purpose if it in fact is inadequate. CASAC has both a right and a duty to demand subsequent drafts.

Paragraph of Page 1-5, line 23 to page 1-6, line 8: **EPA is mischaracterizing the NAAQS review process** that has been in place as a result of the Peacock 2006 memorandum. **The risk and exposure assessment (REA) was not originally intended to be a step to be subsumed into the policy assessment (PA)**. The REA deals with fundamental scientific issues addressing the combinations of air pollutants (indicators), averaging times, exposure durations (e.g., long-term, short-term), and effect endpoints for which exposure and risk can be quantified, what appropriate data and method(s) are available and selected for exposure assessment, what appropriate data and method(s) are available for either identifying benchmark exposure levels or quantifying exposure-response relationships, and what metrics are appropriate for risk characterization.

The purpose of having a sequence of documents in the order of ISA, REA, and PA is to distinguish between matters that are purely scientific in nature, as embodied in the ISA, from matters that commingle policy considerations, as embodied in the PA. The REA is a bridge between the ISA and the PA. The REA applies information, data, and methods from the ISA to make estimates and predictions of exposures and risks. As such, the REA is heavily science-based, and merits a science-focused review before it is used in the PA. Combining the REA and the PA into one document or one step commingles science and policy issues, thereby reducing transparency of the scientific aspects of the assessment while introducing the possibility that the REA will be structured based on pre-judged policy outcomes. It also appears to invite violation of one of the objectives stated in Administrator Pruitt's May 2018 memorandum: to "differentiate science and policy judgments in the NAAQS review process."

In recent reviews for which an REA was not done or was combined into the policy assessment, there was reliance on an REA conducted in a prior review cycle for which the science had been well-vetted by CASAC in advance of reviewing the first draft PA (e.g., the Lead review completed by CASAC in 2013). However, here, **EPA appears to be proposing that a new risk and exposure assessment could be developed without providing it to CASAC for review prior to CASAC's review of the PA**. Given that the PA often relies significantly on insights from the REA, **commingling the REA and PA will beg the question of whether the REA was tailored toward particular pre-judged policy outcomes rather than predicated on the best science** in terms of design, input data, modeling framework, and applications. Equally obviously, the PA would inappropriately be drawing conclusions from an REA that had not been properly scientifically vetted by CASAC review.

With regard to the standard charge questions give on page 1-6, line 25 to page 1-7, line 19, these are generally reasonable and appropriate questions but they do not belong together in terms of how they should be addressed by CASAC, as elaborated below.

With regard to how CASAC should provide advice regarding effects of implementation of NAAQS, this was addressed in a June 26, 2014 letter to the Administrator, as described in more detail in Section 5.10 "CASAC Advice on Implementation of NAAQS."

Page 1-7, lines 24-29. Although public comments are always an important part of the NAAQS review process, **it is simply not the case that a public call for information on "any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of existing, new, or revised NAAQS for consideration" will adequately form a basis for CASAC to formulate "meaningful advice on these questions."** While it is correct that the Clean Air Act states that CASAC shall provide this advice, CASAC is generally tasked with providing advice based on the "latest scientific knowledge." Therefore, meaningful advice on these questions cannot be predicated on anecdotal information provided only by stakeholders who respond to a request for public comment. **CASAC must take a fair, balanced, and open-minded approach based on valid scientific data and inference methods**. There may or may not be adequate scientific data and methodology to provide advice on all of these issues. **EPA has not provided CASAC with any assessment documents on effects from strategies for implementation of NAAQS. Thus, there is not an existing methodological framework for addressing these issues**. The credibility of CASAC's advice is predicated on development of advice based on appropriate data and methods. Furthermore, **the credibility of CASAC's advice will depend critically on whether the CASAC is augmented with a sufficient number of experts in the relevant disciplines to assure a thorough review based on the latest scientific knowledge.**

Page 1-8, lines 11-12: this document should **explain in detail the process by which the May 2018 "Back to Basics" Memorandum was developed**. When was the process of formulating the key points subsequently included in the memorandum defined and initiated? What EPA staff were consulted with respect to their input and advice on revisions to the NAAQS review process, what was their input, and how was their input taken into account in formulating the memo? What public meetings were held to allow for public input? What stakeholders had opportunities for meetings with EPA senior administrative staff to provide their input to these revisions, and what was their input? What consultations were made between EPA and its scientific advisory committees, including the CASAC, the Science Advisory Board, and the Board of Scientific Counselors, regarding the proposed changes to the NAAQS review process and advice on the proposed changes?

Page 1-8, lines 13-14: Who decided and on what basis that the Ozone review must be completed by 2020? What EPA staff were involved in this decision? What opportunity was given for input by NCEA and OAQPS staff regarding this deadline? What opportunity was given to CASAC to consider and advise regarding recent changes to the NAAQS review process and to the proposal for a highly compressed review schedule? Is EPA under a court order or consent decree to complete the Ozone review by 2020?

The IRP should review the history of past reviews of ozone and other criteria pollutants. For each combination of criteria pollutant, type of standard (primary or secondary), and review cycle, what have been the following durations:

- Date from end of the prior review (i.e. publication of the final rule) to the formal announcement of the start of the next review (e.g., call for information for the ISA)
- Date from receipt of CASAC's "closure" letter in a given review cycle (e.g., the final CASAC advice on a given staff paper, ANPR, or policy assessment) and the date of publication of the subsequent final rule.
- Date from the end of the prior review (i.e. publication of the final rule) to the date of the end of the current review (i.e. publication of the final rule).
- Which of these reviews have been under a court order or consent decree?

Such an analysis will reveal (see Section 5) that **EPA has typically substantially delayed the start of a new review cycle after completion of a final review cycle**. For example, according to the terms of the May 2018 "Back to Basics" memo by Pruitt (2018), EPA should immediately begin review of the carbon monoxide standard, since the last review was completed seven years ago. Yet, EPA has not announced any plan to review the CO cycle.

The 2020 deadline for the ozone review, and for the PM review, are self-imposed deadlines, apparently developed without consideration of the scientific exigencies that should underly each review. **Even in cases for which EPA has been under a court order to complete a NAAQS review, or has entered into a consent decree with a court-supervised schedule, the courts have recognized the importance of the scientific review by CASAC required under the CAA, and have allowed far more time for CASAC's role than EPA is proposing to allow under its self-imposed deadlines**.

Page 1-7, lines 28-29: "The EPA is not planning to develop a Risk and Exposure Assessment (REA) Planning Document in this review." Given that the last ozone review was based on information with a deadline of July 2011, and that ozone is one of the most heavily studied of air pollutants, there may be significant new scientific information identified in the upcoming ISA. As EPA acknowledges later in the IRP. **It is already known that there is significant new scientific information to motivate new REAs for both public health and public welfare**. The more detailed review of new scientific information that will comprise the draft ISA may identify additional new information that would motivate extensions of the currently anticipated scope for new REAs for health and welfare. Thus, a decision on the scope and methods for the REA should be made after taking into account new scientific information that will be reviewed in the ISA. EPA should in the meantime plan to develop a plan for a new REA if one is needed.

Page 1-9, lines 1-5: **The Pruitt, 2018 memorandum** implements major changes to the NAAQS review process. However, the process by which the key changes were formulated lacked transparency. The

memorandum itself is internally inconsistent, and poorly formulated. For example, the memo **mischaracterizes or takes out of context some letter reports from CASAC during the transition in which the revised 2006 NAAQS review process was implemented, and by omission failed to point out lessons learned (more details in Section 5)**. Although claiming to call for more transparency and distinction between science and policy issues, **by arbitrarily speeding up the review process, dropping or combining documents, reducing opportunity for public input, and commingling science and policy issues via combined documents, the memo, if implemented, will significantly compromise the quality and integrity of the scientific review process, and taint CASAC's involvement in the process**.

Combining the REA into the PA means that science issues related to the REA will be pre-judged because those judgments will be made at the same time as formulation of the PA. **Thus, implementation of the May 2018 memorandum will clearly commingle science and policy considerations that were kept appropriately kept separate in the prior ozone review**. The only scenario in which combining the REA into the PA would be appropriate is if there is no new science since the last review that would lead to either a reformulation or re-interpretation of the previous REA. **Yet, as EPA appropriately notes later in the IRP, it is known *a priori* that the data and science *have* changed and that new analyses are needed for both the health and welfare REAs**.

Page 1-9, lines 5-6: **"Further, we are striving to ensure that initial draft documents are sufficiently robust and complete to support a single, full review by the CASAC and the public." While we can all agree that this would be a serendipitous outcome, it has never been achieved in practice in the 10 years that I have been involved in the CASAC review process**. This is a nice aspirational goal, but it is not realistic unless there has been no significant change in the science since the last review. However, until the ISA is written and reviewed by the CASAC, it will not be known whether the science is essentially unchanged since the last review. Therefore, **it is unwarranted, and indeed prejudicial, to assume, *a priori*, that a single draft will prove to be adequate**. This is also not a matter of whether EPA staff work hard enough to produce a "robust" document, whatever that means. EPA staff have demonstrated time and again their commitment to put forth the best document that they can, given time and resource constraints. **These documents involve many scientific issues of great complexity, for which a more integrative interpretation may emerge only after iterative deliberations, not just within EPA staff, but also with the CASAC and reflecting public input. EPA is prejudging that CASAC, and the commenting public, have little or nothing to offer in terms of additional scientific perspective that could lead to substantial improvement of a first draft.**

Page 1-9, lines 6-8: "The successfulness of these and other efficiencies implemented in this review will be considered by the EPA in planning for other future NAAQS reviews." This is an ironic statement, considering that the May 2018 memorandum by Administrator Pruitt did not assess the "successfulness" (sic) of the NAAQS review process based on implementation of a revised process since 2006. **The NAAQS review process in the last decade has in fact been extremely successful. For example, EPA, based on CASAC review and advice, has produced appropriately comprehensive and integrated assessments of the science pertaining to pollutants that affect public health and welfare. By following a carefully planned sequence of documents from the ISA to the REA to the PA, both EPA and CASAC have ensured that the review begins with a strong and sole focus on policy-relevant science and transitions to policy only toward the end, after the science is established and the application of science to the REA is established. Furthermore, the NAAQS review process as it existed prior to May 9, 2018 ensured multiple opportunities for public comment**. **Both EPA and CASAC, via the carefully**

structured process set in place as a result of a thorough, deliberative, and public review of the process itself, have produced assessments that are "thorough" and that "accurately reflect the latest scientific knowledge," as required under Sections 108 and 109 of the Clean Air Act. Thus, the system has been working. The May 9, 2018 memorandum attempts to 'fix something that ain't broke.'

The only respect in which the NAAQS review process has fallen short is with respect to meeting the five year review requirement of the CAA, but even in this regard EPA has generally been successful at reducing review time – a point not acknowledged in the memo - and has come very close to achieving the 5-year mandate for each of the criteria pollutants for the last few cycles. With increasing experience, both EPA staff and CASAC are able to conduct reviews more efficiently, not as a result of skipping steps, but based on lessons learned and resolved through careful deliberation. While more needs to be done to achieve the 5 year cycle, the review system is not fundamentally broken (see Section 5 for more details). Thus, the drastic changes to the review cycle as described throughout these comments are unwarranted, and are creating numerous adverse consequences that undermine the quality, credibility, and integrity of the review process.

Page 1-9, lines 9 to 18: **This timelime is inconsistent with achieving the breadth, depth, quality, credibility, and integrity of the scientific review process that is required under the Clean Air Act**. Section 109 of the Clean Air Act (CAA) requires the EPA Administrator to "complete a thorough review" of the NAAQS. CAA Section 108 states that the standards "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare which may be expected from the presence of such pollutant in the ambient air." The EPA Clean Air Scientific Advisory Committee (CASAC) is integral to this statutory mandate of thorough and comprehensive review. Section 109 of the CAA states that "an independent scientific review committee" "shall complete a review of the criteria published under section 108 of this title and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 108 of this title and subsection (b) of this section." EPA should not interfere with CASAC's ability to fulfill the mandate of the CAA to conduct the required "thorough review". **If CASAC needs another draft of a document to enable it to conduct a "thorough" review based on the "latest scientific knowledge," then the EPA should provide CASAC with another draft of the document, whether it is the ISA, REA, or PA.**

The NAAQS review process prior to the May 9, 2018 "Back-to-Basics Process for Reviewing National Ambient Air Quality Standards" memorandum was carefully developed in 2006, and amended in 2007 and 2009, based on a public deliberative process that included input from internal and external stakeholders, including EPA staff in ORD and OAQPS, CASAC, and others. In sharp contrast, **the May 2018 memorandum was developed without a public deliberative process or opportunity for stakeholder input, and the internal process by which ORD and OAQPS, or perhaps other stakeholders, had opportunity to provide input is unknown or did not exist**. T**he lack of an appropriate deliberative process led to a poorly formulated assessment of putative problems with the existing NAAQS review process (see Section 5.4 for examples) and a set of "solutions" that creates larger and more significant problems. EPA should rescind the May 9, 2018 memorandum.**

Page 2-4, line 25. The proposed revision was a range from 0.070 ppm to 0.065 ppm, not 0.07 ppm to 0.065 ppm.

Page 2-6, lines 4-6: this decision was not consistent with CASAC's advice.

Section 2.1 does a good job of reviewing the regulatory history but does not include a review of CASAC's role. **Given that the EPA has very recently made changes to the NAAQS review process, the IRP should clearly explain what was the process for CASAC's role in each of the prior review, and how is the proposed review process for this current review similar to, or different than, the prior reviews?** See Section 5 for details that would support such an overview.

Page 2-10, lines 23-27: This is certainly appropriate, but there is no doubt inter-annual variability in the U.S. background concentrations which also vary at shorter time scales and spatially. Will EPA assess inter-annual variability in U.S. background and its implications? Why would 2016 be a representative year in terms of typical meteorology?

While it is reasonable to use air quality modeling to assess U.S. background, air quality models are imprecise and may have biases. What will EPA do with regard to model evaluation and quantification of bias and imprecision in model predictions? What about uncertainty in emissions, chemical mechanisms, physical transport processes, and boundary conditions? How will these be addressed? For example, will model results with U.S. emissions be compared to monitoring data? Will model predictions be "updated" with monitoring values using Bayesian methods? What monitoring sites might reasonably represent background levels for use in evaluation of model predictions of U.S. background?

Page 3-2, lines 16-19: The text states: the "approach planned for this review of the primary O_3 standard will build on the substantial body of work developed during the course of the last review, taking into account the more recent scientific information and air quality data now available to inform our understanding of the key-policy relevant issues in this review." This implies that **the ISA in this review will be significantly updated compared to that of the last review, which in turn implies a substantial likelihood that the REA will also need to be updated compared to the last review.**

Page 3-3, lines 5-7 "Additionally, the currently available exposure and risk information, whether newly developed in this review or predominantly developed in the past and interpreted in light of current information…" This text implies that it is not yet known whether a new REA is needed. However, if a new REA is needed, then it should be provided for CASAC review as a first draft prior to providing CASAC with a first draft of the PA for review, to avoid commingling science and policy issues prematurely in the review process. However, later text in the IRP (see comments below) clearly indicates the need for a new REAs for both health and welfare.

The key questions on page 3-3 are appropriate. EPA should answer the last question as part of the ISA, at least with respect to whether uncertainties identified in the last review have been reduced. The final assessment of key uncertainties remaining at the end of this review cycle would typically be included in the PA and addressed by CASAC in its advice regarding the PA.

Page 3-4. The text here is generally reasonable but begs the question of what scientific information will be established prior to the first draft of the REA. Logically, there needs to be an REA that includes evaluation of the various alternatives that would provide a foundation for policy recommendations in the PA.

Given that public health and welfare, and billions of dollars in benefits and costs, are at stake, EPA can and should do its "due diligence" in the science review by having a proper review process with

separate ISA, REA, and PA documents that are sequenced such that findings from the previous document — after appropriate scientific vetting — can be taken into account.

Top of page 3-6. **Missing here is the interpretation of "protect public health" with an "adequate margin of safety" is that protection must be afforded to at-risk populations, but not necessarily every individual in an at-risk population**.

Top of page 3-7: The IRP should clearly state what was the cut-off data for the literature review that was the basis of the ISA. This cut-off date is the effective date of the "health effects evidence base". The cut-off date was July 2011. This is mentioned later but it would helpful to mention it here.

Page 3-37: The section that ends on this page is generally good. However, what is not clear from the description is that **the Administrator did not follow CASAC's advice for setting a secondary standard based on a biologically relevant metric**. CASAC considered the concordance between a secondary standard based on a biologically relevant metric versus one based on the same indicator, averaging time, and form as the primary standard. CASAC recommended that the secondary standard be set based on a biologically relevant metric: specifically, the CASAC recommended "retaining the current indicator (ozone) but establishing a revised form of the secondary standard to be the biologically-relevant W126 index accumulated over a 12-hour period (8 a.m. – 8 p.m.) over the 3-month summation period of a single year resulting in the maximum value of W126 (henceforth W126)" (Frey, 2014, CASAC report EPA-CASAC-14-004). Thus, the description of the decision making process would be clearer by including the statement that the Administrator's decision differed from CASAC's recommendation.

Page 4-1, lines 23-25: Given that the cited ISA is exclusively for a secondary standard, it is bit puzzling that EPA uses the secondary NOx/SOx/PM ISA as the model for the planned Ozone ISA, which is in the context of both a primary and secondary standard. Now that the first draft of the PM ISA is available, it may be better to refer to that, since it includes scientific information pertaining to both primary and secondary standards.

The plan for an integrated synthesis is good. CASAC has many times recommended the inclusion of an integrated synthesis. This plan is consistent with prior CASAC advice and with EPA practice.

However, **it is unusual that subsequent parts of the ISA would be treated as appendices rather than chapters. This deviates from well-established practice. What is the reason for this change? Will this affect the content? Is this a substantive change or just one of labeling? If this represents a substantive change that deviates from well-established practices that have emerged from the last decade of CASAC advice, then the IRP should have more clearly explained and attempted to justify such change. Failure to do so undermines the ability of the public to understand and comment on EPA's proposal.**

The content of the Preamble to the ISA (EPA/600/R-15/067, 2015) has been extensively reviewed by CASAC for 10 years in multiple review cycles and is appropriate for continued use in this review.

Page 4-4. Lines 10-19: should add that prior studies may also be included in newer meta-analyses, or might be re-interpreted taking into account new evidence.

Page 4-4, lines 20-29: Missing here seems to be the role of exposure assessment methods not just in the context of epidemiologic studies but in the context of quantifying inter-individual variability in

personal exposures that might be compared with benchmark personal exposure concentrations or used in combination with exposure-response curves inferred form controlled human studies or personal-exposure-based epidemiologic studies. See also comments below.

The priority focus indicated on page 4-5, lines 10-22 is appropriate.

Page 4-5, **"Population, Exposure, Comparison, Outcome, and Study Design (PECOS)." This is a new term to the ISAs. While this seems like a well-founded concept, discussion of whether, how, and to what extent this would fundamentally change how inferences are made in the ISA would be helpful. It seems that each of these elements have already been considered in past ISAs. Is the intent here to add more structure to the identification and assessment of these components?**

Page 4-7, lines 19-20: This appears to the first place that the literature cutoff data for the current review is mentioned. What are the considerations that went into choosing this date? What if CASAC requests a second draft of the ISA? What if the 2020 deadline for this review is relaxed?

Page 4-8: Has SWIFT-AS been used for previous ISAs? Has it been validated in terms of accurately identifying relevant references compared to searches that did not use SWIFT-AS?

Table 4-1 – what about study design?

Page 4-23, line 34: should insert a discussion regarding consistency between multiple epidemiologic studies, before discussing coherence with other lines of evidence.

Page 4-24, line 3. Should add text regarding mode of action.

Page 4-25, line 10 – and to other health endpoints?

Page 4-25, line 16… and accounted for modifiers.

Page 4-26, lines 12-13: **while exposure methods in the context of interpreting epidemiologic results are important, this is not the only role for exposure methods. For example, an exposure simulation model such as APEX could be, and has been, used to assess personal exposures with respect to benchmark exposures or exposure-response relationships inferred from controlled human studies. Thus, the coverage of exposure assessment in the ISA should not be limited only to the context of interpreting epidemiologic studies**. For example, stochastic population-based modeling has had a role in prior REAs for ozone. **This point comes up later in the IRP**. **The data and methods for such modeling should be within the scope of the ISA. Or EPA should explain why it is not the scope of the ISA. Would the same March 2019 cut-off date for the ISA also apply to the REA?**

Page 4-32: last paragraph. **This paragraph presumes that CASAC will concur that the first draft of the ISA, with modifications if any recommended by CASAC, does not require further review by CASAC and will be adequate for its intended purpose. This may or may not be the actual outcome of the CASAC review of the first draft of the ISA. Since the NAAQS review process was revised after 2006 to include an ISA, there have not been fewer than two drafts of an ISA in any review**.

Page 5-2, lines 17-18: "while also bearing in mind practical and logistical considerations such as available resources and timeline for the review."

- This is a very important statement.

- **EPA should allocate adequate resources for this review**.
- The timeline for the review should be adequate. As noted elsewhere in these comments, the **EPA has imposed a deadline that leads to a curtailed schedule of only about one year for CASAC's role, which is far shorter than CASAC reviews in any other review cycle for ozone or any other pollutant in the last 10 years or more**.
- Whether a new REA is warranted should not be constrained by a self-imposed deadline. **Whether a new REA is warranted should be based on the science, consistent with the requirement under the CAA that the NAAQS review be "thorough" and based on the "latest scientific knowledge."**
- EPA must relax its deadline to allow for the following:
    - **CASAC may need to see second draft of the ISA**
    - **The science evidence base may have changed enough to warrant a new REA**
    - **The first draft of the REA should be available to CASAC and reviewed before EPA completes the first draft of the PA.**
    - **CASAC may need to see second drafts of the REA and PA**
    - **The REA is actually two documents: HREA and WREA.**
    - **CASAC needs adequate time to review all of this information**.

Page 5-2, lines 24-35: **"We are planning that the quantitative exposure and risk analyses newly developed in this review will be presented in the draft PA." This is appropriate only in the circumstance that no update to the HREA or WREA from the last review is warranted. In the event of substantive updates, the new HREA and/or WREA should be submitted as draft(s) for CASAC review PRIOR to providing CASAC with a draft PA. Otherwise, science and policy issues will be commingled, reducing transparency and distinction between science and policy issues.**

Figure 1 is very good and illustrates the key steps in the HREA. **This context for exposure modeling needs to be kept in mind in the ISA, since the ISA should establish the scientific basis for the entire review.** Thus, the ISA should review and evaluate exposure modeling and dosimetry modeling methods.

Page 5-16, lines 7-9: **"In this review, there are newly available ambient air quality data that better reflect concentrations at or near the current standard, updated emissions data and air quality models, and updates to the exposure model to better estimate exposure-based risk": this text implies a strong likelihood of substantial updates to the exposure assessment and dosimetry assessments in the health REA compared to the last review.**

With regard to epidemiologic-based risk approaches, improved air quality data might also be a sufficient basis for new analyses.

Page 5-18, lines 1-2: "we are preliminarily planning to focus new analyses in this review on exposure-based risk analyses." **This seems reasonable, as long as this is in the context of preparing a first draft of the REA that will be reviewed by CASAC before a first draft of the PA.** As noted above, the PA must

take account the findings of the REA, and that REA must therefore receive proper scientific vetting in the form of thorough CASAC review before preparation of the PA. CASAC often has substantial comments on exposure assessment and dosimetry modeling, and i**t is not reasonable to presume *a priori* that scientific questions regarding these modeling approaches, and their input data, will be fully resolved without iteration between EPA and CASAC**. **Given that EPA has already identified that there are expected to be significant changes in the exposure and dosimetry models, a stand-alone first draft REA is needed**.

In contrast, in other review cycles for which an REA was combined into the PA, such as for the most recent lead review, CASAC concurred, after reviewing the ISA, that a new REA was not warranted, and that the previous REA could be reinterpreted. A similar situation is clearly not presented with respect to ozone.

Page 5-18, lines 10-12: "Given the rapid timeline for this review, we would expect to focus on a streamlined set of study areas and air quality scenarios compared to the expansive set assessed in the last review." **CASAC should NOT agree to this time line**. As noted elsewhere in this comments, the **EPA has imposed adeadline that leads to a curtailed schedule of only about one year for CASAC's role, which is far shorter than the duration of CASAC reviews in any other review cycle for ozone or any other pollutant in the last 10 years or more. Whether a new REA is warranted should be based on the science, consistent with the requirement under the CAA that the NAAQS review be "thorough" and based on the "latest scientific knowledge." Neither EPA nor CASCAC should follow a "rapid" timeline that undermines the quality, credibility, and integrity of the science review process. Further, CASAC should not agree to a "streamlined" approach if that means inadequate coverage of key sources of variability that should be considered in the assessment.**

Page 5-28, line 12, with respect to the welfare REA, the IRP has text regarding the "expedited nature of this review". Similar to comments above, this is an artificial situation created by a deadline that does not allow adequate time for scientific review. See comments immediately above.

Page 5-28, lines 14 to 19: **based on this text, it seems likely that a new WREA is warranted. Such a WREA should be provided as a stand alone draft for CASAC review and advice prior to providing CASAC with a draft PA.**

Page 6-1, lines 21-23: "the PA will describe the underlying interpretations of the scientific evidence, risk/exposure information and any other quantitative analyses that might support such alternative policy options." **This text illustrates precisely why the HREA and WREA need to be reviewed by CASAC prior to review of the PA. Risk/exposure information is a precursor to and underlying foundation of the PA. The HREA and WREA involve scientific data and methods. Scientific components of the review should be completed separately from the more policy-focused deliberations by CASAC on the PA**.

Page 6-2, line 7: **should state that "sensitive groups" are conceptualized in the science review as "at-risk" groups. The draft ISA for particulate matter, and other prior ISA's, have text regarding at-risk groups that make clear that some are more at risk than others. This language should be incorporated in the IRP.**

Page 6-2, lines 25-27: **In characterizing the "past practice" of CASAC, EOPA should do so accurately. Past practice of CASAC in the last ozone review was three drafts of the ISA, two drafts of the HREA, and two drafts of the PA.**

Whether one draft of the PA is adequate is highly context and situation dependent. EPA should not prejudge that only one draft of the PA will be adequate, and should allow for the possibility that CASAC will need to see a second draft of the PA, as has been past practice. Here, again, EPA's deadline curtails the science review and the role of both the CASAC and the public in that review.

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

H. Christopher Frey, Ph.D.

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

5.1 Statutory Mandate for Scientific Review of the NAAQS

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

5.2 Recent History of the NAAQS Review Process

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

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

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

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

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

5.3 Brief Primer on CASAC

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

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

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

5.4 The Five Year Requirement

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

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

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

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

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

5.5 Wait, and Then Hurry Up!

The May 2018 memorandum states that the NAAQS review will be completed by October 2020 for ozone and by December 2020 for particulate matter.[1] Administrator Pruitt took office on February 17, 2017. EPA did not announce the start of the current ozone review until June 26, 2018. Although the current PM review has nominally been underway for more than two years, EPA did not release the first draft of the ISA until October 2018.[15] There are approximately two years from now to the deadlines indicated in the May 2018 memorandum. EPA has never completed a NAAQS review cycle in such a short time.

5.6 Can the Review Process be Shortened?

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

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

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

5.7 Combining Multiple Steps into One Step

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

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

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

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

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

5.8 Sudden Death: Eliminating the PM and Ozone Review Panels

On October 11, 2018, members of the CASAC PM Review Panel received an email from EPA stating that "your service on the panel has concluded." The PM Review Panel was appointed in 2015 and originally had 26 members. Also on October 11, 2018, candidates for the CASAC O_3 Review Panel were informed that "the Agency will not form a CASAC Ozone Panel." The ozone review panel for the review cycle completed in 2015 had 20 members. There was no prior consultation with members of the PM Review Panel, nor any public indication that elimination of the panels was being considered, nor any public process for providing input related to this issue.

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

5.9 Transforming CASAC from a Scientific to a Stakeholder Committee

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

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

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

The memorandum states that "no member of an EPA federal advisory committee currently receive EPA grants," but that this "principle should not apply to state, tribal, or local government agency recipients of EPA grants."[16] This is illogical for four reasons. One is the obvious inconsistency of implying that receiving a grant creates a conflict of interest for one but not another class of persons. The second is the longstanding recognition that receipt of a peer-reviewed scientific research grant, for which the Agency does not manage the work nor control the output, is not a conflict of interest. Per the Office of Management and Budget (OMB): "When an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects."[17] A 2013 report by the EPA Office of Inspector General reaffirmed that receipt of an EPA research grant is not a conflict of interest.[18] However, there can be situations in which a member of an advisory committee should recuse themselves from discussions that might pertain to their own work. Thus, third, the CASAC has had recusal policies in place for dealing with this issue and situations in which a member's work may come up for deliberation. Fourth, the memorandum does not acknowledge that persons with financial or professional ties to regulated industries have at the very least, the same appearance of conflict of interest.

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

5.10 CASAC Advice on Implementation of NAAQS

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

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

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

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

5.11 Lack of Transparency about Transparency

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

5.12 A Way Forward

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

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

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

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

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6.0 CASAC Should Recommend Formation of an Ozone Review Panel

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

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

6.1 October 10, 2018 Press Release

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

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

Furthermore, **the October 10, 2018 press release was announced without any prior public process for obtaining input from EPA staff, CASAC, or other stakeholders**. As such, **the decision announced in the October 10 press release, as confirmed the next day with an email to candidates for the ozone review panel, to not form an ozone review panel is arbitrary**. **The ill-founded nature of this decision is readily apparent from the long history of the use of augmented CASAC panels and from EPA's intent to form an Ozone Review Panel as indicated in a Federal Register notice of July 27, 2018**. **No reasonable explanation was offered regarding why the EPA chose not to form an Ozone Review Panel less than three months after announcing that such a panel would be formed**. Reportedly, EPA has claimed that it can legally ask the 7-member chartered CASAC to conduct the review. There is no question that the 7-

member chartered CASAC that must approve any report from CASAC to the EPA Administrator, which has been long established practice, but as the track record of at least three decades clearly indicates, CASAC benefits from and requires the input of additional scientific experts in formulating its advice to the Administrator. **The arbitrary decision of the Acting Administrator is detrimental to the quality of the scientific review process**.

6.2 July 2018 Call for Nominations for the Ozone Review Panel

On July 27, 2018, EPA announced in the Federal Register (Vol. 83, No. 145, pp. 35635-35636) that it would "form a CASAC ad hoc panel to provide advice through the chartered CASAC on the scientific and technical aspects of air quality criteria and the National Ambient Air Quality Standards (NAAQS) for ozone." The request for nominations stated that EPA "is seeking nominations for subject matter experts to serve on the CASAC Ozone Review Panel for the next review of the Ozone NAAQS that begins in fiscal year (FY) 2018. The Panel will be charged with reviewing the science and policy assessments, and related documents, that form the basis for the EPA's review of the Ozone NAAQS, and will provide advice through the Chartered CASAC."

The breadth of expertise needed for a review panel is illustrated by the July 27, 2018 request for nominations for an Ozone Review Panel: **"The SAB Staff Office is seeking nominations of nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone. Experts are sought in: Air quality, atmospheric science and chemistry, causal inference, dosimetry, toxicology, controlled clinical exposure, epidemiology, biostatistics, human exposure modeling, risk assessment/modeling, uncertainty analysis, ecology and effects on welfare and the environment, and environmental economics."** Beyond the breadth of scientific topics listed here, **it has also been common practice that each panel has more than one expert in a given scientific discipline, so as to achieve a balanced representation of the current state of science pertinent to a review.**

6.3 History of Augmented Review Panels

The previous four ozone review panels have been comprised of members of the chartered CASAC augmented with additional expert consultants. In the 1987 to 1992 review, 12 consultants augmented the 7 member chartered CASAC for a total of 19 members of the "Ozone Review Committee." In the 1995 to 1996 review period, six members of the chartered CASAC were augmented with 10 expert consultants to form a panel with 16 members. In the 2005 to 2008 review activity, the CASAC Ozone Review Panel included 7 members of the chartered CASAC and 18 additional expert consultants, for a total panel of 25 members. In the most recently completed 2010 to 2014 review cycle, the 7-member chartered CASAC was augmented with 13 additional experts for a total of 20 members of the Ozone Review Panel. Thus, the use of augmented ad hoc review panels for ozone dates back more than 30 years.

Table 1 summarizes data regarding ad hoc review panels for review of primary standards for all six criteria, based on review of the CASAC reports to the EPA administrator for each review cycle for each pollutant. For many of the earlier review cycles in the late 1970s and in the 1980s, the letter reports from CASAC do not list the members of the chartered CASAC or consultants who augmented CASAC. Thus, it was not possible to compile data for every CASAC review of a primary standard. However, data

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 review CASAC reports posted online.*

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

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

[a]*All of this information was obtained from www.epa.gov/casac by review CASAC reports posted online.*

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. CASAC Subcommittee on Health Effects of Particulate Matter and Sulfur Oxides included six consultants in addition to members of the chartered CASAC. The CASAC Subcommittee on Welfare Effects of Particulate Matter and Sulfur Oxides included five consultants in addition to members of the chartered CASAC. The consultants were different for these two review activities. Thus, there were 11 consultants who augmented the chartered CASAC for this review cycle. The dates on which these subcommittees met are not readily available, however.

Therefore, although there are not as many details available in the public record to quantify the membership or meeting dates of either subcommittees or augmented panels prior to 1987, there is evidence in the public record that **augmentation of CASAC with additional experts has been a routine practice for four decades**.

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

In the case of ozone, for which there are health effects data from multiple scientific disciplines, including epidemiology, toxicology, and controlled human studies, it has been common practice to have multiple experts in each of these disciplines to assure both breadth and depth of expertise. **The ozone review requires many other scientific disciplines as illustrated by the list given in the July 27, 2018 Federal Register request for nominations**.

The 7-member chartered CASAC does not have the breadth of deep expertise required for a review of the ozone NAAQS that meets the requirements of the Clean Air Act for a "thorough review" that "shall accurately reflect the latest scientific knowledge" of the "extent and kind of ... effects". The only credible way to provide a "thorough review" that "shall accurately reflect the latest scientific knowledge" is to engage scientists who are active at the leading edge of scientific work in disciplines and areas related to the subject matter of a review, as described in the July 27, 2018 Federal Register request for nominations, and as illustrated by the history of CASAC Review Panels summarized in Table 1.

The 7-member chartered CASAC is not required to agree with decisions of the EPA that adversely affect the quality of the scientific review process. The CASAC should recognize that it does not have adequate expertise to conduct the scientific review of the ozone without augmentation by "nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone," including multiple experts in key disciplines to assure rigorous depth. **The CASAC should recommend that an Ozone Review Panel be formed** that is augmented with additional experts and that provides both the breadth and depth of expertise required for a thorough review based on the latest scientific knowledge. **CASAC should similarly recommend that the recently disbanded CASAC PM Review Panel be reconvened**.

On November 7, 2018, a memorandum from Aaron Yeow to Thomas Brennan, titled "Determinations Associated with the Clean Air Scientific Advisory Committee (CASAC) Review of the Ozone National Ambient Air Quality Standards (NAAQS)," was issued. This memorandum attempts to justify that the 7-member chartered CASAC is an adequate body to conduct the review of the ozone NAAQS. The memorandum states that the 7-member chartered CASAC has "expertise in toxicology, engineering, medicine, ecology, and atmospheric science." **Compared to the July 27, 2018 call for nominations for the Ozone Review Panel, the 7-member chartered CASAC lacks expertise in the following key areas: dosimetry, epidemiology, biostatistics, human exposure modeling, and environmental economics. Thus, the 7-member chartered CASAC is an inadequate group for conducting an assessment of the ISA, and requires augmentation with additional experts representing missing scientific disciplines. Furthermore, it is not adequate in many cases to have only one member who has expertise in a particular discipline.** For example, it is very clear that review of ozone requires expertise related to toxicological studies, epidemiological studies, clinical human studies, dosimetry, air quality measurement, exposure assessment, foliar injury, climate impacts, and so on, for which relevant expert perspectives, knowledge, and experience are needed to ensure a credible review.

The July 27, 2018 call for nominations sought "nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone." Thus, the 7-member CASAC does not meet EPA's own stated requirements for a properly constituted panel qualified to review the ozone NAAQS.

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

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

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

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

Aaron,

Can you please forward this email to CASAC PM panel?

Appreciated.

****

Dear CASAC PM Review Panel members,

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

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

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

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

Thank you kindly,

Khanna

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

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

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

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

Aaron,

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

Appreciated.

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CASAC Ozone Panel Candidates,

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

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

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

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

Thank you kindly,

Khanna

****

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

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November 26, 2018

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

Dear Dr Cox:

As a former member of two CASAC Review panels (Ozone and Particulate Matter) and an author and reviewer of two Criteria Documents (the format that preceded the current Integrated Science Assessment; also on Ozone and PM), I would like to offer some personal perspective and professional judgment regarding the current EPA plan to conduct the 5-year review of the NAAQS for Ozone. By way of introduction, I am a Plant Physiologist with considerable experience and expertise in effects of ozone and of PM on vegetation, particularly crops and weeds.

The intention of the Clean Air Act as amended is to provide a thorough scientific review of current literature on the impacts of Criteria Pollutants, including ozone, on health and welfare endpoints. Recent memoranda issued by the EPA Administrator (specifically on 31 October 2017 and 9 May 2018) seek to establish radically new procedures for this review. In light of my own experience with such reviews, I wish to advise you in the strongest terms that the proposed procedures cannot lead to a scientifically justifiable review of the latest scientific knowledge, as required by statute.

The current, unprecedented, intention of EPA to proceed with this review without an external Review Panel to advise the chartered CASAC, places an impossible burden on the 7-member CASAC. The available, relevant literature is simply too voluminous, and covers too many distinct fields and sub-fields of investigation, to be adequately reviewed by such a small group. This would be true given a much longer time frame than that currently envisioned by EPA.

The composition of the chartered CASAC has been radically altered without adequate public or agency input. What was once a group of preeminent subject matter experts from industry, agencies and academia, now has the appearance of a stakeholders group. Whereas the previous selection process could be justified on the basis of objective criteria, such as scientific publications or other demonstrable experience, the basis of the current appointments is not transparent, leading to questions of potential or apparent conflict of interest. The current exclusion from the possibility of membership in CASAC of academic researchers, but not of other researchers, who have received funding from EPA is without

justification. The lack of parallelism in allowing those with funding from regulated industries to serve is even less justifiable. Finally, the recent wholesale turnover of 5 out of 7 members of the CASAC leaves the CASAC without the institutional memory or experience to undertake the review in an efficient manner. These factors, singly and taken together, can only weaken the previous strong confidence among the scientific and regulated communities in the deliberations of CASAC.

The timeline that has been established for this Ozone review, with termination in 2020, is inadequate to the task. The Clean Air Act provides for a 5-year period for reevaluation of the NAAQS. Typically, much of this period is required to conduct the review (independent of delays by EPA in initiating the reviews, which have been addressed by the courts). Time-saving procedures such as the predetermination by EPA that a single draft of the Integrated Science Assessment will be sufficient, are without justification. The number of required drafts will depend on the complexity of the new science, the adequacy of its review in the first and subsequent drafts, and on the diligence of EPA in correcting errors and omissions identified by CASAC in each draft. Similarly, the intention to combine a Risk and Exposure Assessment with a Policy Assessment is illogical and cannot lead to an adequate document of either type. A determination not to prepare an updated REA, for health or welfare endpoints, cannot be reasonably made until the state of new science has been evaluated in the ISA. Risks and exposures must be determined objectively and scientifically before they can be interpreted in terms of feasible or desirable policy outcomes. The sequence of ISA followed by REA and only then by PA was specifically intended to separate science from policy. It is essential to maintain this separation in order to preserve the integrity of the CASAC review process, and to continue the general acceptance of legitimacy that has thus far been accorded to CASAC reviews.

CASAC must be free to evaluate both adverse and beneficial effects of current or revised NAAQS and of potential strategies to attain them, without bias or mandate to consider one without the other or one preferentially over the other. These considerations, both of beneficial and adverse effects, must, by statute, be kept separate from the scientific review of the literature and the CASAC recommendation of an appropriate NAAQS.

It is my recommendation to you and the current CASAC, that you formally advise the EPA Administrator that the proposed procedures for an abbreviated review of the new science during this ozone NAAQS review are not adequate. I suggest that you point out that the resulting review will not fulfill the requirements of the Clean Air Act with amendments, will not be considered legitimate by many elements of the scientific and regulated communities, and may ultimately result in the entire process being disallowed. The courts have previously held that advice to EPA from CASAC must be given serious consideration. If, in this case, EPA does not give such serious consideration to CASAC concerns, it may be necessary for CASAC to decline to participate in a flawed process.

Sincerely,

/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

Member, 2009-2014, Clean Air Scientific Advisory Committee for Ozone--NAAQS Review Panel, Integrated Science Assessment released February 2013

Member, 2007 to 2010, Clean Air Scientific Advisory Committee for Particulate Matter--NAAQS Review Panel, Integrated Science Assessment released December 2009

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

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November 26, 2018

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

Dear Dr. Cox:

As a former member of the CASAC Advisory Panel for the last revision of the ozone NAAQS, I am writing to express my concerns regarding the protocols and timelines of the upcoming review. My expertise is in the area of plant physiological ecology and the responses of native plants to ozone exposure.

The CASAC is tasked with providing expert advice to the EPA Administrator concerning developments in scientific research since the last 5-year review. This involves reviewing thousands of peer-reviewed papers covering a broad range of topics, from public health issues such as chronic respiratory problems, epidemiological studies of populations at risk, and cardio-vascular responses, to secondary welfare issues such as plant and ecosystem responses to ozone exposure. Elimination of the advisory panel to the CASAC puts an undue burden on the 7-members of the CASAC, who have neither the breadth nor depth to assimilate fully this vast literature.

The lack of transparency in the formation of CASAC is troubling, while the constitution of its members seems to accommodate a double standard: those who have accepted funding from industry can serve on the CASAC, whereas academic researchers who have funding from the EPA cannot. Eliminating the expert advice from this latter group diminishes the ability of CASAC to perform its job adequately and reduces trust by the public in the standard setting process.

The self-imposed timelines established for completing the new review process appear arbitrary and are too short. Combining the REA and PA processes results in a conflation of science and policy that compromises the review process and falls far short of the quality and thoroughness required by the Clean Air Act and its Amendments. Failure to allow for revisions of the ISA is without merit and may not allow for the level of scientific rigor that the public expects. In a cascade of failure, this would constrain development of appropriate risk assessments, which, in turn, would limit the ability of OAQPS to develop an acceptable PA. The procedures used in the last assessment, which allow adequate time for revisions, separate timelines for the REA and PA documents, and abundant opportunities for public comment,

worked well. Any potential benefit from changing the timelines and the review process, simply to accommodate an arbitrary goal of timeliness, will not outweigh the diminishment in the quality of the NAAQS review process by the EPA.

The scientific quality and credibility of the public health and secondary welfare goals are too valuable to risk for the mere sake of efficiency. Under the proposed rule changes, it is not clear that the CASAC will be able to provide advice to the current EPA Administrator of the appropriate quality that meets the requirements of the CAA calling for a thorough review of the latest scientific knowledge. As a result, it runs the risk of losing its integrity and the trust of the public with regard to protecting their health and that of the environment around them.

Sincerely,

/signed/

Dr. Howard S. Neufeld, Professor and
Chair, AppalAIR (Appalachian Atmospheric Interdisciplinary Research Group)

James S. Ultman
Professor Emeritus, Departments of Chemical Engineering and Biomedical Engineering
Pennsylvania State University
University Park, PA

CASAC Ozone Review Panel: Member 2005-2008, 2009-2015
CASAC Oxides of Nitrogen Review Panel: Member 2007-2009
CASAC Sulfur Oxides Review Panel: Member 2007-2009, 2013-2018

With expertise in the dose distribution of inhaled reactive gases into the respiratory track, I was appointed to five CASAC review panels (RP) over the past ten years. In addition to providing scientific input, I have been able to observe and contribute to the refinement of the various stages of the overall NAAQS review process (i.e. the Integrated Research Plan → Integrated Science Assessment → Risk & Exposure Assessment → Policy Assessment).

The October 10, 2018 decision by EPA Acting Administrator Andrew Wheeler not to form an RP for the current ozone NAAQS review is an effort to shorten this process. In that case, a complete scientific review of the ozone standard is the sole responsibility of the seven member chartered CASAC rather than the larger and more technically multifaceted RP in addition to the CASAC. I am convinced this attempted streamlining of the ozone review will result in a less thorough evaluation of the current scientific literature and therefore a less reliable health risk analysis underpinning the policy assessment.

This decision by the Acting Administrator overlooks the value added by an RP, not only because of its technical diversity, but also by the unique interactions between its members. Several areas of importance in the NAAQS review of ozone (as well as other air pollutants) have and continue to be strengthened by discussions among the RP members. How to account for background ozone concentrations, what groups of individuals constitute susceptible populations, and what criteria should be applied to conclude causal effects of ozone exposure are reoccurring themes during RP discussions. These deliberations provide a firm foundation for the final decisions of the chartered CASAC members.

Another concern I have is the change in direction suggested in the May 9 memorandum by then Administrator Scott Pruitt regarding a "Back to Basics Process for Reviewing National Ambient Air Quality Standards." This memo calls for streamlining the review process by combining documents, possibly creating an ISA-REA-PA hybrid in place of the serial review of the three documents as has been done in the past. What is not fully appreciated by this suggestion is that the conclusions reached in each document serve as the necessary input for the next document in the chain. The ISA establishes the health criteria for the review, the REA establishes the science for quantifying risk, and the PA applies the policy-relevant science from the ISA and REA in formulating policy recommendations for consideration by the Administrator. It is impractical to achieve a sound review by linking the three steps in one document.

I am troubled by several aspects of the IRP for the current review of the ozone standard. First, for the reasons give above, I am highly skeptical of the plan to combine the REA with the PA documents. The IRP also restricts the review of the ISA to a single draft only. In my experience from reviewing ozone, nitric oxide and sulfur oxide standards, a second draft of the ISA is almost always necessary. Given the complexity of the document and the limited timeframe that EPA staff often has to adequately address all aspects of a complete scientific assessment, restriction to a single draft of an ISA is not reasonable. Whether or not a second draft is needed should be determined by CASAC after reviewing the first draft.

Over these past 10 years I have seen valuable refinements in the organization of the ISA. This has resulted in a more-or-less standardized format consisting of initial chapters that summarize the aims of the scientific review, the history of previous reviews, and highlights of the current review analyses. This introductory material written for a less technical audience is followed by separate detailed chapters regarding each scientific element (e.g. atmospheric chemistry→exposure & dosimetry→animal & human experiments→statistical population studies). The current IRP proposes a less comprehensive ISA that includes only summaries in the main body of the text. The details of the scientific literature review and analyses would be relegated to appendices. Such an approach can obscure many important details and limitations considered in reaching final conclusions and recommendations.

I am in favor of streamlining the review process. However, compressing the content of the ISA, combining the REA with the PA document, and limiting refined drafts of the documents will degrade the soundness of the final recommendations of CASAC to the EPA Administrator. Similarly, I oppose the elimination of the RP whose deliberations are an important, time-tested complement to the deliberations of the chartered CASAC. In light of these observations, I make the following recommendations:

1) The IRP for the current ozone NAAQS review be modified to allow separate reviews of the ISA, REA and PA including the possibility of more than one draft when deemed necessary by CASAC. The final IRP should also allow for the creation of a RP panel to work in conjunction with the chartered CASAC.

2) EPA should form a working group of administrative and scientific staff to systematically identify the financial and procedural bottlenecks in the current review process for all pollutants, and how they can be overcome. Consideration should be given to the participation of EPA as well as CASAC in this process. The deliberations of this working group should be open and transparent as was the case for the 2006 process previously used by EPA to seek input and ideas on ways for streaming the NAAQS review process.