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House of Representatives

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March 19, 2014

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator McCarthy:

The Committee on Science, Space, and Technology has longstanding concerns with the Environmental Protection Agency's (EPA) scientific advisory processes. In particular, there has been a troubling lack of independence and transparency within EPA's Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel. In establishing CASAC, Congress gave clear direction that this committee is intended "to have complete independence."[1] The CASAC Ozone Review Panel appears to violate agency policies designed to ensure balance, independence, and impartiality. Additional transparency is necessary to assure Congress and the American people that EPA is basing its costly regulatory decisions on the best available science and not a predetermined regulatory agenda.

In a hearing before the Committee last November, you stated that CASAC "provides independent advice to the EPA Administrator on the science that supports the EPA's National Ambient Air Quality Standards."[2] However, recent testimony and the current makeup of the panel reveal a number of problems, including: panelists reviewing their own work; a lack of turnover among CASAC Ozone Review Panel members; and, existing financial relationships between panelists and the Agency. Dr. Robert Phalen, Professor of Medicine and Co-Director of the Air Pollution Health Effects Laboratory at University of California, Irvine, and a former member of the CASAC panel on fine particulate matter, stated in testimony that the "current [CASAC] process… is seriously flawed, it is narrowly focused, and it is even ethically questionable."[3] Due to the substantial economic cost associated with finalizing a more stringent ozone standard, EPA should make every effort to ensure the transparency of the regulatory process.

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[1] H.R. Rep. No. 95-294 at 182-83 (1977).
[2] Committee on Science, Space, and Technology, "Strengthening Transparent and Accountability within the Environmental Protection Agency," Testimony of EPA Administrator Gina McCarthy, 113th Cong., 1st sess., 14 November, 2013, https://science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-113-SY-WState-GMccarthy-20131114.pdf.
[3] Committee on Science, Space, and Technology, "Quality Science for Quality Air," 112th Cong., 1st sess., 4 October 2011, http://www.gpo.gov/fdsys/pkg/CHRG-112hhrg70587/html/CHRG-112hhrg70587.htm.

Lowering the ozone National Ambient Air Quality Standards (NAAQS) to the range being discussed by CASAC could represent the most expensive regulation in history, with EPA's own cost estimates approaching nearly $100 billion per year. An ozone NAAQS below the existing standards may place large swaths of the United States in non-attainment with the Clean Air Act and result in severe economic sanctions. Moreover, testimony before this Committee indicates that standards in the range EPA is considering are below naturally-occurring background levels in many parts of the country.[4] Setting standards at these levels could therefore limit growth and impose penalties on communities whose means of compliance is beyond their control.

This Committee is not alone in its concerns about the independence and transparency of the CASAC process, and this Ozone Review panel in particular. As noted below, independent scientists who have been involved with CASAC have testified to our Committee with serious concerns.

Recusals and Reviewing One's Own Work

EPA's *Peer Review Handbook* states that "An independent peer reviewer is an expert who was not associated with the generation of the specific work product either directly… or indirectly…."[5]

Within the NAAQS process, EPA's CASAC Ozone Review panelists are asked to review three documents generated by EPA: the Integrated Science Assessment;[6] the Health and Welfare Risk and Exposure Assessments;[7] and the Policy Assessment.[8] Among the current CASAC Ozone Review panel, **16 of the 20 panel members** are cited by EPA in the current versions of these key documents. Indeed, the Agency cites the work of these panel members **more than 700 times** in these regulatory science documents they are being asked to critically assess.

This does not appear to be an isolated incident, as Dr. Roger McClellan, a former Chair of CASAC, testified, "The [CASAC] membership has been excessively dominated by scientists that to a large extent have developed the scientific information contained in the documents."[9] In addition, a 2013 review of CASAC's processes by the EPA Inspector General (IG) found multiple instances where recusals for concerns related to independence were not documented.

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[4] Committee on Science, Space, and Technology, "Background Check: Achievability of New Ozone Standards," 113th Cong., 1st sess., 12 June 2013, https://science.house.gov/hearing/subcommittee-environment-background-check-achievability-new-ozone-standards.

[5] U. S. Environmental Protection Agency, *Peer Review Handbook*, 3rd Edition, Peer Review Advisory Group, Science Policy Council, http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf.

[6] U. S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, *Integrated Science Assessment for Ozone and Related Photochemical Oxidants*, 2013. EPA 600/R-10/076F, http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=511347.

[7] U. S. Environmental Protection Agency, National Ambient Air Quality Standards, Ozone Standards, Documents from Current Review, Risk and Exposure Assessments, http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_2008_rea.html.

[8] U. S. Environmental Protection Agency, National Ambient Air Quality Standards, Ozone Standards, Documents from Current Review, Policy Assessments, http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_2008_pa.html.

[9] Committee on Science, Space, and Technology, "Quality Science for Quality Air," 112th Cong., 1st sess., 4 October 2011, http://www.gpo.gov/fdsys/pkg/CHRG-112hhrg70587/html/CHRG-112hhrg70587.htm.

The IG also found those recusals often came after the fact, lacked detail or their resolution was not adequately documented.[10] Independent reviewers should not be reviewing their work and the Agency needs to guarantee panelists recuse themselves for Agency documents that rely upon or cite their work.[11]

Lack of Turnover and Financial Relationships with EPA

EPA's *Peer Review Handbook* states "that the agency [should] rotate membership among qualified scientists in order to obtain fresh perspectives and reinforce the reality and perception of independence from the agency."[12] Despite this requirement, half of the current CASAC Ozone Review Panel members (10 out of 20) also served on the Agency's panel for the reconsideration of the 2008 Ozone NAAQS and five of these members served on both the reconsideration panel and the CASAC Ozone Review Panel for the 2008 NAAQS. Moreover, these panels were highly critical of the Administrator's decision concerning the 2008 ozone standard, suggesting bias in the current panel makeup.

EPA's *Peer Review Handbook* also states that Federal grants or contracts may constitute a direct financial stake, and thus a conflict or lack of impartiality in a specific review for potential peer reviewers. And in 2013, EPA's Inspector General found that "[a] prospective or active member's research or grant is a potential area of concern if the [Federal Advisory Committee], panel, or subcommittee plans to address work performed under the research grant."[13] Yet, since 2000, **70 percent or 14 of the 20 members** of the CASAC Ozone Review Panel have been principal or co-investigators for EPA grants totaling more than $120 million.[14] Many of these grants focus on ozone- and air pollution-related issues at the heart of these advisory activities.

The lack of turnover in a panel whose composition includes members with a direct financial relationship with the Agency related to the very issues under review suggests a critical lack of impartiality. As Dr. Michael Honeycutt, Director of Toxicology at the Texas Commission on Environmental Quality, stated before the Committee, "Having study authors, grant recipients, and panelists who have taken public stands on relevant topics who are handpicked by the Administrator gives the perception that the CASAC may not be truly independent."[15]

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[10] U. S. Environmental Protection Agency, Office of Inspector General, 2013. *EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees*, Report no. 13-P-0387, http://www.epa.gov/oig/reports/2013/20130911-13-P-0387.pdf.

[11] Dr. Honeycutt testified that: "It is not appropriate for scientists to peer review their own work; it presents a clear conflict of interest. When a panel reviews a document in which a member's work is cited, that member should recuse himself from review of the document." Available from: http://www.gpo.gov/fdsys/pkg/CHRG-112hhrg70587/html/CHRG-112hhrg70587.htm.

[12] U. S. Environmental Protection Agency, *Peer Review Handbook*, 3rd Edition, Peer Review Advisory Group, Science Policy Council, http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf.

[13] U. S. Environmental Protection Agency, Office of Inspector General, 2013. *EPA Can Better Document Resolution of Ethics and Partiality Concerns in Managing Clean Air Federal Advisory Committees*, Report no. 13-P-0387, http://www.epa.gov/oig/reports/2013/20130911-13-P-0387.pdf.

[14] These totals only include grants from the National Center for Environmental Research. Grant information available at: http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/search.welcome.

[15] Committee on Science, Space, and Technology, "Improving EPA's Scientific Advisory Process," 113th Cong., 1st sess., 20 March 2013, http://www.gpo.gov/fdsys/pkg/CHRG-113hhrg80553/pdf/CHRG-113hhrg80553.pdf.

Need for Transparency

In testimony before the Committee last year, Dr. Roger McClellan stated that "[v]ery little of the CASAC panel work is done in public view. Most of the discussion takes place off-line and is only manifest in the written draft comments of the CASAC Panel Members in response to EPA staff written questions."[16] In light of these serious concerns, it is unacceptable for EPA to move forward with new rules without first addressing potential conflicts of interest and a lack of transparency within a panel intended to provide the Agency with independent scientific assessments.

Please provide all communications between EPA staff, CASAC staff, and the CASAC Ozone Review Panel related to potential revisions to the ozone NAAQS. This should include all e-mail correspondence and meeting records since the start of the panel formation process in 2008. Please provide these communications to the Committee by March 25, 2014.

Your staff has indicated that the upcoming CASAC Ozone Review Panel meeting to be held March 25-27, 2014 will be webcast live on the Agency's website. Please ensure that an archived version of this webcast will be available online to the public following the meeting.

Sincerely,

Lamar Smith

Lamar Smith
Chairman
Committee on Science, Space, and Technology

[16] Committee on Science, Space, and Technology, "Improving EPA's Scientific Advisory Process," 113th Cong., 1st sess., 20 March 2013, http://www.gpo.gov/fdsys/pkg/CHRG-113hhrg80553/pdf/CHRG-113hhrg80553.pdf.