October 1, 2020

Submitted via regulations.gov

Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460
Attn: Docket No. EPA-HQ-OAR-2018-0279
FRL-10012-49-OAR

Re: *Comment on Proposed Action: Review of the Ozone National Ambient Air Quality Standards*, 85 Fed. Reg. 49830 (August 14, 2020)

Dear Administrator Wheeler:

This comment letter is submitted on behalf of a group of 40 legal scholars whose names appear below. We are affiliated with 33 universities in 18 states, and all have substantial professional experience in the areas of administrative and environmental law. We write to express our serious concerns with the role of EPA's Clean Air Scientific Advisory Committee (CASAC) in developing the above-referenced Proposed Action. In our view, recent changes to the science advisory committee's role and composition render the Proposed Action legally deficient, and will result in standard-setting that contravenes Congress's will. First, the current CASAC lacks the depth and breadth of expertise necessary to review proposed National Ambient Air Quality Standards as Congress intended, to ensure the application of the best and latest science to standard-setting. Second, CASAC, as currently constituted, fails to meet basic standards for the composition of federal expert panels. And finally, EPA has used a shortened process that commingles science and policy and cannot ensure that the science behind the standard is up-to-date and of the highest quality.

The current CASAC is unqualified to give scientific advice on primary and secondary National Ambient Air Quality Standards (NAAQS) for ozone. It thus is unqualified to aid EPA in promulgating NAAQS, and its work is unable to aid courts effectively in reviewing EPA's decisions. While the direct consequences of this lack of qualification are a failure of the scientific integrity of the NAAQS-setting process, there are also significant legal implications, because the operation of the current CASAC is at odds with the role Congress gave CASAC, contravenes

federal guidelines for peer review, and cannot ensure that EPA's standards meet the substantive statutory requirements. These failures mean that EPA's decision cannot meet even the deferential standard of arbitrary and capricious review, and that the agency has failed to ensure that the ozone ambient air quality standards will be set at the statutorily mandated levels: those levels requisite to protect public health and welfare, with an adequate margin of safety.

I. The Current CASAC Lacks the Necessary Depth and Breadth of Expertise to Discharge Its Statutory Duty to Review the Ozone NAAQS.

The Clean Air Act requires the appointment and operation of the CASAC as a key tool to ensure the integrity and accuracy of the NAAQS. Unfortunately, the current seven-member CASAC lacks sufficient scientific experience and expertise to provide the required scientifically adequate review of the ozone NAAQS.

The Clean Air Act charges CASAC to conduct science-based review of proposed standards. CASAC must "complete a review of the criteria published under section 7408 of this title and the national primary and secondary ambient air quality standards"; "recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards"; "advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards"; "describe the research efforts necessary to provide the required information"; "advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity"; and "advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards." 42 U.S.C. § 7409(d)(2). All but the last of these charges self-evidently require that the Committee's work be scientific in nature, and thus that CASAC be composed primarily of research scientists with relevant expertise. So important is the scientific role CASAC plays in standard-setting that Congress requires EPA to explain and justify any departure from CASAC's recommendations. 42 U.S.C. § 7607.

The current CASAC, however, is unqualified to play the role Congress intended. It is unqualified to review the draft Integrated Science Assessment (ISA) that forms the scientific basis for the "criteria" that, by statute, provide the factual support for the health-based levels at which the NAAQS are set. CASAC is also unqualified to review the draft Policy Assessment

(PA) that informs the judgment of the Administrator in setting science-based NAAQS that meet the legal standard. As a result, the committee is incapable of providing the necessary advice to ensure the NAAQS "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 [ozone] in the ambient air, in varying quantities," as the Clean Air Act requires.[1] The current committee is manifestly unable to perform the task in front of it successfully. Three reasons compel this conclusion.

First, the number of academic experts serving as current CASAC members is extraordinarily low compared to previous membership composition. In the past, CASAC was—following past practice, federal guidelines, and Congress's intent—heavy with academics who study air pollution and its effects. The CASAC in June 2014, for example, was composed of four academic researchers and three scientists at nonprofits, including one scientist at a nonprofit association of air quality agencies of Northeast states.[2] Even the CASAC in November 2017 consisted of four academic researchers, two state regulators (Colorado and Georgia), and an industry consultant.[3] The current CASAC, however, is made up of only two academic researchers, four state and county regulators (Georgia, Texas, Utah, and Jefferson County [Alabama]), and an industry consultant who chairs the committee. Cutting the number of academic researchers serving on the committee from four to only two severely impairs the integrity and quality of the scientific suggestions CASAC is able to offer to EPA for ozone NAAQS setting.

Second, the current CASAC has no experts on key scientific issues relevant to the health and welfare effects of ozone. According to Dr. H. Christopher Frey, Chair of CASAC from 2012 to 2015, the current CASAC "lacks expertise in epidemiology, exposure assessment, impacts on plants, and climate impacts. Furthermore, CASAC lack[s] diversity of expertise in key areas,

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[1] 42 U.S.C. § 7408(a)(2); *see* H. Christopher Frey, Public Comment on the CASAC Review of EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Ozone (External Review Draft – October 2019) 18 (Dec. 5, 2019), *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/9FB1491880D2E312852584C70060F33D/$File/Written+Statement+H+Christopher+Frey+CASAC+O3+Draft+PA+191205+Submitted.pdf.

[2] CASAC, CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards viii (June 26, 2014), *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/$File/EPA-CASAC-14-004+unsigned.pdf.

[3] Clean Air Scientific Advisory Committee (CASAC), States at the Table (last updated Nov. 8, 2017), https://www.csg.org/aapca/CASAC.aspx.

such as controlled human studies, for which there was only one expert."[4] The same view is shared by the current CASAC member Dr. Mark Frampton, who publicly wrote that "[f]or this ozone review, additional expertise is needed in epidemiology, toxicology, and human clinical studies, and that expertise should include active investigators in the field. While the chartered CASAC does include one physician, the review would have benefitted, especially with regard to some of the key issues in the PA, from input from additional physicians with expertise in the respiratory effects of ozone exposure and impacts on asthma."[5]

Third, compounding the fact that CASAC is lacking the appropriate depth and breadth of scientific expertise among its members, EPA has also limited the support CASAC may obtain from other independent experts. EPA abandoned the four-decade tradition of forming an Ozone Review Panel to assist CASAC in providing sound scientific advice on the ozone NAAQS. This panel has provided much deeper and broader expertise to every prior review of ozone NAAQS, and has always been recognized as a necessary component of developing adequate standards. Only after the CASAC publicly admitted its lack of scientific proficiency and urged EPA to reconvene the Ozone Review Panel did the EPA select 12 subject matter experts that CASAC members may consult with, but only through CASAC's chair, and only in writing.[6] Former review panels, by contrast, were able to thoroughly review each chapter of "EPA's analysis of the science on a pollutant and then report[] to CASAC," and "[m]embers of CASAC also consulted with panelists in oral deliberations, usually face to face."[7] Current CASAC members likewise agreed that compared to the current pool of consultants, "the traditional review process, allowing interactive discussion between the CASAC and a pollutant-specific review panel,

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[4] H. Christopher Frey, Public Comment on the Review of the Ozone National Ambient Air Quality Standards 2-3 (Aug. 31, 2020) [hereinafter Frey, Public Comment], *available at* https://www.environmentalprotectionnetwork.org/wp-content/uploads/2020/08/Frey-Oral-Statement-to-EPA-Ozone-NAAQS-200831-Submitted.pdf; *see also* H. Christopher ("Chris") Frey @H_C_Frey (July 13, 2020, 11:50 AM) ("CASAC ha[s] no experts in epidemiology, and lack[s] breadth and diversity of experience and perspectives in toxicology, controlled human studies, risk assessment, etc. Plus, there were no experts on the effects of ozone on climate change, nor diversity on flora effects."), https://twitter.com/H_C_Frey/status/1282749293896577027.

[5] CASAC, CASAC Review of the EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019) A-13 (Feb. 19, 2020), *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/4713D217BC07103485258515006359BA/$File/EPA-CASAC-20-003.pdf.

[6] *Administrator Wheeler Announces New CASAC Member, Pool of NAAQS Subject Matter Experts*, EPA (Sept. 13, 2019), https://www.epa.gov/newsreleases/administrator-wheeler-announces-new-casac-member-pool-naaqs-subject-matter-experts.

[7] Cheryl Hogue, *US EPA's science advisers split on tightening air pollution limit*, Chemical & Eng'g News (Nov. 10, 2019), https://cen.acs.org/environment/pollution/US-EPAs-science-advisers-split/97/i44.

enables significantly more discussion and deliberation among experts with differing backgrounds and opinions, potentially resulting in a more comprehensive examination of some controversial topics."[8]

The low number of academic experts serving on the committee, the lack of experience and expertise in key scientific fields essential to understanding the state of the science regarding public health and welfare effects of ozone at varying concentrations, and the failure of EPA to appoint an Ozone Review Panel to assist CASAC's review of the ISA and the PA have rendered the current CASAC unqualified to advise EPA on setting ozone NAAQS that protect health and welfare at a level that meets the relevant scientific and legal standards.

II. The Current CASAC Fails to Meet Basic Standards for the Composition of Federal Expert Panels, and Has Already Been Held By a Federal Court to Have Been Appointed Based on Criteria Contrary to Law.

The current CASAC composition contravenes best practices developed for use across all federal agencies. It fails to meet basic, longstanding guidelines for federal agency peer review. This failure is another factor rendering the standard-setting process scientifically and legally unsound.

EPA's Peer Review Handbook identifies CASAC's role as "provid[ing] independent advice to the EPA Administrator on the technical bases for the EPA's national ambient air quality standards program, including peer review of Integrated Science Assessments, Risk and Exposure Assessments, and Policy Assessments for criteria air pollutants." As a Scientific FAC [Federal Advisory Committee], CASAC is

> required to be balanced in terms of scientific points of view for the charge to be addressed. For example, the SAB Staff Office considers a balanced list of peer reviewers to be one characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation) and the collective breadth of experience to adequately address the charge to the peer reviewers.[9]

[8] CASAC, *supra* note 5, at 1.
[9] EPA, U.S. EPA Peer Review Handbook 4th Edition 72 (Oct. 2015), *available at* https://www.epa.gov/sites/production/files/2015-10/documents/epa_peer_review_handbook_4th_edition_october_2015.pdf.

The 2004 OMB Peer Review Bulletin that followed Congress's enactment of the Information Quality Act also provides relevant guidance, reflecting best practices for federal agencies. While the OMB Peer Review Bulletin does not, by its terms, apply directly to CASAC's work, that bulletin notes that "[a]n existing peer review mechanism mandated by law should be implemented by the agency in a manner as consistent as possible with the practices and procedures outlined in this Bulletin."[10] Those existing peer review mechanisms include "a formal scientific advisory committee established by the agency" such as CASAC.

The OMB Bulletin's analysis is instructive. It notes that the "most important factor in selecting reviewers is expertise: ensuring that the selected reviewer has the knowledge, experience, and skills necessary to perform the review" and instructs that "[a]gencies shall ensure that, in cases where the document being reviewed spans a variety of scientific disciplines or areas of technical expertise, reviewers who represent the necessary spectrum of knowledge are chosen."[11] The Bulletin also indicates the need for balance, and emphasizes that this "balance"—consistent with National Academy of Sciences policy—"refers not to balancing of stakeholder or political interests but rather to a broad and diverse representation of respected perspectives and intellectual traditions within the scientific community."[12]

While CASAC was previously constituted consistent with the EPA Peer Review Handbook and the Peer Review Bulletin's requirements of expertise and balance, the current CASAC composition is in evident conflict with these guidelines and requirements.

First, the current CASAC lacks necessary expertise. As documented above, the current CASAC composition contravenes the mandate for "the inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation) and the collective breadth of experience to adequately address the charge to the peer reviewers."[13] It fails to include the necessary range of expert researchers with expertise in the relevant areas of toxicology, epidemiology, and other fields, and instead includes other types of stakeholders without the

[10] OMB, Final Information Quality Bulletin for Peer Review 34, *available at* https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf.
[11] *Id.* at 16.
[12] *Id.* at 24.
[13] EPA, *supra* note 9.

expertise to adequately meet CASAC's charge. The inclusion of only two academic researchers does not even come close to meeting the mandate for this committee's composition.

Second, the appointment criteria and the composition of the current CASAC have run afoul of the requirement that federal advisory committees and other peer review panels have "balance," or "a broad and diverse representation of scientific perspectives and traditions instead of balancing of stakeholder or political interests."[14] The current CASAC lacks experience and expertise key to the ozone review. The committee includes only two academic researchers, in addition to four regulators from conservative states (Georgia, Texas, Utah, and Jefferson County [Alabama]) "appointed primarily based on geographic location and government affiliation, rather than scientific expertise"[15] and an industry consultant. As a result, the committee fails to meet the standard of "balance."

Moreover, the current CASAC was appointed under an October 2017 Pruitt Directive that barred nongovernmental recipients of EPA scientific research grants to serve on the committee. The Directive has been vacated by a federal court for being arbitrary and capricious. *See Nat. Res. Def. Council, Inc. v. EPA*, 438 F. Supp. 3d 220, 224, 231 (S.D.N.Y. 2020). EPA created the Directive to replace all seven members of CASAC in one year (October 2017 – October 2018), prohibiting leading research scientists who were recipients of EPA scientific grants to join the committee.[16] This alone compels the conclusion that the CASAC's composition does not meet the requirement of "balance," and moreover calls into question the integrity and lawfulness of any decisions that rely on CASAC review for input into decisionmaking.

Meeting neither the "expertise" nor the "balance" requirements for peer review panels, and with its members having been found by a federal court to have been appointed under an unlawful directive to eliminate most qualified scientists from consideration, the composition of the current CASAC fails to satisfy the basic standards for a federal expert panel.

[14] OMB, *supra* 10, at 24.
[15] Frey, Public Comment, *supra* note 4, at 3.
[16] *See id.*

III. The Shortened Process and the Commingling of Science and Policy Render the Review, and the Proposed Action Setting NAAQS for Ozone, Unsound.

EPA started this ozone NAAQS review in June 2018 (Federal Register call for information) and structured the whole review process to finish in late 2020 or early 2021 (final rulemaking), lasting around two and a half years.[17] CASAC and the public were scheduled to do just one round of review on the draft ISA and PA before the release of the final documents. In contrast, previous ozone reviews took around seven to eight years: the last ozone review ran from September 2008 (Federal Register call for information) to October 2015 (final rulemaking), and the one before that was conducted between September 2000 (Federal Register call for information) and March 2008 (final rulemaking), both containing two rounds of review on draft ISAs, PAs, and Risk and Exposure Assessments (REAs). [18] The seven-to-eight-year review periods in the past failed to meet the Clean Air Act requirement of "five-year intervals" for NAAQS reviews, delaying the standards. *See* 42 U.S.C. § 7409(d). But a two-and-a-half year cycle is manifestly inadequate. The lengthy timelines of previous ozone reviews illustrate that fully using the five-year review cycle is necessary because of the need for serial assessments and reviews that separately consider scientific and policy considerations, and the need to review and revise based on expert feedback. The delayed start and accelerated timeline of the current review led to inadequate review time, harming the quality of EPA's scientific review process.

In addition to a compressed review schedule, EPA removed key steps in the review process to a degree that inappropriately commingled science and policy. Most significantly, EPA both skipped the separate REA drafting and review process, and also required CASAC to review the Integrated Science Assessment and the Policy Assessment simultaneously.

First, EPA failed to conduct a separate REA and instead "incorporate[d] the REA-related analyses into the PA, combining what had been two documents into a single document for review by the CASAC and the public."[19] The REA is ordinarily a key science-based evidentiary assessment evaluating the science behind the standards. The PA, by contrast, is a policy-oriented

[17] EPA, Integrated Review Plan for the Review of the Ozone National Ambient Air Quality Standards 1-9 (Aug. 2019), *available at* https://www.epa.gov/sites/production/files/2019-08/documents/o3-irp-aug27-2019_final.pdf.
[18] *See Ozone (O3) Air Quality Standards: Documents from Previous Reviews*, EPA, https://www.epa.gov/naaqs/ozone-o3-air-quality-standards.
[19] EPA, *supra* note 17.

document. As explained by the current EPA: "the role of the PA is to help 'bridge the gap' between the Agency's assessment of the current evidence and quantitative analyses (of air quality, exposure and risk), and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the NAAQS."[20] Combining the REA and the PA commingles scientific and policy considerations in one document, eliminating necessary CASAC review and public comment on the draft REA that forms the basis for scientific assessment. The failure to have CASAC review the REA before development of the PA forces CASAC and EPA to review the policy considerations based on unreviewed scientific analysis. Lack of opportunity for public comment on the scientific assessment in the REA also creates transparency concerns about the ozone review process, making it difficult for EPA to accept and consider input from other independent scientists at a time when that input would be most useful.

Second, EPA released the draft ISA (in September 2019) and draft PA (in October 2019) nearly concurrently, requiring CASAC to review them at the same time, while logically the ISA provides the scientific basis for the PA and must precede it. "A key principle of the 2006 revisions to the NAAQS review process, which were modified in part in 2007 and 2009, is that the scientific foundation of the review must be established before addressing policy issues."[21] CASAC recommended that EPA let it review a second draft of the PA after the release of the final ISA, but EPA did not adopt this recommendation. The decision to conduct PA and ISA review simultaneously "risks commingling policy issues prematurely before the science issues are adequately vetted and settled, which in turn creates the potential for policy choices to be made irrespective of the science."[22] As acknowledged by the current CASAC member Dr. Mark Frampton, "[b]y preparing the PA prior to CASAC's review of the ISA, EPA is short-circuiting the process, and in effect severely limiting CASAC's ability to advise EPA on the ozone NAAQS."[23]

The inappropriately accelerated review process and the lack of clear distinction between science and policy issues render CASAC unable to conduct considered and insightful review of

[20] Review of the Ozone National Ambient Air Quality Standards, 85 Fed. Reg. 49,830, 49,861 (proposed Aug. 14, 2020) (to be codified at 40 C.F.R. pt. 50), *available at* https://www.govinfo.gov/content/pkg/FR-2020-08-14/pdf/2020-15453.pdf.
[21] H. Christopher Frey, *supra* note 1, at 10.
[22] *Id.*
[23] CASAC, *supra* note 5.

key documents that affect EPA's decision. This shortcut process, in turn, cannot ensure the integrity and soundness of the current NAAQS ozone review, and means that the standard reflected in the Proposed Action may not "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare," as required by statute.

IV. EPA's Failures Render Its Standard Development Process Arbitrary, Capricious, and Contrary to Law.

The current CASAC's lack of expertise and balance, the lack of an ozone-specific advisory panel comprised of experts, and the truncated standard development process—detailed above and in Dr. Frey's comments—render EPA's standard development process legally deficient. EPA's decisionmaking process cannot and does not apply the latest and best scientific knowledge to set the health- and welfare-protective ambient air quality standards Congress requires.

In setting ambient air quality standards, as with all its actions, EPA "must examine the relevant data and articulate a satisfactory explanation for its action," and in reviewing that explanation, a court "must consider whether the decision was based on a consideration of the relevant factors and whether there was a clear error of judgment." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An agency's decision must be vacated as arbitrary, capricious, or contrary to law where it "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

Here, EPA's proposed decision is arbitrary, capricious, and contrary to law. EPA's decision to retain the Ozone NAAQS at 70 ppb is the product of a deeply flawed process, in which both the internal and independent scientific review processes have been shortcut, and the agency has not applied the necessary expertise to the task Congress has given it. By appointing a scientific review committee that is both unlawfully-constituted and lacking in the necessary expertise contemplated by Congress and the committee's charter, and by bypassing and rushing

crucial steps in the standard development process, EPA failed to conduct the necessary scientific review Congress intended, leading to an outcome that cannot be scientifically supported and fails to meet Congress's mandates for the agency's work.

The lack of integrity in the scientific basis for EPA's proposed decision is fatal to its standard-setting here. The "criteria" used to set the NAAQS are, by law, the product of deep scientific inquiry that applies cutting-edge science to answer the key statutory question of what ambient air quality standards are "requisite to protect the public health," allowing "an adequate margin of safety," and "requisite to protect the public welfare." 42 U.S.C. § 7409((b). Air quality criteria must "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." 42 U.S.C. § 7408 (a)(2). But as former CASAC Chair Dr. Christopher Frey has noted in separate comments, "[c]hanges in the NAAQS review process since 2017 have led to a situation in which standards will not reflect air quality criteria . . . since the CASAC and the process under which it is operating is incapable of properly assessing what that science is."[24]

The DC Circuit Court of Appeals, in *Mississippi v. EPA*, 744 F.3d 1334 (D.C. Cir. 2013), explained the role Congress gave to CASAC. The Court in *Mississippi* highlighted the Committee's role as an essential provider of independent scientific expertise in the standard-setting process:

> When Congress created CASAC, the promulgation of NAAQS was in its infancy. In describing the role it envisioned for CASAC, Congress emphasized the valuable role that advisory committees and expert groups had played in reviewing the first criteria documents and air quality standards issued in the late 1960s and early 1970s, explaining that "[f]or nearly 10 years the scientific basis for setting ambient air quality standards has been reviewed, evaluated, subjected to outside criticism, and reevaluated." H. Rep. No. 95-294, at 179-81, 1977 U.S.C.C.A.N. 1077, at 1258-60. CASAC was intended to replicate this role by "provid[ing] an independent source of review and advice to the Administrator and to the Congress." *Id.* at 182. Thus, Congress explained that it established CASAC "[b]ecause of the admitted need for greater research, the importance of the national ambient air quality standards, the continuing controversy over the standards, and the committee's desire for continued independent scientific review of the Environmental Protection Agency's exercise of judgment." *Id.* at 1346.

[24] H. Christopher Frey, *supra* note 1, at 6.

As the Court in *Mississippi* noted, CASAC's "central role" is thus "one of scientific analysis." *Id.* at 1354. Its "'main function' [is] to 'to assess the health and environmental effects of ambient air pollution.'" *Id.* (citation omitted). The Court, quoting the legislative history, noted that Congress's intent was that CASAC "provide an outside mechanism for evaluating whether any pollutant may reasonably be anticipated to endanger public health or environment, for evaluating the scientific and medical data which might bear on this question, and for reviewing gaps in the available data and recommending additional needs for research." *Id.* (internal citation and internal quotation marks omitted). And crucially, Congress expected that CASAC members would "be selected on the basis of their special expertise" in fields such as "environmental toxicology, epidemiology and/or clinical medicine." *Id.* (internal citation and internal quotation marks omitted). CASAC's Charter confirms that this continues to be CASAC's role, requiring members to be "persons who have demonstrated high levels of competence, knowledge, and expertise in scientific/technical field relevant to air pollution and air quality issues."[25]

Unfortunately, the current CASAC composition and EPA's approach to review fail to fulfill Congress's mandate for the Committee, fail to meet the requirements of CASAC's Charter, and fail to ensure that EPA's decision "accurately reflect[s] 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." *See* 42 U.S.C. § 7408 (a)(2). As detailed above, CASAC's composition violates core principles of federal peer review, making its input into the decisionmaking process incapable of ensuring that the agency has considered the latest and most accurate scientific knowledge. Deprived of the traditional interactive discussion and deliberation process with a review panel, CASAC cannot ensure that obtaining written responses from the 12 external consultants adequately complements its expertise in key scientific fields relevant to ozone NAAQS setting. And that deficiency is exacerbated by a process that fails to ensure that the scientific basis for the standard is well-founded because it does not leave sufficient time for review and consideration of expert input. Finally, the scientific inquiry into health- and welfare-protective standards—a health-based approach to standard-setting that has been affirmed by the Supreme Court in *Whitman v.*

[25] EPA, EPA Clean Air Scientific Advisory Committee (CASAC) Charter, *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/currentcharter.

American Trucking Associations, 531 U.S. 457 (2001)—has not been kept separate from the agency's policy considerations, further tainting the outcome of the agency's process.

Ultimately, the process has failed to meet even the deferential standard of arbitrary and capricious review, and, most importantly, has failed to ensure that the ozone ambient air quality standards will be set at the statutorily mandated levels: levels requisite to protect public health and welfare, based on the latest scientific knowledge.

Congress charged EPA with setting ambient air quality standards that protect public health and welfare: much of the structure of air quality regulation under the Clean Air Act depends on proper implementation of Congress's command to set health- and welfare-based standards that reflect the state of the art of scientific knowledge. Congress directed EPA to use the highest-quality scientific information to inform the agency's setting of the NAAQS, and the role of CASAC is central to that process. The Proposed Action disregards Congress's text and intent because the process failed to incorporate scientific principles and processes that ensured the use of the best science. We therefore urge EPA to withdraw the Proposed Action and reconvene a proper CASAC and review panels, with a properly phased process of evaluating scientific and policy considerations, to set the NAAQS for ozone.

Sincerely,[26]

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