

**Public Comment on the  
Review of the Ozone National Ambient Air Quality Standards  
Docket ID No. EPA–HQ–OAR–2018–0279**

**ORAL COMMENT BY:**

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I am a past chair of the CASAC and chaired the CASAC Ozone Review Panel from 2012 to 2014.<sup>1,2,3,4,5,6</sup>

EPA Administrators Pruitt and Wheeler imposed changes to the National Ambient Air Quality Standards (NAAQS) scientific review process that were arbitrary, capricious, and harmful to its integrity, quality, and credibility. Members of the prior CASAC Ozone

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- <sup>1</sup> Frey, H.C., and J.M. Samet (2012), CASAC Review of the EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (Third External Review Draft – June 2012), EPA-CASAC-13-001, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Lisa P. Jackson, U.S. Environmental Protection Agency, Washington, DC, November 14, 2012.
  - <sup>2</sup> Frey, H.C., and J.M. Samet (2012), CASAC Review of the EPA's Health Risk and Exposure Assessment for Ozone (First External Review Draft - Updated August 2012) and Welfare Risk and Exposure Assessment for Ozone (First External Review Draft - Updated August 2012), EPA-CASAC-13-002, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Lisa P. Jackson, U.S. Environmental Protection Agency, Washington, DC, November 19, 2012.
  - <sup>3</sup> Frey, H.C., and J.M. Samet (2012), CASAC Review of the EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (First External Review Draft – August 2012), EPA-CASAC-13-003, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Lisa P. Jackson, U.S. Environmental Protection Agency, Washington, DC, November 26 2012
  - <sup>4</sup> Frey, H.C. (2014), CASAC Review of the EPA's Welfare Risk and Exposure Assessment for Ozone (Second External Review Draft), EPA-CASAC-14-003, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Gina McCarthy, U.S. Environmental Protection Agency, Washington, DC, June 18, 2014
  - <sup>5</sup> Frey, H.C. (2014), CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, EPA-CASAC-14-004, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Gina McCarthy, U.S. Environmental Protection Agency, Washington, DC, June 26, 2014
  - <sup>6</sup> Frey, H.C. (2014), CASAC Review of the EPA's Health Risk and Exposure Assessment for Ozone (Second External Review Draft – February, 2014), EPA-CASAC-14-005, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Gina McCarthy, U.S. Environmental Protection Agency, Washington, DC, July 1, 2014

Review Panel identified and evaluated these changes in detailed letters to CASAC.<sup>7,8</sup> I have submitted numerous individual comments to CASAC.<sup>9,10,11,12,13</sup>

1. The current CASAC lacks breadth, depth, and diversity of expertise, experience, and perspectives. For example, CASAC lacks expertise in epidemiology, exposure assessment, impacts on plants, and climate impacts. Furthermore,

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- <sup>7</sup> Frey, H.C., J.M. Samet, A.V. Diez Roux, G. Allen, E.L. Avol, J. Brain, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, S.R. Kleeberger, F.J. Miller, H.S. Neufeld, A.G. Russell, H.H. Suh, J.S. Ultman, P.B. Woodbury, and R. Wyzga, "CASAC Advice on the EPA's Integrated Review Plan for the Ozone National Ambient Air Quality Standards (External Review Draft)," 24 page letter with 42 pages of attachments, submitted to Chair, Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency and to Docket EPA-HQ-OAR-2018-0279, November 26, 2018. [https://yosemite.epa.gov/sab/sabproduct.nsf/0AC9E8672B0CA54985258351005BE54F/\\$File/Ozone+Letter+181126+Submitted-rev2.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0AC9E8672B0CA54985258351005BE54F/$File/Ozone+Letter+181126+Submitted-rev2.pdf)
  - <sup>8</sup> Frey, H.C., A.V. Diez Roux, G. Allen, E.L. Avol, J. Brain, D.P. Chock, D.A. Grantz, J.R. Harkema, D.J. Jacob, D.M. Kenski, S.R. Kleeberger, F.J. Miller, H.S. Neufeld, A.G. Russell, J.S. Ultman, K.C. Weathers, P.B. Woodbury, and R. Wyzga, Advice from the former U.S. EPA Clean Air Scientific Advisory Committee Ozone Review Panel on EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants (External Review Draft – September 2019), and EPA's Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards (External Review Draft – October 2019), Letter to EPA Administrator Andrew Wheeler from members of the former Clean Air Scientific Advisory Committee Ozone Review Panel (2009-2015), December 2, 2019. [https://yosemite.epa.gov/sab/sabproduct.nsf/B2AF0B23ABE6A60E852584C4007312E3/\\$File/EPA+CASAC+O3+Review+ISA+PA+Letter+191202+Final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/B2AF0B23ABE6A60E852584C4007312E3/$File/EPA+CASAC+O3+Review+ISA+PA+Letter+191202+Final.pdf)
  - <sup>9</sup> Frey, H.C., "Public Comment on the CASAC Review of EPA's Integrated Review Plan for Ozone (External Review Draft – October 2018)," Presented orally on November 29, 2018, Meeting of the EPA Clean Air Scientific Advisory Committee, via teleconference. [https://yosemite.epa.gov/sab/sabproduct.nsf/8E91D0CBD54482618525835B004D171F/\\$File/Frey+Oral+Statement+CASAC+O3+IRP+Telecon+181129.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/8E91D0CBD54482618525835B004D171F/$File/Frey+Oral+Statement+CASAC+O3+IRP+Telecon+181129.pdf)
  - <sup>10</sup> Frey, H.C., The NAAQS Review Process for Ozone Should be Suspended Until Process Deficiencies are Corrected, Oral and Written Statement to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, December 4, 2019. 3 pages. [https://yosemite.epa.gov/sab/sabproduct.nsf/CDA054276E31962E852584C6004E05EE/\\$File/Frey+Oral+Statement+O3+draft+ISA+191204+Submitted.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/CDA054276E31962E852584C6004E05EE/$File/Frey+Oral+Statement+O3+draft+ISA+191204+Submitted.pdf)
  - <sup>11</sup> Frey, H.C., Review of the Draft Policy Assessment for Ozone Must Be Properly Conditioned and Unbiased, Consistent with the Decision Context Set Forth by Congress, Oral and Written Statement to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, December 5, 2019, 3 pages. [https://yosemite.epa.gov/sab/sabproduct.nsf/17D91D5E81518DD5852584C700610395/\\$File/Frey+Oral+Statement+O3+draft+PA+191205.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/17D91D5E81518DD5852584C700610395/$File/Frey+Oral+Statement+O3+draft+PA+191205.pdf)
  - <sup>12</sup> Frey, H.C., The NAAQS Ozone Science Review Process is Broken and Not Credible: EPA Should Start Over, Written Statement to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, December 5, 2019, 37 pages. [https://yosemite.epa.gov/sab/sabproduct.nsf/9FB1491880D2E312852584C70060F33D/\\$File/Written+Statement+H+Christopher+Frey+CASAC+O3+Draft+PA+191205+Submitted.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/9FB1491880D2E312852584C70060F33D/$File/Written+Statement+H+Christopher+Frey+CASAC+O3+Draft+PA+191205+Submitted.pdf)
  - <sup>13</sup> Frey, H.C., CASAC Should Acknowledge that the Scientific Review of the Ozone National Ambient Air Quality Standards is Undermined by Ad Hoc Changes to the Review Process, Written Statement to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, February 10, 2020, 24 pages. [https://yosemite.epa.gov/sab/sabproduct.nsf/C5E9EBCEAD0C18998525850B0048DB96/\\$File/Frey+Written+Statement+to+CASAC+Ozone+ISA+and+PA+200210+Submitted.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/C5E9EBCEAD0C18998525850B0048DB96/$File/Frey+Written+Statement+to+CASAC+Ozone+ISA+and+PA+200210+Submitted.pdf)

CASAC lacked diversity of expertise in key areas, such as controlled human studies, for which there was only one expert.

2. CASAC included only two research scientists.
3. In a 2015 Wall Street Journal op ed, Dr. Cox, who chaired CASAC in this review, stated that it is “cynical” to “use” “asthma patients to promote a pro-regulation political agenda.”<sup>14</sup> Thus, Dr. Cox has the appearance of lack of impartiality.
4. CASAC members were appointed under a Pruitt policy that has been vacated by a Federal court. Leading research scientists, some of whom were recipients of EPA scientific grants, were kicked off in favor of persons with views friendly to the political goals of the current administration. All seven members of CASAC were replaced in one year. The new members were appointed primarily based on geographic location and government affiliation, rather than scientific expertise.
5. Several documents were redacted from the review process, including second drafts of science and policy assessments, and multiple risk and exposure assessment documents. This undermined the ability of the review to be thorough and accurate, and reduced opportunity for public comment.
6. There should have been closure on the Integrated Science Assessment before release of the first draft of the Policy Assessment
7. CASAC was deprived of an Ozone Review Panel. For four decades, CASAC was augmented with review panels averaging 15 additional experts. Mr. Wheeler issued a decision not to form an Ozone Review Panel three months after nominations were solicited for such a panel. He speciously claimed this was done to “streamline” the process. These panels worked with CASAC on the

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<sup>14</sup> Cox, Tony (2015), The EPA's Next Big Economic Chokehold, Wall Street Journal, September 2.

same schedule as CASAC, and did not slow the process. I know, because I've served on 10 such panels.<sup>15,16,17,18,19,20,21,22,23,24,25</sup>

8. The later formation of an Ad Hoc Pool of Consultants, several of whom are part of a small network of consultants for the same regulated industries, did not provide CASAC with the needed ozone expertise. The pool was not allowed to deliberate with CASAC. The pool was only allowed to answer written questions

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- <sup>15</sup> Frey, H.C. (2014), CASAC Review of the EPA's Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards, EPA-CASAC-14-004, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Gina McCarthy, U.S. Environmental Protection Agency, Washington, DC, June 26, 2014.
  - <sup>16</sup> Frey, H.C., and A. Diez-Roux (2014), CASAC Review of the EPA's Integrated Review Plan for the Primary National Ambient Air Quality Standard for Sulfur Dioxide (External Review Draft - March 2014), EPA-CASAC-14-006, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Gina McCarthy, U.S. Environmental Protection Agency, Washington, DC, July 24, 2014.
  - <sup>17</sup> Frey, H.C. (2014), CASAC Review of the EPA's Integrated Science Assessment for Oxides of Nitrogen – Health Criteria (First External Review Draft – November 2013), EPA-CASAC-14-002, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Gina McCarthy, U.S. Environmental Protection Agency, Washington, DC, June 10, 2014.
  - <sup>18</sup> Frey, H.C. (2013), CASAC Review of the EPA's Policy Assessment for the Review of the Lead National Ambient Air Quality Standards (External Review Draft – January 2013), EPA-CASAC-13-005, Letter Report from the Clean Air Scientific Advisory Committee to Acting Administrator Bob Perciasepe, U.S. Environmental Protection Agency, Washington, DC, June 4, 2013.
  - <sup>19</sup> Brain, J.D., and J.M. Samet (2010), Review of the Policy Assessment for the Review of the Carbon Monoxide National Ambient Air Quality Standards (NAAQS): External Review Draft, EPA-CASAC-10-013, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Lisa Jackson, U.S. Environmental Protection Agency, Washington, DC, June 8, 2010.
  - <sup>20</sup> Russell, A., and J.M. Samet (2011), CASAC Comments on the Policy Assessment for the Review of the Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Oxides of Sulfur (February 2011), EPA-CASAC-11-005, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Lisa Jackson, U.S. Environmental Protection Agency, Washington, DC, May 17, 2011.
  - <sup>21</sup> Samet, J.M. (2009), Comments and Recommendations Concerning EPA's Proposed Rule for the Revision of the National Ambient Air Quality Standards (NAAQS) for Nitrogen Dioxide, EPA-CASAC-09-014, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Lisa Jackson, U.S. Environmental Protection Agency, Washington, DC, September 9, 2009.
  - <sup>22</sup> Samet, J.M. (2011), Clean Air Scientific Advisory Committee (CASAC) Response to Charge Questions on the Reconsideration of the 2008 Ozone National Ambient Air Quality Standards, EPA-CASAC-11-004, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Lisa Jackson, U.S. Environmental Protection Agency, Washington, DC, March 30, 2011.
  - <sup>23</sup> Samet, J.M. (2010), CASAC Review of Policy Assessment for the Review of the PM NAAQS – Second External Review Draft (June 2010), EPA-CASAC-10-015, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Lisa Jackson, U.S. Environmental Protection Agency, Washington, DC, September 10, 2010.
  - <sup>24</sup> Diez Roux, A. (2016), CASAC Review of the EPA's Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – April 2016), EPA-CASAC-16-003, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Gina McCarthy, U.S. Environmental Protection Agency, Washington, DC, August 31, 2016.
  - <sup>25</sup> Samet, J.M. (2009), Clean Air Scientific Advisory Committee's (CASAC) Review of EPA's Risk and Exposure Assessment (REA) to Support the Review of the SO<sub>2</sub> Primary National Ambient Air Quality Standards: Second Draft, EPA-CASAC-09-007, Letter Report from the Clean Air Scientific Advisory Committee to Administrator Gina McCarthy, U.S. Environmental Protection Agency, Washington, DC, May 18, 2009.

from CASAC members, not the EPA charge questions. Responses were cherry-picked.

9. CASAC applied a risk-seeking requirement for burden of proof based on near scientific certainty. However, such a risk attitude is not consistent with the Clean Air Act.
10. These deficiencies are reflected in EPA's proposed rule.

Controlled human studies are typically the key foundation of the evidence-based approach of the Policy Assessment. Yet, such studies cannot be done on many at-risk subpopulations, e.g., severely asthmatic subjects, for ethical reasons. Thus, there is absence of direct evidence for many at-risk groups. This does not mean that CASAC may ignore such groups.

CASAC acknowledges in its consensus statements that asthma has important features beyond airflow limitation, key features of asthma pathophysiology can be affected by exposure to ozone, and the evidence- and risk-based approaches are based almost exclusively on healthy adults. Why, therefore, did CASAC conclude that the current primary standard is adequate, when the direct scientific evidence does not address at-risk populations?

CASAC failed to advise the Administrator that levels lower than the current standard would provide additional margin of safety, particularly for at-risk populations.

In the last review, there were multiple experts for effects on plants, but there were none in this review. The salient flora-related end points for the secondary standard are foliar injury, relative biomass loss, and crop yield loss. Furthermore, there were no CASAC experts regarding the effect of ozone on radiative forcing related to climate change. In 2019, the Court of Appeals remanded the secondary standard to EPA for further explanation. This CASAC lacks credibility to provide input on this matter.

The courts should not defer to this CASAC as a valid source of expert advice. EPA should start over with a credible review process and a properly constituted CASAC.