

**EPA ADVISORY COMMITTEES:  
HOW SCIENCE SHOULD INFORM DECISIONS**

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**JOINT HEARING**  
BEFORE THE  
SUBCOMMITTEE ON INVESTIGATIONS AND  
OVERSIGHT  
SUBCOMMITTEE ON ENVIRONMENT  
COMMITTEE ON SCIENCE, SPACE, AND  
TECHNOLOGY  
HOUSE OF REPRESENTATIVES  
ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

JULY 16, 2019

**Serial No. 116-38**

Printed for the use of the Committee on Science, Space, and Technology



Available via the World Wide Web: <http://science.house.gov>

U.S. GOVERNMENT PUBLISHING OFFICE

37-035PDF

WASHINGTON : 2019

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**EPA ADVISORY COMMITTEES:  
HOW SCIENCE SHOULD INFORM DECISIONS**

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**TUESDAY, JULY 16, 2019**

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,  
JOINT WITH THE SUBCOMMITTEE ON ENVIRONMENT,  
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,  
*Washington, D.C.*

The Subcommittees met, pursuant to notice, at 2:30 p.m., in room 2318 of the Rayburn House Office Building, Hon. Mikie Sherrill [Chairwoman of the Subcommittee on Investigations and Oversight] presiding.

**COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY  
SUBCOMMITTEE ON INVESTIGATIONS & OVERSIGHT  
SUBCOMMITTEE ON ENVIRONMENT  
U.S. HOUSE OF REPRESENTATIVES**

**HEARING CHARTER**

***EPA Advisory Committees: How Science Should Inform Decisions***

Tuesday, July 16, 2019  
2:00 p.m.  
2318 Rayburn House Office Building

**PURPOSE**

The purpose of this hearing is to discuss the current state of federal advisory committees at the EPA in light of the findings published in the July 2019 Government Accountability Office (GAO) report, *EPA's Advisory Committees: Improvements Needed for the Member Appointment Process*. The hearing will provide an opportunity to discuss how the appointment process for EPA's science advisory committees has changed in recent years. The Committee will also examine how three key boards at EPA – the Clean Air Scientific Advisory Committee, the Board of Scientific Counselors, and the Science Advisory Board – are utilized to ensure EPA decision making is grounded in the best available science.

**WITNESSES**

- **Mr. J. Alfredo Gomez**, Director, Natural Resources and Environment, U.S. Government Accountability Office
- **Dr. Thomas A. Burke**, PhD, MPH, Jacob I. and Irene B. Fabrikant Professor and Chair in Health Risk and Society, Bloomberg School of Public Health, Johns Hopkins University
- **Dr. Deborah Swackhamer (Swack-hammer)**, Professor Emerita, Humphrey School of Public Affairs, University of Minnesota
- **Dr. Jonathan Samet (Sah-met)**, MD, MS, Dean, Colorado School of Public Health

**OVERARCHING QUESTIONS**

- What is the role of federal advisory committees at EPA?
- How has EPA historically populated its scientific advisory committees, specifically the Clean Air Scientific Advisory Committee, the EPA Science Advisory Board, and the EPA Board of Scientific Counselors?
- What are the findings of GAO's report *EPA's Advisory Committees: Improvements Needed for Member Appointment Process*?

## **BACKGROUND**

### ***Federal Advisory Committees***

Federal Advisory Committees (FACs) play an important role across the federal government as an opportunity to receive advice and recommendations from non-federal experts on a wide array of topics. FACs can be established through statute, by presidential directive, or at the discretion of a federal agency. The Federal Advisory Committee Act (FACA) lays out a standard set of requirements and processes as well as mechanisms for formal oversight for all FACs. FACA requires all FAC meetings be open to the public, (unless excepted) and generally requires that all records from meetings be made publicly available.<sup>1</sup> Each agency is also required to have a Designated Federal Officer (DFO) for each FAC to help coordinate the committee activities. The General Services Administration's Committee Management Secretariat was established to ensure compliance of FACs with the FACA and handles all administrative issues related to FACs.<sup>2</sup>

On June 14, 2019 the President issued an Executive Order on *Evaluating and Improving the Utility of Federal Advisory Committees*,<sup>3</sup> which would require each agency to terminate at least one third of all non-statutorily required FACs and sets a government-wide maximum of 350 FAC committees to be met by September 1, 2019. Currently there are over 1,000 FACs across the federal government.<sup>4</sup>

### ***Federal Advisory Committees at the EPA***

EPA currently has 22 FACs that provide external expert advice and recommendations on a variety of topics ranging from chemicals,<sup>5</sup> to drinking water,<sup>6</sup> to children's health protection.<sup>7</sup> Three advisory committees that provide feedback on scientific decisions throughout the agency include the Clean Air Scientific Advisory Committee (CASAC), the EPA Science Advisory Board (SAB), and the EPA Board of Scientific Counselors (BOSC).

**Clean Air Scientific Advisory Committee** - The CASAC was established in the Clean Air Act Amendments of 1977 to provide advice to the Administrator on National Ambient Air Quality Standards (NAAQS) for the six criteria air pollutants, among other things.<sup>8</sup> The membership of the seven-member panel is set in statute to include one physician, one state air pollution control agency representative, and one member of the National Academy of Sciences. Historically, the seven-member panel has been supported by pollutant-specific subcommittees and panels to provide additional expert review for each criteria pollutant. The Chair of the CASAC also serves

<sup>1</sup> FACA; 5 U.S.C. Appendix—Federal Advisory Committee Act; as amended

<sup>2</sup> GSA, Committee Management Secretariat, accessed here: <https://www.gsa.gov/about-us/organization/office-of-governmentwide-policy/office-of-asset-and-transportation-management/committee-management-secretariat>

<sup>3</sup> Executive Order 13875, "Evaluating and Improving the Utility of Federal Advisory Committees," June 14, 2019, accessed here: <https://www.federalregister.gov/documents/2019/06/19/2019-13175/evaluating-and-improving-the-utility-of-federal-advisory-committees>

<sup>4</sup> GSA, "FACA 101," April 4, 2018, accessed here: <https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/finding-information-on-faca-committees/faca-101>

<sup>5</sup> U.S. EPA, Science Advisory Committee on Chemicals (SACC), accessed here: <https://www.epa.gov/tsca-peer-review>

<sup>6</sup> U.S. EPA, National Drinking Water Advisory Council (NDWAC), accessed here: <https://www.epa.gov/ndwac>

<sup>7</sup> U.S. EPA, Children's Health Protection Advisory Committee (CHPAC), accessed here: <https://www.epa.gov/children/chpac>

<sup>8</sup> The six criteria pollutants for which EPA sets NAAQS are: carbon monoxide, lead, ground-level ozone, nitrogen dioxide, particulate matter, and sulfur dioxide.

as a member of the chartered SAB.<sup>9</sup> The CASAC is managed out of the SAB Staff Office within the Office of the Administrator.<sup>10</sup>

**EPA Science Advisory Board** – the SAB was established in the 1978 Environmental Research, Development and Demonstration Authorization Act (ERDDAA) to provide scientific advice to the Administrator and designated Congressional Committees as requested. The SAB consists of its chartered board, standing and ad hoc committees, and panels and workgroups.<sup>11</sup> The chartered SAB is one of the largest FACs at the agency and is to be composed of about 45 members. The SAB provides independent advice to the Administrator on scientific and technical aspects of environmental issues. The SAB is managed out of the SAB Staff Office within the Office of the Administrator.

**EPA Board of Scientific Counselors** – the BOSC provides advice and feedback on all aspects (technical and management) of the research programs for EPA's Office of Research and Development (ORD) and coordinates with the SAB accordingly. ORD requested the establishment of the BOSC in 1996 under FACA to advise the Assistant Administrator for Research and Development.<sup>12</sup> Though not a part of the SAB, BOSC consults and coordinates with the SAB accordingly. Recommendations from the BOSC are made to the EPA Administrator through the Assistant Administrator for Research and Development. The BOSC is to be composed of approximately 20 members.<sup>13</sup>

#### ***Actions affecting FACs at EPA***

On October 31, 2017, former Administrator Scott Pruitt issued an agency memorandum that laid out new requirements for participation in EPA's advisory committees.<sup>14</sup> The new requirements included: barring recipients of EPA grants from participating on any EPA FAC; increasing participation of state, tribal, and local government officials on EPA FACs; enhancing geographic diversity amongst EPA FAC membership; and increasing rotation of FAC members to provide new perspectives.

Additionally, former Administrator Pruitt took the unusual step of dismissing members who were eligible to be renewed for a second consecutive term. This was despite EPA's previous commitment to members who were eligible that they could expect to have their membership renewed. This decision also went against years of precedent.<sup>15</sup>

<sup>9</sup> U.S. EPA, "Charter: Clean Air Scientific Advisory Committee," Date Filed with Congress: June 5, 2019, accessed here: [https://yosemite.epa.gov/sab/sabproduct.nsf/Web/CASAC/2019casaccharter/\\$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/Web/CASAC/2019casaccharter/$File/CASAC%202019%20Renewal%20Charter%203.21.19%20-%20final.pdf)

<sup>10</sup> U.S. EPA, "About the Science Advisory Board (SAB) and the SAB Staff Office," Accessed here:

<https://www.epa.gov/aboutepa/about-science-advisory-board-sab-and-sab-staff-office>

<sup>11</sup> U.S. EPA, "Charter: EPA Science Advisory Board," Date Filed with Congress: September 12, 2017, accessed here, [https://yosemite.epa.gov/sab/sabproduct.nsf/Web/2017SABcharter/\\$File/SABCharterSept2017.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/Web/2017SABcharter/$File/SABCharterSept2017.pdf)

<sup>12</sup> National Academies of Sciences, Engineering, and Medicine, "Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices," 2000, National Academies Press, accessed here: <https://www.nap.edu/read/9882/chapter/3#31>

<sup>13</sup> U.S. EPA, "Charter: EPA Board of Scientific Counselors," Date Filed with Congress, May 9, 2018, accessed here: [https://www.epa.gov/sites/production/files/2018-05/documents/epa\\_bosc\\_2018\\_renewal\\_charter\\_5-9-18.pdf](https://www.epa.gov/sites/production/files/2018-05/documents/epa_bosc_2018_renewal_charter_5-9-18.pdf)

<sup>14</sup> E. Scott Pruitt, "Strengthening and Improving Membership on EPA Federal Advisory Committees," U.S. EPA, October 31, 2017, accessed here: <https://www.epa.gov/faca/strengthening-and-improving-membership-epa-federal-advisory-committees>

<sup>15</sup> Eilperin, Juliet and Dennis, Brady, "EPA dismisses half of key board's scientific advisers; Interior suspends more than 200 advisory panels," The Washington Post, May 8, 2017, accessed here: <https://www.washingtonpost.com/news/energy->



In October 2018, then-Acting Administrator Andrew Wheeler disbanded the 20-person CASAC Particulate Matter Review Panel and never empaneled experts for a similar panel on ozone.<sup>16</sup> CASAC pollutant-specific panels are not required under the Clean Air Act but have historically provided specialized expert review for individual criteria pollutants.<sup>17</sup> In a letter to Administrator Wheeler in April 2019 following a review of the Integrated Science Assessment (ISA) for particulate matter (PM), the CASAC acknowledged that “[a]dditional expertise is needed for the Clean Air Scientific Advisory Committee (CASAC) to provide a thorough review of the particulate matter (PM) National Ambient Air Quality Standard documents” and that the “breadth and diversity of evidence to be considered exceeds the expertise of the statutory CASAC members... The CASAC recommend[ed] that the EPA reappoint the previous CASAC PM panel or appoint a panel with similar expertise.”<sup>18</sup> Administrator Wheeler has yet to respond to CASAC’s recommendation to reappoint a PM panel.

***Findings of July 2019 GAO Report on Appointment Process for EPA Advisory Committees***

In July 2019, the GAO finished work on report on the appointment process of advisory committees at the EPA.<sup>19</sup> GAO’s audit specifically looked at EPA’s process for appointing FAC members, how well EPA abided by that process, and whether or not any characteristics of the EPA FACs changed after January 2017. The full report will be made public on Monday, July 15. Upon its publication, the Committee will issue an addendum to this charter with the report’s findings and recommendations.

**Additional Reading**

Stuessy, Meghan M. *Federal Advisory Committees: An Introduction and Overview*. Congressional Research Service. October 27, 2016. <https://www.crs.gov/reports/pdf/R44253>

Stuessy, Meghan M. CRS Insight. June 27, 2019. Executive Order to Reduce the Number of Federal Advisory Committees. <https://www.crs.gov/Reports/IN11139?source=search&guid=ba8c15d7c2c44919a2d42bfc87b03c4f&index=3#>

U.S. Government Accountability Office, *EPA’s Science Advisory Board: Improved Procedures Needed to Process Congressional Requests for Scientific Advice*, GAO-15-500, June 2015. <https://www.gao.gov/products/GAO-15-500>

[environment/wp/2017/05/07/epa-dismisses-half-of-its-scientific-advisers-on-key-board-citing-clean-break-with-obama-administration/?utm\\_term=.b4e3a3ff4834](https://www.environment/wp/2017/05/07/epa-dismisses-half-of-its-scientific-advisers-on-key-board-citing-clean-break-with-obama-administration/?utm_term=.b4e3a3ff4834)

<sup>16</sup> Reilly, Sean, “EPA scraps science panel: ‘Your service... has concluded,’” E&E News, October 12, 2018, accessed here: <https://www.eenews.net/stories/1060102455>

<sup>17</sup> Friedman, Lisa, “E.P.A. to Disband a Key Scientific Review Panel on Air Pollution,” The New York Times, October 11, 2018, accessed here: <https://www.nytimes.com/2018/10/11/climate/epa-disbands-pollution-science-panel.html>

<sup>18</sup> Louis Anthony Cox et al, “CASAC Review of the EPA’s *Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)*,” U.S. EPA, April 11, 2019, accessed here: <https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBBBC3025E13B4852583D90047B352/%24File/EPA-CASAC-19-002+.pdf>

<sup>19</sup> U.S. Government Accountability Office, “EPA Advisory Committees: Improvements Needed for the Member Appointment Process,” July, 2019, GAO-19-280.

**COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY  
SUBCOMMITTEE ON INVESTIGATIONS & OVERSIGHT  
SUBCOMMITTEE ON ENVIRONMENT  
U.S. HOUSE OF REPRESENTATIVES**

**ADDENDUM TO THE HEARING CHARTER**

***EPA Advisory Committees: How Science Should Inform Decisions***

Tuesday, July 16, 2019  
2:00 p.m.  
2318 Rayburn House Office Building

In July 2019, the Government Accountability Office (GAO) finished work on its report on the appointment process of advisory committees at the Environmental Protection Agency (EPA). The Senate offices who requested this report, entitled “*EPA Advisory Committees: Improvements Needed for the Member Appointment Process*,” released it from embargo on July 15, 2019 at 1:30 p.m.<sup>1</sup>

**Summary of Report**

EPA’s established process to appoint members to FACs includes three main phases to ensure implementation of the Federal Advisory Committee Act: soliciting nominations, evaluating candidates, and obtaining approvals. GAO’s audit specifically looked at “(1) EPA’s process for appointing advisory committee members, (2) the extent to which EPA followed its process for selecting members from October 2016 through March 2018, and (3) how, if at all, selected characteristics of EPA advisory committees changed after January 2017.”

During the audit, GAO found that the agency followed its established internal appointment procedures for most of the 22 FACs at the EPA, except for the appointment of 20 members in fiscal year 2018 to the EPA Science Advisory Board (SAB) and CASAC. EPA staff responsible for FAC member appointments to these two committees did not prepare standard draft membership grids with staff rationales for member appointments, as called for by EPA’s internal process. All consultation with EPA management on member appointments occurred at in-person meetings, and GAO did not obtain any documentation regarding the rationale for choosing committee members.

GAO found that EPA did not consistently ensure that FAC members appointed as special government employees (SGEs) met federal ethics requirements, with 23% of the financial disclosure forms reviewed not bearing a signature from an ethics official confirming the SGE

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<sup>1</sup> “EPA Advisory Committees: Improvements Needed for the Member Appointment Process,” GAO-19-280, Government Accountability Office, July 2019, accessed here: <https://www.gao.gov/assets/710/700171.pdf>

was in compliance with ethics rules. The agency also did not conduct periodic reviews of its ethics program.

Additionally, GAO determined that there were notable changes to certain characteristics<sup>2</sup> of EPA FACs after January 2017 as compared to after January 2009. Both the SAB and BOSC saw a notable decrease in members affiliated with academic institutions after January 2017; a 27% decrease on SAB and 45% decrease on BOSC. There was also a notable change in membership turnover following January 2017, with 71% of BOSC members leaving, and 62% of the CASAC members leaving.

The GAO report provided two recommendations to EPA: first that the Administrator direct EPA staff responsible for FAC member appointments to develop and include draft membership grids in appointment packets that include staff rationale for appointments, as called for in EPA's internal process and; second, that the EPA's Designated Ethics Official should direct the agency's Ethics Office to include in its periodic review of EPA's ethics program, spot-checks of the quality of financial disclosure reviews for SGEs appointed to FACs.

EPA disagreed with the first finding of the report – that the Agency follow its appointment procedures by developing membership grids – and requested that it be removed from the report. EPA did not dispute the second recommendation – that the Agency evaluate its ethics review process – and noted that the Ethics Office was understaffed at the time of the audit. The Agency says it has resolved these staffing issues.

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<sup>2</sup> Characteristics reviewed by the GAO include committee composition, regional affiliation, membership turnover, and number of committee meetings.

Chairwoman SHERRILL. This hearing will come to order. Without objection, the Chair is authorized to declare recess at any time. Good afternoon, and welcome to today's joint hearing of the Investigations and Oversight and Environment Subcommittees. I'm pleased to be here with my colleagues, Ranking Member Norman, Chair Fletcher, and Ranking Member Marshall. We're here today to discuss the vital role that advisory committees play in ensuring the Environmental Protection Agency's (EPA's) actions are informed, and supported by the best available science.

Advisory committees have been, and continue to be, involved in issues of great importance to the advancement of knowledge, and the development of national policies and regulations. The EPA currently has 22 Federal advisory committees that provide advice to the EPA Administrator and other senior leaders on a variety of environmental and health issues. These committees consist of subject-matter experts who bring a range of skills and insight. The committee can include scientists, economists, health officials, and business leaders. Federal law, through the *Federal Advisory Committee Act*, or *FACA*, formalizes a process to ensure advice is solicited in an objective and transparent manner, and it requires each committee to be balanced in terms of the points of view and the functions to be performed. It's essential that these committees aid the EPA in fulfilling its mandate to protect human health and the environment.

Unfortunately, over the course of the last 2-1/2 years we've seen a multi-pronged attack on these committees. In 2017, former Administrator Pruitt barred EPA grant holders, some of the most prominent researchers in their fields, from serving on advisory committees. Administrator Pruitt claimed this was to prevent conflicts of interest, but he did not prohibit people who are paid by the industries that the EPA regulates, an arguably greater conflict of interest, from serving on advisory committees. Administrator Pruitt also broke precedent and declined to renew the memberships of advisory committee members whose terms had not expired, flushing out years of experience, and bringing in a number of climate deniers and unqualified individuals, which weakens the quality and integrity of the advice the advisory committee offers.

The attack on advisory committees at the EPA continued with the Administration's manipulations of the Clean Air Scientific Advisory Committee, or the CASAC. CASAC was established by Congress on a bipartisan basis as part of the 1977 amendments to the *Clean Air Act*. The architects of those amendments, Ed Muskie of Maine and Howard Baker of Tennessee, recognized a generation ago how important independent science advice would be to informing EPA's air quality programs. And, as I see it, healthy air to breathe remains a bipartisan concern for Congress. Unfortunately, last October Administrator Wheeler dismissed the Particulate Matter Review Panel of CASAC. This specialized 24-member panel was instituted under CASAC's authority to ensure that research on particulate matter, a known health hazard, was adequately reviewed before setting an updated health standard. Administrator Wheeler instead tasked the seven member CASAC with reviewing the science, even though it lacks an epidemiologist, among other vital specialties.

In April, CASAC wrote a letter to Administrator Wheeler stating that they are ill equipped to review the draft assessment of particulate matter (PM), and requesting that he reinstate the expert sub-panel. However, the Administrator still has not acknowledged this request, and on Monday the EPA informed committee staff that there still is not a plan in place to respond to CASAC's letter, let alone to re-establish the expert panel. It's concerning that EPA intends to develop health standards based on the advice of a committee that itself admits it's underqualified to review the relevant science.

This month the Government Accountability Office (GAO) issued a report outlining another mode of attack on advisory committees—the appointment process. GAO found that for two committees, the EPA Science Advisory Board and CASAC, EPA disregarded its own procedures for evaluating advisory committee candidates, and failed to assess nominees' financial disclosure reports. This undermines the transparency and integrity we expect from these important expert panels, and I look forward to hearing more about these findings from our GAO witness here today, Mr. Gomez.

The attack on science extends beyond the EPA. On June 14 the White House released an executive order requiring agencies to cut one-third of the FACA committees instituted under their purview. We know this won't save the government any money because it's an experiment that we have tried before. When a similar order was issued in the 1990s by President Clinton's Administration, it actually drove costs up by 3 percent. It appears that this order is an attempt to hinder agencies' ability to solicit objective, transparent, expert advice.

So, I'm pleased to welcome our witnesses appearing here today. Before us we have individuals with a wealth of experience on EPA's vital scientific advisory committees, and I look forward to hearing about how these committees inform EPA's important work, and we can ensure the Agency is best serving the American people. So thank you for your willingness to appear before our Subcommittee, and for this hearing.

[The prepared statement of Chairwoman Sherrill follows:]

Good morning, and welcome to today's joint hearing of the Investigations and Oversight and Environment Subcommittees. I'm pleased to be here with my colleagues, Ranking Member Norman, Chair Fletcher, and Ranking Member Marshall.

We're here today to discuss the vital role that advisory committees play in ensuring EPA's actions are informed and supported by the best available science. Advisory committees have been and continue to be involved in issues of great importance to the advancement of knowledge and the development of national policies and regulations. The EPA currently has 22 Federal advisory committees that provide advice to the EPA administrator and other senior leaders on a variety of environmental and health issues. These committees consist of subject matter experts who bring a range of skills and insight. The committee can include scientists, economists, health officials, and business leaders. Federal law, through the *Federal Advisory Committee Act*, or *FACA*, formalizes a process to ensure advice is solicited in an objective and transparent manner, and it requires each committee to be balanced in terms of the points of view and the functions to be performed. It is essential that these committees aid EPA in fulfilling its mandate to protect human health and the environment.

Unfortunately, over the course of the last two and a half years, we have seen a multi-pronged attack on these committees. In 2017, former Administrator Pruitt barred EPA grant holders - some of the most prominent researchers in their fields - from serving on advisory committees. Administrator Pruitt claimed this was to prevent conflicts of interest, but he did not prohibit people who are paid by the industries that EPA regulates - an arguably greater conflict of interest - from serving

on advisory committees. Administrator Pruitt also broke precedent and declined to renew the memberships of advisory committee members whose terms had not expired, flushing out years of experience and bringing in a number of climate deniers and unqualified individuals, which weakens the quality and integrity of the advice the advisory committee offers.

The attack on advisory committees at the EPA continued with the Administration's manipulations of the Clean Air Scientific Advisory Committee, or CASAC. CASAC was established by Congress on a bipartisan basis as part of the 1977 amendments to the Clean Air Act. The architects of those amendments - Ed Muskie of Maine and Howard Baker of Tennessee - recognized a generation ago how important independent science advice would be to informing EPA's air quality programs. And as I see it, healthy air to breathe remains a bipartisan concern for Congress.

Unfortunately, last October, Administrator Wheeler dismissed the Particulate Matter Review Panel of CASAC. This specialized 24-member panel was instituted under CASAC's authority to ensure that research on particulate matter - a known health hazard - was adequately reviewed before setting an updated health standard. Administrator Wheeler instead tasked the seven-member CASAC with reviewing the science, even though it lacks an epidemiologist, among other vital specialties.

In April, CASAC wrote a letter to Administrator Wheeler, stating that they are ill-equipped to review the draft assessment of particulate matter and requesting that he reinstate the expert subpanel. However, the Administrator still has not acknowledged this request. On Monday, EPA informed Committee staff that there still is not a plan in place to respond to CASAC's letter, let alone to reestablish the expert panel. It is concerning that EPA intends to develop health standards based on the advice of a committee that admits it is unqualified to review the relevant science.

This month, the Government Accountability Office issued a report outlining another mode of attack on advisory committees - the appointment process. GAO found that for two committees, the EPA Science Advisory Board and CASAC, EPA disregarded its own procedures for evaluating advisory committee candidates and failed to assess nominees' financial disclosure reports. This undermines the transparency and integrity we expect from these important expert panels. I look forward to hearing more about these findings from our GAO witness today, Mr. Gomez.

The attack on science extends beyond EPA. On June 14, the White House released an executive order requiring agencies to cut one third of the FACA committees instituted under their purview. We know this won't save the government any money, because this is an experiment we have tried before. When a similar order was issued in the nineties by President Clinton's administration, it actually drove costs up by 3 percent. It appears that this order is an attempt to hinder agencies' ability to solicit objective, transparent, expert advice.

I'm pleased to welcome our witnesses appearing here today. Before us we have individuals with a wealth of experience on EPA's vital scientific advisory committees. I look forward to hearing about how these committees inform EPA's important work, and we can ensure the Agency is best serving the American people. Thank you for your willingness to appear before our Subcommittees for this hearing.

Chairwoman SHERRILL. The Chair now recognizes Mr. Norman for an opening statement.

Mr. NORMAN. Thank you, Chairwoman Sherrill, and Chairwoman Fletcher, for convening this hearing. We're here today to discuss the current state of the Federal advisory committees, specifically at the EPA, and the appointment process for these committees. Unfortunately, this hearing is less of a discussion, rather than just another example of partisan politics, unfortunately. By limiting the scope of this hearing specifically to the EPA, the majority has prevented us from conducting oversight of other agencies within our jurisdiction.

But even the narrow focus of the EPA wasn't enough. While the Science Advisory Board, the SAB, the Board of Scientific Counselors, the BOSC, and the Clean Air Scientific Advisory Committees, the CASAC, are all represented here today, they seem to be the only ones that we'll be discussing. Along with EPA's other advisory committees, the SAB and the CASAC build scientific con-

sensus, and provide input and recommendations from the EPA's diverse stakeholders.

While our witnesses do valuable work for their panels, they only represent three of EPA's 22 committees. That means, in a hearing about EPA's advisory committees, 19 committees are unrepresented, as well as every other agency's Federal advisory committees. Why are we limiting this hearing, when so many more panels fall within the Science Committee's jurisdictions? My colleagues on the other side of the aisle seem to be using this opportunity as a thinly veiled cover to simply attack the EPA and this Administration's effort to improve the selection process.

Today we'll hear about how academics are supposedly being kicked off these committees, and the critical steps were overlooked in the appointment process. But, upon further examination of the data, including data produced by the GAO in their report, I believe this Committee needs to carefully examine the facts around these misleading assumptions. The purpose of the *Federal Advisory Committee Act, FACA*, is clear. Committees should be fairly balance in expertise and points of view. Yet, in 2017, 77 percent of SAB members represented academia. Having over three-fourths of a panel affiliated with one stakeholder group doesn't strike me as being balanced. It is clear to me that EPA's leadership followed the direction of the law as they worked to restore balance to this critical committee.

We will also discuss GAO's findings that 20 members of SAB and CASAC were appointed without EPA staff providing a membership grid with recommendations. While this step is detailed in EPA's internal policy guidelines, no law was broken, and no mismanagement occurred. Instead, senior officials at the EPA replaced this step with a more rigorous process, where the Administrator was thoroughly briefed on the qualification of multiple candidates. It is the Administrator's job to set guidance, and ensure the Agency can achieve its goals. We should be applauding him for taking the time to examine each candidate, and, in an effort to do better, the appointment process. I also want to commend the Science Advisory Board Staff Office, the SABSO, for their diligent work to ensure the best candidates are chosen to serve on the FACs. Sadly, these individuals are not present as we evaluate whether the new review process is effective.

The rushed nature of this hearing is disappointing, yet not surprising to me. Members of this Committee were given limited time to review the GAO's report, which was released 24 hours ago. I want to thank Mr. Gomez for being here to walk us through it, but I know we could've had a more productive discussion if we all had time to read it and understand it. I'm sure we'll have another hearing on President Trump's executive order on Federal advisory committees, so why we rushed to hold this narrow Subcommittee hearing is beyond me, when, in just a week or two, we would've had more knowledge, could involve more members, and have a broader debate. The only answer I came to is that the majority would've missed the chance to take another partisan swing at the Trump Administration. Moving forward, I hope we can take a more holistic approach, and allow Members the time to review the data before jumping to skewed conclusions.

Thank you, Madam Chair, and I yield back the balance of my time.

[The prepared statement of Mr. Norman follows:]

Thank you, Chairwoman Sherrill and Chairwoman Fletcher, for convening this hearing.

We are here today to discuss the current state of Federal advisory committees, specifically at the EPA, and the appointment process for these committees.

Unfortunately, this hearing is less of a discussion, rather just another example of partisan politics. By limiting the scope of this hearing “specifically” to the EPA, the majority has prevented us from conducting oversight of other agencies within our jurisdiction.

But even the narrow focus on the EPA wasn’t enough. While the Science Advisory Board (SAB), the Board of Scientific Counselors (BOSC), and the Clean Air Scientific Advisory Committee (CASAC) are all represented here today, they seem to be the only ones we’ll be discussing.

Along with EPA’s other advisory committees, the SAB and CASAC build scientific consensus and provide input and recommendations from EPA’s diverse stakeholders.

While our witnesses do valuable work for their panels, they only represent three of EPA’s 22 committees.

That means - in a hearing about EPA’s advisory committees - 19 committees are unrepresented, as well as every other agencies’ Federal Advisory Committees

Why are we limiting this hearing when so many more panels fall within the Science Committee’s jurisdiction? My colleagues on the other side of the aisle seem to be using this opportunity as a thinly veiled cover to simply attack the EPA and this Administration’s effort to improve the selection process.

Today, we’ll hear about how academics are supposedly being kicked off these committees and that critical steps were overlooked in the appointment process. But upon further examination of the data, including data provided by GAO in their report, I believe this Committee needs to carefully examine the facts around these misleading assumptions.

The purpose of the *Federal Advisory Committee Act (FACA)* is clear: committees should be fairly balanced in expertise and points of view. Yet, in 2017, 77% of S-A-B members represented academia.

Having over three-fourths of a panel affiliated with one stakeholder group doesn’t strike me as balanced. It is clear to me that EPA leadership followed the direction of the law as they worked to restore balance to this critical committee.

We’ll also discuss GAO’s finding that 20 members of SAB and CASAC were appointed without EPA staff providing a membership grid with recommendations. While this step is detailed in EPA’s internal policy guidelines, no law was broken and no mismanagement occurred.

Instead, senior officials at the EPA replaced this step with a more rigorous process, where the Administrator was thoroughly briefed on the qualifications of multiple candidates.

It is the Administrator’s job to set guidance and ensure the agency can achieve its goals. We should be applauding him for taking the time to examine each candidate in an effort to better the appointment process.

I also want to commend the Science Advisory Board Staff Office (SABSO), for their diligent work to ensure the best candidates are chosen to serve on FACs. Sadly, these individuals are not present as we evaluate whether the new review process is effective.

The rushed nature of this hearing is disappointing, yet not surprising, to me. Members of this Committee were given limited time to review GAO’s report, which was released just 24 hours ago.

I thank Mr. Gomez for being here to walk us through it, but I know we could have had a more productive discussion if we all had time to read it and understand it.

I’m sure we will have another hearing on President Trump’s Executive Order on Federal Advisory Committees.

So why we rushed to hold this narrow subcommittee hearing is beyond me, when in just a week or two, we would have more knowledge, could involve more members, and have a broader debate? The only answer I came to is that the majority would have missed the chance to take another partisan swing at this Administration.

Moving forward, I hope that we can take a more holistic approach and allow members the time to review the data before jumping to skewed conclusions.

Thank you, Madam Chair, and I yield back the balance of my time.



Chairwoman SHERRILL. Thank you. And the Chair now recognizes the Chair for the Subcommittee on the Environment, Mrs. Fletcher, for an opening statement.

Chairwoman FLETCHER. Good afternoon. I would like to join Chairwoman Sherrill in welcoming all of our witnesses to today's hearing on advisory committees at the EPA. The EPA is, at its core, a public health agency. It works to protect all Americans, especially the vulnerable populations from polluted air, water, and soil. The EPA promulgates environmental standards and protections that are informed by the most cutting-edge science. Much of this science is conducted at the Agency by dedicated career scientists and engineers, and through extramural research grants funded by the EPA. However, a critical component to ensuring the best science is utilized by the Agency is through expert advisory committees and boards that provide external advice and recommendations on a variety of topics.

Advisory committees have long played a vital role in the Federal Government to supplement the knowledge of Federal agencies by providing additional expertise. The advisory committee process is an opportunity for public engagement and Federal decisionmaking, as meetings are generally accessible to the public. As Chairwoman Sherrill discussed, Congress, understanding the need for independent scientific advice to inform the EPA Administrator's regulatory decisionmaking, established the Clean Air Scientific Advisory Committee, or CASAC, and the EPA Science Advisory Board, SAB. These committees allow EPA to broaden its access to additional scientific expertise not contained within the Agency itself.

Scientific advisory committees at the EPA provide advice and recommendations that are used to inform research, regulation standards, compliance, and enforcement functions of the Agency. The CASAC plays a critical role in reviewing the National Ambient Air Quality Standards, or NAAQS, by calling upon specialized expertise to ensure that the most robust and relevant science is used to protect the air that we breathe. The Science Advisory Board, by far the largest advisory committee at the EPA, provides feedback on science throughout the Agency's decisionmaking process, while the Board of Scientific Counselors, or BOSC, informs the EPA's science and research priorities.

Appointment to these and other advisory boards at the EPA has historically been considered a great honor, a recognition of the member's preeminence and expertise in the field. We are fortunate to have three such experts who have served as members and chairs of CASAC, SAB, and the BOSC as part of our distinguished witness panel today. My colleague expressed frustration that other committees are not present at this hearing, and I would like to note that the minority, as always, was given an opportunity to invite whomever they saw fit, and declined. Further, I believe this panel is more than qualified to address the matter at hand. Mr. Gomez has presented the facts on the grounds from his thorough audit of the Agency, and our three other witnesses bring years of experience of public service, both within and outside the Agency. I do anticipate that there will be future hearings on these issues, and encourage the minority to take all future opportunities to invite witnesses to these important hearings.

Given the clear role the advisory committees play in helping the EPA meet its mission, the finding of the GAO's report yesterday raises serious concerns, and identified problems with the three committees that are before us today. The deficiencies in the appointment process found for the SAB and CASAC are very troubling, as these committees are responsible for reviewing the science that underpins many Agency decisions that directly impact public health.

According to the *Federal Advisory Committee Act*, members of these boards should be clear of conflicts of interest, and meet the highest ethical standards before joining advisory committees. EPA's inconsistent compliance with its own ethics policy related to advisory committee members raises doubts about the Agency's actions. The American people should feel confident that all our agencies, including and especially the EPA, are operating in their best interest—protecting them, not sidelining transparency as a means to an end. The President's recent executive order, purportedly to improve Federal advisory committees, does not seem to have a basis for requiring the termination of one-third of Agency advisory committees, and instituting a limit of committees across the Federal Government. I want to commend Chairwoman Johnson for asking the agencies within this Committee's jurisdiction how they plan on implementing this order so we can try to ensure that valuable scientific expertise is not indiscriminately cut because of arbitrary limits.

The EPA is responsible for protecting public and environmental health through the application of strong science to environmental and regulatory decisions throughout the Agency. Baseless attempts to modify, change, and, in some cases, undermine the Agency's established process to accomplish this goal should be of concern to us all. I look forward to discussing the troubling findings of this GAO report, as well as hearing from our other distinguished witnesses, who have served on multiple advisory committees and the EPA, how these findings will impact the future of science at the Agency. With that, I yield back.

[The prepared statement of Chairwoman Fletcher follows:]

Good afternoon. I would like to join Chairwoman Sherrill in welcoming all of our witnesses to today's hearing on advisory committees at the EPA.

The EPA is at its core a public health agency. It works to protect all Americans, especially the most vulnerable populations, from polluted air, water, and soil. The EPA promulgates environmental standards and protections that are informed by the most cutting-edge science. Much of this science is conducted at the Agency by dedicated career scientists and engineers, and through extramural research grants funded by the EPA. However, a critical component to ensuring the best science is utilized by the Agency is through expert advisory committees and boards that provide external advice and recommendations on a variety of topics.

Advisory committees have long played a vital role in the Federal Government to supplement the knowledge of Federal agencies by providing additional expertise. The advisory committee process is an opportunity for public engagement in Federal decision-making, as meetings are generally accessible to the public. Congress, understanding the need for independent scientific advice to inform the EPA Administrator's regulatory decision making, established the Clean Air Scientific Advisory Committee, or CASAC, and the EPA Science Advisory Board, or SAB. These committees allow EPA to broaden its access to additional scientific expertise not contained within the Agency itself.

Scientific advisory committees at the EPA provide advice and recommendations that are used to inform research, regulations, standards, compliance, and enforcement functions of the Agency. The CASAC plays a critical role in reviewing the Na-

tional Ambient Air Quality Standards, or NAAQS by calling upon specialized expertise to ensure that the most robust and relevant science is used to protect the air we breathe. The Science Advisory Board, by far the largest advisory committee at the EPA, provides feedback on science throughout the Agency's decision-making process, while the Board of Scientific Counselors, or BOSC, informs the EPA's science and research priorities.

Appointment to these, and other, advisory boards at the EPA has historically been considered a great honor; a recognition of the member's preeminence and expertise in the field. We are very fortunate to have three such experts who have served as members and Chairs of the CASAC, SAB, and the BOSC, as part of our distinguished witness panel today.

Given the clear role advisory committees play in helping EPA meet its mission, the findings of the GAO's report released yesterday raise serious concerns. The deficiencies in the appointment process found for the SAB and CASAC are very troubling as these committees are responsible for reviewing the science that underpins many Agency decisions that directly impact public health. According to the Federal Advisory Committee Act, members of these boards should be clear of conflicts of interest and meet the highest ethical standards before joining advisory committees. EPA's inconsistent compliance with its own ethics policy related to advisory committee members raises doubts about the Agency's actions. The American people should feel confident that all our agencies, including and especially the EPA are operating in their best interest, protecting them - not sidelining transparency as a means to an end.

The President's recent Executive Order purportedly "improve" Federal advisory committees does not seem to have a basis for requiring the termination of one-third of Agency advisory committees and instituting a limit of committees across the Federal Government. I want to commend Chairwoman Johnson for asking the agencies within this Committee's jurisdiction how they plan on implementing this Order so that we can try to ensure that valuable scientific expertise is not indiscriminately cut because of arbitrary limits.

The EPA is responsible for protecting public and environmental health through the application of strong science to environmental and regulatory decisions throughout the Agency. Baseless attempts to modify, change, and in some cases undermine, the Agency's established processes to accomplish this goal should be of concern to us all.

I look forward to discussing the troubling findings of this GAO report, as well as hearing from our other distinguished witnesses who have served on multiple advisory committees at the EPA, how these findings will impact the future of science at the Agency.

And with that I yield back the balance of my time.

Chairwoman SHERRILL. Thank you. The Chair now recognizes the Ranking Member for the Subcommittee on Environment, Mr. Marshall, for an opening statement.

Mr. MARSHALL. Thank you so much, Chairwoman Sherrill, and Ranking Member Norman, for holding this hearing. First and foremost, I'd like to address what seems to be the elephant in the room, President Trump's executive order on Federal advisory committees. While not explicitly stated as part of the purpose of this hearing, I think we can all see the majority's intention is to make this hearing a chance for former EPA advisory members to defend the charter of their committee. As Mr. Norman mentioned, we all agree EPA's major advisory committees, these mandatory committees, especially the Science Advisory Board, and Clean Air Scientific Advisory Committee, play a strategic role in carrying out the mission to protect human health and the environment. No one's proposing we eliminate those mandatory panels, or the critical input they provide to the Agency.

But the President's executive order isn't focused on these, or any other committee authorized by Congress. It doesn't even direct agencies to keep or terminate any particular committee. It's focused on halting wasteful spending, and improving the quality of our advisory committees governmentwide. President Trump's exec-

utive orders direct each agency to review their advisory committees, eliminate one-third of their discretionary advisory committees, and caps the total number of discretionary committees at 350 across the Federal Government. From what I've seen in the media, people take this to mean President Trump is trying to eliminate hundreds of advisory committees because he doesn't value the science they provide. Nothing could be further from the truth. The executive order clearly states that one-third of discretionary advisory committees should be eliminated. Discretionary advisory committees are those committees created by an agency head at some point, not through law or executive order. Based on the text of the executive order, EPA would need to eliminate just two committees to comply.

Next let's address the impact of capping the total number of discretionary committees at 350. Currently there are over 1,000 Federal advisory committees. Again, let's look at those actual words in the executive order, which states that the cap applies only to discretionary committees. At present there are just over 400 discretionary committees. Eliminating 50 committees, especially as there has not been a systemic review in 26 years, does not seem like a daunting challenge to me. I think it's important to note that President Reagan issued a memorandum similarly to this in 1985, and President Clinton issued an executive order in 1993 requiring the exact same one-third elimination as President Trump. So, historically, ensuring we are maximizing the use of our Federal advisory committees has been a bipartisan effort. It's critical that we review advisory committees to ensure their alignment with the current needs and mission of this Agency. Think about how science can change in just a few years: 26 years ago the first smartphone was still a decade away from introduction, and now it seems that everyone is able to use one. This executive order will help Federal agencies re-evaluate their needs, and focus on the future of science, not the needs of the past.

The final issue to highlight is what appears to be a narrow and limiting scope of this hearing. The Science Committee has jurisdiction over \$42 billion in Federal research and development, including numerous agencies with Federal advisory committees. If my colleagues in the majority were genuine about examining how science informs decisions at Federal agencies, we'd be hearing from representatives from other agencies like NASA, Department of Energy, and the National Science Foundation. Each of these have their own advisory committees with unique needs and challenges. Narrowing the focus on this hearing to just EPA, which only has 2 percent of the Federal advisory committees, is puzzling. I'd also like to mention that the two EPA committees we will talk about the most today, SAB and CASAC, are authorized by statute, and therefore ineligible to be eliminated by the EPA Administrator under the executive order. I believe there is a need to conduct oversight of the 1,000 advisory committees currently in operation, as well as the \$400 million these committees cost the taxpayer each year. That's \$400,000 per committee, by my math.

I encourage my colleagues in the majority work with us to conduct meaningful oversight of these committees, and the best way to manage them efficiently and effectively. Instead, we find our-

selves here today, focused on the smallest fraction of our Committee's jurisdiction. Thank you, Madam Chair, and I yield back.

[The prepared statement of Mr. Marshall follows:]

Thank you for holding this hearing, Chairwoman Sherrill and Ranking Member Norman.

First and foremost, I'd like to address what seems to be the elephant in the room: President Trump's Executive Order on Federal Advisory Committees. While not explicitly stated as part of the purpose for this hearing, I think we can all see the majority's intention is to make this hearing a chance for former EPA advisory members to defend the charter of their committee.

As Mr. Norman mentioned, we all agree EPA's major advisory committees, especially the Science Advisory Board (SAB) and Clean Air Scientific Advisory Committee (CASAC), play a strategic role in carrying out the mission to protect human health and the environment.

No one is proposing we eliminate those panels or the critical input they provide to the Agency.

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President Trump's Executive Order directs each agency to review their advisory committees, eliminate one-third of their discretionary advisory committees, and caps the total number of discretionary committees at 350 across the Federal Government.

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Next let's address the impact of capping the total number of discretionary committees at 350. Currently, there are just over 1,000 Federal Advisory Committees. Again, let's look at the actual words in the Executive Order, which state that the cap applies only to discretionary committees. At present, there are just over 400 discretionary committees. Eliminating 50 committees - especially after there has not been a systematic review in 26 years - does not seem like a daunting challenge to me.

I think it's important to note that President Reagan issued a memorandum similar to this in 1985, and President Clinton issued an executive order in 1993 requiring the exact same one-third elimination as President Trump. So historically, ensuring we are maximizing the use of our Federal Advisory Committees has been a bipartisan effort.

It is critical that we review advisory committees to ensure their alignment with the current needs and mission of each agency. Think of how science can change in just a few years. Twenty-six years ago, the first smartphone was still a decade away from introduction - and now everyone seems to always be on one. This executive order will help Federal agencies reevaluate their needs and focus on the future of science, not the needs of the past.

The final issue I'd like to highlight is what appears to be a narrow and limiting scope of this hearing. The Science Committee has jurisdiction over \$42 billion in Federal research and development, including numerous agencies with Federal advisory committees.

If my colleagues in the majority were genuine about examining how science informs decisions at Federal agencies, we would be hearing from representatives from other agencies like NASA, the Department of Energy, and the National Science Foundation. Each of these has its own advisory committees with unique needs and challenges. Narrowing the focus of this hearing to just the EPA, which only has 2% of all Federal Advisory Committees, is puzzling to me.

I'd also like to mention that the two EPA committees we will talk about the most today, SAB and CASAC, are authorized by statute and therefore ineligible to be eliminated by the EPA Administrator under the Executive Order.

I believe there is a need to conduct oversight of the 1,000 advisory committees currently in operation, as well as the \$400 million these committees cost the taxpayer each year.

I encourage my colleagues in the majority to work with us to conduct meaningful oversight of these committees and the best way to manage them efficiently and ef-

fectively. Instead, we find ourselves here today, focused on the smallest fraction of our Committee's jurisdiction. Thank you, Madam Chair. I yield back.

Chairwoman SHERRILL. Thank you. And we are honored today to have the Full Committee Chairwoman, Ms. Johnson, with us today. The Chair now recognizes the Chairwoman for an opening statement.

Chairwoman JOHNSON. Thank you very much, and let me thank both Chairs, and both Ranking Members. I'd like to join you also in welcoming our witnesses this afternoon. In fact, we have a panel full of familiar faces today. Every member of our distinguished panel has offered their expertise to this Committee in the past, and I'm honored to welcome some of you back, and some of the most esteemed voices in environmental and health science in the Nation. Thanks to each of you for your tireless work, both in academia and on various EPA advisory committees. And thanks to you, Mr. Gomez of the GAO, for ensuring these important committees operate effectively.

Science advisory committees are crucial to ensuring the best science informs all aspects of decisionmaking at the Environmental Protection Agency. They provide the expertise that allows us to be sure we are protecting the health of Americans and our environment to the best of our ability. It has been troubling to observe these important committees being dismantled and manipulated over the past 2-1/2 years. The most recent blow to advisory committees was an executive order issued by the President in June. This order directed agencies to cut one-third of FACA committees not established by Congress or the President. It also caps the total number of FACA committees at 350 across the Federal Government. Such directives are clumsy at best, and malicious at worst. There's no reason to presume that one-third of the committees have exhausted their usefulness. A cap on committees serves only to create a barrier for agencies to solicit expert advice in a transparent manner.

Last week, I did send a letter to science agencies inquiring about the metrics they will use to determine which committees to cut. I look forward to reviewing these responses. I hope that the White House will reconsider this harmful order, which serves only to decrease the transparency of the advice solicited by agencies across the government. I would be remiss not to mention the circumstances under which Dr. Swackhamer joined us the last time she testified before this Committee. Just as today, Dr. Swackhamer testified in her capacity as an independent scientist back in 2017. However, days before the hearing, she was contacted by an EPA political official, who had somehow obtained a copy of her prepared remarks, and encouraged her to edit her testimony in a manner I consider to be misleading. I hope Dr. Swackhamer has not experienced similar interference in her preparation to join us here today.

Unfortunately, we have yet to receive a final report on this matter from the EPA Inspector General. I look forward to hearing from all of you. Transparency and the application of credible science is a cornerstone of environmental and public health protections. I look forward to working with my colleagues, and today's distinguished witnesses, to ensuring that EPA continues to value these prin-

ciples. Thank you, and I yield back to Congresswoman Sherrill. Thank you.

[The prepared statement of Chairwoman Johnson follows:]

Thank you to both our Chairs, and I would like to join you in welcoming our witnesses this afternoon. In fact, we have a panel full of familiar faces today - every member of our distinguished panel has offered their expertise to this Committee in the past, and I'm honored to welcome back some of the most esteemed voices in environmental and health science in the nation. Thank you to each of you for your tireless work both in academia and on various EPA advisory committees. And thank you to Mr. Gomez of the GAO for ensuring these important committees operate effectively.

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Thank you, and I yield back to Chairwoman Sherrill.

Chairwoman SHERRILL. Thank you. And if there are Members who wish to submit additional opening statements, your statements will be added to the record at this point. At this time I would like to introduce our witnesses.

Mr. Alfredo Gomez is the Director of Natural Resources and Environment at the U.S. Government Accountability Office. His office authored the recently released GAO report, "EPA Advisory Committees: Improvements Needed For the Member Appointment Process," which we will be discussing today.

Dr. Thomas Burke is a professor, and the Chair in Health Risk and Society at the Bloomberg School of Public Health at Johns Hopkins University. Prior to his current position, Dr. Burke served as the EPA Science Advisory and Deputy Assistant Administrator for Research and Development from January 2015 to January 2017. He also served on EPA's Science Advisory Board, and is a founding member of the Board of Scientific Counselors.

Next we have Dr. Deborah Swackhamer. Dr. Swackhamer is a Professor Emerita at the University of Minnesota's Humphrey School of Public Affairs. Previously, she served in a number of sci-

entific advisory positions, including Chair of the EPA Science Advisory Board from 2008 to 2012, and Chair of the Board of Science Counselors from 2015 to 2017.

And, last, we have Dr. Jonathan Samet, the Dean of the Colorado School of Public Health. Dr. Samet served as Chair of the EPA Clean Air Scientific Advisory Committee from 2008 to 2012. And we will start with Mr. Gomez.

**TESTIMONY OF J. ALFREDO GOMEZ,  
DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT,  
U.S. GOVERNMENT ACCOUNTABILITY OFFICE**

Mr. GOMEZ. Chairwomen Sherrill and Fletcher, Ranking Members Norman and Marshall, and Members of the Subcommittee, good afternoon. I'm pleased to be here. My statement today summarizes key findings from our report on the U.S. Environmental Protection Agency's process for appointing members to the Federal advisory committees it manages under the *Federal Advisory Committee Act*. These committees play an important role at EPA by providing advice that helps the Agency develop regulations, accredit laboratories, and manage research programs, among other activities. Our report describes EPA's established process for appointing members to serve on EPA advisory committees. It evaluates the extent to which EPA followed its process for Fiscal Year 2017 through March 2018, and describes how, if at all, EPA's advisory committees changed after January 2017. As it's been noted, at the time of our report EPA had 22 advisory committees, and the way we conducted our work, we reviewed relevant Federal laws, regulations, and guidance, and reviewed all EPA appointment documentation for 17 of the 22 committees that appointed members for Fiscal Years 2017 through March 2018.

With regards to the first finding, EPA has established—has an established process for appointing advisory committee members that involves three main phases: Soliciting nominations, evaluating candidates, and obtaining approvals from relevant EPA offices before the Administrator, or Deputy Administrator, makes final decisions. This process is laid out in the Agency's "Federal Advisory Committee Handbook." Each phase involves several steps. For example, a key step for evaluating candidates involves EPA preparing documents that reflect staff recommendations on the best qualified and most appropriate candidates for achieving balanced committee membership.

In evaluating the extent to which EPA followed its process, we found that EPA followed its process for all of the committees we reviewed, except for two: The EPA Science Advisory Board and the Clean Air Scientific Advisory Committee. EPA did not follow a key step for appointing 20 members to these two committees. We found that the appointment packets for these two committees did not contain documents to reflect staff recommendations on the best qualified and most appropriate candidates to serve on advisory committees, which is called for in the EPA's established process. Instead of developing these documents, EPA stated that they held a series of briefings with senior management. EPA management then decided whom to appoint after reviewing the entire list of personnel nominated for committee membership. EPA stated that this change



is within the discretion of the Administrator, and was a more robust process.

We agree that conducting such briefings is within the discretion of the Administrator. However, it remains that, for these two committees, EPA did not follow its established committee appointment process that I just described. If it had followed its established process, staff assessments of the best qualified candidates would have been documented in a transparent way in the appointment packets. In addition, EPA would have had better assurance that its committee appointment procedures were uniform, as encouraged by the *Federal Advisory Committee Act*.

Last, we looked at how the committees changed across the two most recent Presidential Administrations. We were only looking for notable changes, which we described as a 20 percentage point difference. We looked at four committee characteristics: Committee composition, regional affiliation, membership turnover, and number of committee meetings held. We found notable changes in all of the characteristics, except in the number of committee meetings held, for four of the advisory committees. For example, we found that the percentage of academics serving on EPA's Science Advisory Board decreased by 27 percent from January 2017 to March 2018.

In summary, we made two recommendations to EPA. One was that EPA follow its committee appointment process for all of its advisory committees. The second was for EPA to strengthen oversight of its ethics program. So, Chairwomen Sherrill and Fletcher, and Ranking Members Marshall and Norman, this completes my statement. I'd be happy to answer questions.

[The prepared statement of Mr. Gomez follows:]

United States Government Accountability Office



Testimony before the Subcommittees on Investigations and Oversight, and Environment, Committee on Science, Space, and Technology, House of Representatives

For Release on Delivery  
Expected at 2 p.m. ET  
Tuesday, July 16, 2019

## EPA ADVISORY COMMITTEES

### Improvements Needed for Member Appointment Process

Statement of J. Alfredo Gomez, Director,  
Natural Resources and Environment

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Chairwomen Sherrill and Fletcher, Ranking Members Norman and Marshall, and Members of the Subcommittees:

Thank you for the opportunity to discuss our report, publicly released yesterday,<sup>1</sup> on the U.S. Environmental Protection Agency's (EPA) process for appointing members to the federal advisory committees it manages under the Federal Advisory Committee Act (FACA).<sup>2</sup> These committees play an important role at EPA by providing advice that helps the agency develop regulations, accredit laboratories, and manage research programs, among other activities. As of March 31, 2018, EPA managed 22 such committees.

Questions have been raised about EPA's process for appointing members to its federal advisory committees following recent policy changes affecting who serves on these committees. In light of these questions, we were asked to review issues related to how EPA appoints advisory committee members. This statement summarizes key findings from our report, which (1) describes EPA's established process for appointing members to serve on EPA advisory committees; (2) evaluates the extent to which EPA followed its process from fiscal year 2017 through the first two quarters of fiscal year 2018; and (3) describes how, if at all, selected characteristics of EPA's advisory committees changed after January 2017.

To perform the work for the report, among other things, we reviewed relevant federal laws, regulations, and guidance; reviewed all EPA documentation used to support appointment decisions from the 17 committees that appointed or reappointed members from fiscal year 2017 through the first two quarters of fiscal year 2018; reviewed portions of financial disclosure forms for 74 individuals appointed or reappointed to committees during this period to determine if their forms were consistent with key federal requirements and guidance; and analyzed information from the U.S. General Services Administration's (GSA) FACA database,<sup>3</sup> which contains information about FACA committees that agencies,

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<sup>1</sup>GAO, *EPA Advisory Committees: Improvements Needed for the Member Appointment Process*, GAO-19-280, (Washington, D.C.: July 8, 2019).

<sup>2</sup>Pub. L. No. 92-463, 86 Stat. 770 (1972), codified, as amended at 5 U.S.C. app. 2.

<sup>3</sup>GSA has certain government-wide responsibilities for implementing FACA, including maintaining the government-wide FACA database that tracks certain characteristics of advisory committees.

including EPA, are required to provide annually.<sup>4</sup> We also interviewed agency officials involved with appointing committee members. Additional information on our scope and methodology can be found in the report. Our work was performed in accordance with generally accepted government auditing standards.

### EPA's Established Process for Appointing Members to Serve on Advisory Committees Includes Soliciting Nominations, Evaluating Candidates, and Obtaining Approvals

As we state in the report, according to our review of EPA's *Federal Advisory Committee Handbook*, EPA's established process for appointing advisory committee members involves three main phases: soliciting nominations, evaluating candidates, and obtaining approvals from relevant EPA offices before the Administrator or Deputy Administrator makes final appointment decisions.<sup>5</sup> EPA developed the *Federal Advisory Committee Handbook* to clarify roles and responsibilities for complying with relevant requirements. Under FACA, an agency establishing an advisory committee must, among other things, require the committee's membership to be balanced in terms of the points of view represented and the functions to be performed by the committee.<sup>6</sup> Also, one purpose of FACA is to ensure that uniform procedures govern the establishment and operation of advisory committees.<sup>7</sup>

Each of the three main phases in EPA's established process involves several interim steps. For example, a key step for evaluating candidates

<sup>4</sup>We analyzed information on four characteristics of committees before and after the two most recent changes in presidential administrations: committee composition (i.e., are a committee's members affiliated with academia, consulting, industry, government, a non-government organization, or other), regional affiliation (i.e., with which regions of the country are committee members affiliated), membership turnover (i.e., the percentage of committee members who no longer served on a committee), and the number of meetings committees held). In following our approach for identifying notable changes, each change identified as notable had at least a 20 percentage point difference in the change to the characteristic after January 2017 compared to after January 2009. We did not test for statistically significant differences for reasons including the small committee sizes.

<sup>5</sup>U.S. Environmental Protection Agency, *Federal Advisory Committee Handbook*, (Washington, D.C.: August 2017). EPA issued an earlier version of the handbook in March 2012.

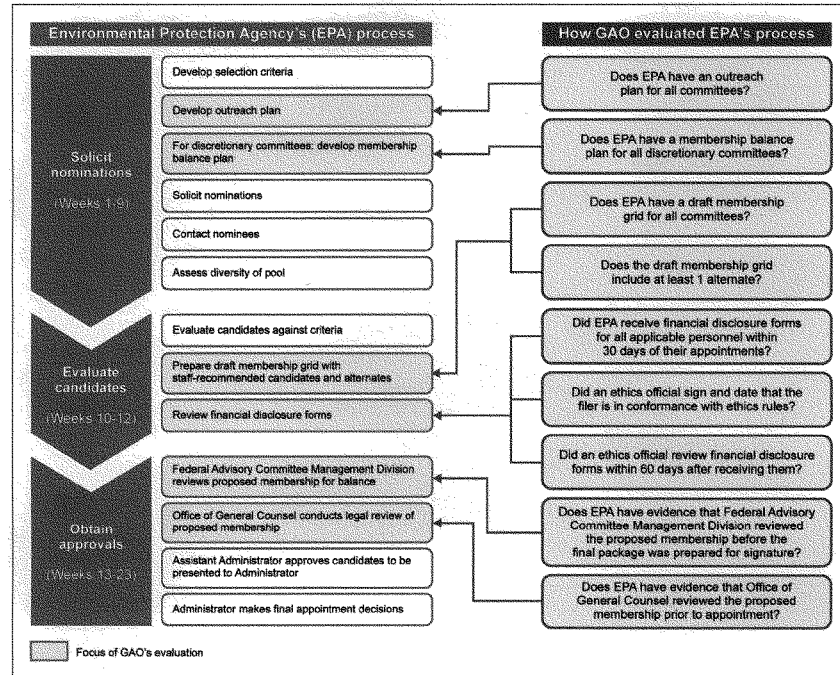
<sup>6</sup>5 U.S.C. App § 5(b)(2), (c). Courts that have reviewed challenges to advisory committee composition under these provisions have either held that the balance requirements are nonjusticiable or tendered a very high degree of deference to the agency's selection of committee members. *Bull. Market Corrective Rulemaking: Drawing On EU Insights To Rationalize U.S. Regulation*, 67 Admin. L. Rev. 629, 678 n.203 and accompanying text (2015).

<sup>7</sup>5 U.S.C. App. 2 § 2(b)(4).

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involves EPA staff members preparing draft membership grid documents that reflect their recommendations on the best qualified and most appropriate candidates for achieving balanced committee membership, according to the *Federal Advisory Committee Handbook*. Figure 1 shows EPA's established process and the steps we reviewed to evaluate the extent to which EPA followed its process from fiscal year 2017 through the first two quarters of fiscal year 2018. Unless noted otherwise, explanations of these steps can be found in the *Federal Advisory Committee Handbook*, which documents the agency's established process.

**Figure 1: EPA's Established Process for Appointing Advisory Committee Members and How GAO Evaluated EPA's Process from Fiscal Year 2017 through the Second Quarter of Fiscal Year 2018**



Source: GAO analysis of EPA's Federal Advisory Committee Handbook (Washington, D.C.: August 2017). | GAO-19-681T

Note: We reviewed those aspects of the process for which EPA was to have documentary evidence, and we evaluated the implementation of ethics oversight requirements that are relevant to EPA's committee member appointment process.

**EPA Generally Followed Its Established Process but Did Not Follow a Key Step for Appointing 20 Committee Members to Two Committees or Ensure Certain Members Met Federal Ethics Requirements**

As we state in our report, our review of agency documents that supported appointment decisions for the 17 committees that appointed or reappointed committee members from fiscal year 2017 through the first two quarters of fiscal year 2018 found that EPA generally followed its established process for most of its 22 advisory committees. However, in fiscal year 2018, EPA did not follow a key step for appointing 20 committee members to two committees we reviewed: the EPA Science Advisory Board (SAB) and Clean Air Scientific Advisory Committee (CASAC), which advise the agency on environmental regulatory matters, among other things.<sup>8</sup> Our review found that the 2018 appointment packets for these two committees did not contain draft membership grid documents reflecting EPA staff rationales for proposed membership, as called for by EPA's established process.<sup>9</sup>

As a result, we recommended that the EPA Administrator direct EPA officials responsible for appointing advisory committee members to follow a key step in its appointment process—developing and including draft membership grids in appointment packets with staff rationales for proposed membership—for all committees. By doing so, the agency would have better assurance that it will (1) consistently meet FACA's purpose of encouraging uniform appointment procedures and (2) show how it made appointment decisions to achieve the best qualified and most appropriate candidates for balanced committee membership.

EPA disagreed with this recommendation. In written comments on a draft of the report, EPA stated that it followed all membership steps outlined in agency guidance with the exception of two committees, the SAB and CASAC, for which it substituted the development of membership grids with what the agency states was a more rigorous examination of the candidates (a series of briefings with senior management discussing the

<sup>8</sup>The objective of the SAB, the agency's largest advisory committee, is to provide independent advice and peer review to EPA's Administrator on the scientific and technical aspects of environmental issues. CASAC reviews, among other things, EPA's national primary and secondary ambient air quality standards and recommends new standards and revisions of existing standards as may be appropriate.

<sup>9</sup>Appointment packets contain the documents used by EPA management to make appointment and reappointment decisions. Example of documents in the appointment packets include committee charters, which specify the committee's mission, scope, objectives, cost, membership, management, and recordkeeping; outreach plans, which document the agency's plan for recruiting committee members; and draft membership grid documents, which reflect EPA staff recommendations about who should be appointed to serve on advisory committees and why.

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strengths and weaknesses of potential candidates). EPA stated that this is within the discretion of the EPA Administrator and that the vetting of candidates for the SAB and CASAC occurred in a different manner than in previous years with a process more robust than membership grids.

We agree that conducting such briefings is within the discretion of the EPA Administrator, and we did not assess the outcomes of the membership appointment process. However, it remains that, for the SAB and CASAC, EPA did not follow a key step in which agency staff are to document in draft membership grids and include in appointment packets their rationales for recommending the candidates they deem best qualified and most appropriate for achieving balanced committees.

There may be benefits to following any number of alternative processes for appointing committee members. However, as EPA stated in its *Federal Advisory Committee Handbook*, EPA developed the handbook to help agency officials comply with FACA requirements. For these two advisory committees, EPA did not follow its established committee appointment process, impeding the agency's ability to ensure that it consistently meets—across all of its advisory committees—FACA's purpose of encouraging uniform committee appointment procedures. In addition, by directing officials responsible for appointing committee members to document staff rationales for proposed membership, the agency would have better assurance that it could demonstrate how it made appointment decisions to achieve the best qualified and most appropriate candidates for balanced membership.

Moreover, we found in the report that EPA did not consistently ensure that committee members appointed as special government employees (SGE)—who are expected to provide their best judgment free from conflicts of interest and are required by federal regulations to disclose their financial interests—met federal ethics requirements.<sup>10</sup> For about 23 percent, or 17 of the 74 financial disclosure forms we reviewed, an ethics official had not signed and dated that the SGE filing the form was in compliance with federal ethics rules. EPA also did not periodically review

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<sup>10</sup>If EPA expects a federal employee to serve no more than 130 days in any 365-day period, guidance from the U.S. Office of Government Ethics (OGE), which oversees the executive branch's ethics program, states that the employee should be designated as an SGE. OGE guidance explains the circumstances under which advisory committee members may be designated as SGEs. See DO-05-012 and *Informal Advisory Memorandum* 82 x 22 (Washington, D.C.: July 9, 1982). See also 18 U.S.C. § 202(a).



its ethics program, as called for by federal regulations, such as through audits or spot checks, to evaluate the quality of financial disclosure reviews for SGEs. As a result, we recommended that EPA's Designated Agency Ethics Official direct EPA's Ethics Office, as part of its periodic review of EPA's ethics program, to evaluate—for example, through audits or spot checks—the quality of financial disclosure reviews for SGEs appointed to EPA advisory committees. Until EPA's Ethics Office does so, it will not have reasonable assurance that it will address noncompliance with federal ethics requirements for its advisory committees.

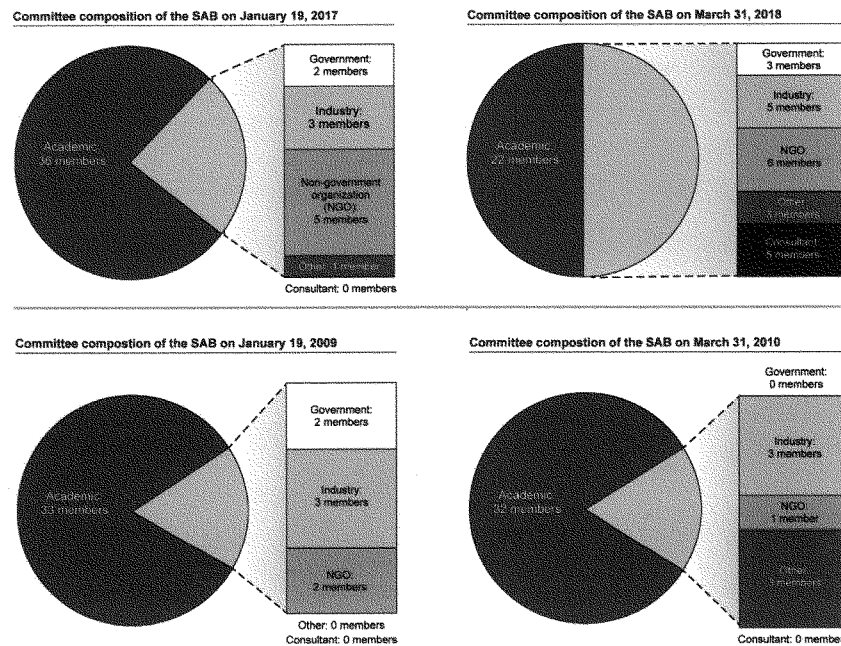
EPA officials acknowledged that taking this additional oversight measure could enhance the agency's ethics program. In addition, in written comments on a draft of the report, EPA noted that the agency has resolved staffing issues and is engaging in a thorough review of all employees' (including SGEs serving on federal advisory committees) ethics forms to ensure they meet all ethics requirements.

#### **Selected Characteristics of Four EPA Advisory Committees Changed Notably after January 2017, but There Were No Notable Changes for 14 Committees**

As we stated in our report, of the four characteristics we reviewed from GSA's FACA database—committee composition, regional affiliation, membership turnover, and number of meetings committees held—one or more of the first three changed notably for four of 18 EPA advisory committees after January 2017.<sup>11</sup> We compared the four characteristics of committees before and after the two most recent changes in presidential administrations. Each change identified as notable had at least a 20 percentage point difference in the change to the characteristic after January 2017 compared to the period after January 2009. For example, we found that the percentage of committee members with an academic affiliation serving on the SAB decreased by 27 percentage points, or from 77 percent (36 of 47 members) on January 19, 2017, to 50 percent (22 of 44 members) about 15 months later on March 31, 2018. See figure 2.

<sup>11</sup>Of the 22 advisory committees EPA managed on March 31, 2018, we did not analyze the four characteristics of four committees because they were established after the beginning of the time frame we analyzed. Also, we did not analyze all four characteristics for the remaining 18 committees because of data reliability issues or the nature of the characteristic. Our report provides additional information about the characteristics we analyzed for which committees.

**Figure 2: Committee Composition of EPA's Science Advisory Board (SAB) after January 2017 and January 2009**



Source: GAO analysis of data from the U.S. Environmental Protection Agency (EPA) and the U.S. General Services Administration's Federal Advisory Committee Act database. | GAO-19-681T

Note: The "other" category includes committee members: (1) affiliated with more than one category; (2) not affiliated with any of the categories; or (3) for which the Federal Advisory Committee Act (FACA) database did not provide sufficient information for us to assign a category.

EPA raised issues with how we conducted some of our data analyses and with some of the data points we presented, which we addressed in the report.

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Chairwomen Sherrill and Fletcher, Ranking Members Norman and Marshall, and Members of the Subcommittees, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

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**GAO Contact and  
Staff  
Acknowledgments**

If you or your staff have any questions about this testimony, please contact Alfredo Gomez, Director, Natural Resources and Environment, at (202) 512-3841 or [gomezj@gao.gov](mailto:gomezj@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. In addition to the contact named above, Joseph Dean Thompson (Assistant Director) and Mary Koenen (Analyst in Charge) made key contributions to the testimony. Other staff who made contributions to the report cited in the testimony were Karen Chen, Charlie Egan, Richard Johnson, James Lager, Amber Sinclair, and Kiki Theodoropoulos.

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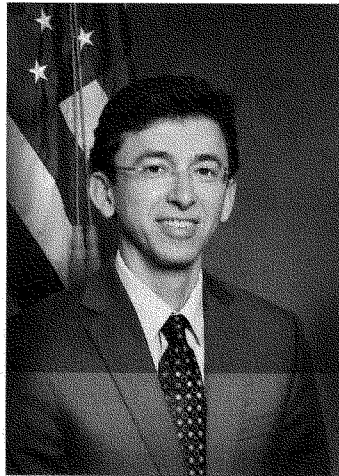


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J. Alfredo Gómez serves as a Director in the Natural Resources and Environment team of the U.S. Government Accountability Office (GAO). He manages the team's work in environmental protection issues. His portfolio includes work in cleanup of hazardous substances, drinking and clean water issues, ecosystem restoration, pesticides, toxic chemicals, climate change, and EPA-wide management issues. Mr. Gómez has produced numerous reports and testimonies addressing a wide range of environmental, natural resource, agency management, and food safety issues. Mr. Gómez began his GAO career in the Chicago Regional Office in 1991, working on environmental protection issues. He left GAO to work for the Honolulu City Council where he audited local government agencies, and subsequently returned to GAO in 1998. Mr. Gómez holds a bachelor's degree in Chemical Engineering from Rice University and a master's degree in Public Policy Studies from the Harris School at the University of Chicago.

Chairwoman SHERRILL. Thank you. Next the Chair recognizes Dr. Thomas Burke for his remarks.

**TESTIMONY OF DR. THOMAS A. BURKE,  
JACOB I. AND IRENE B. FABRIKANT PROFESSOR AND  
CHAIR IN HEALTH RISK AND SOCIETY,  
BLOOMBERG SCHOOL OF PUBLIC HEALTH,  
JOHNS HOPKINS UNIVERSITY**

Dr. BURKE. Thank you for the opportunity to address the Subcommittees today. I'm Dr. Tom Burke, Professor at Johns Hopkins University, Bloomberg School of Public Health. I speak today as an individual, and my views don't necessarily represent those of Johns Hopkins University, or Johns Hopkins Health System. Before joining the Hopkins faculty, I worked as a New Jersey State official, serving as the Director of Science for the Department of Environmental Protection, and then as Deputy Commissioner of Health for the State. Most relevant to today's topic, from 2015 to 2017, I was the EPA Science Advisor, and Deputy Assistant Administrator for Research and Development.

Science has been called the backbone of the EPA. Credible and transparent science is core to the EPA mission, and the implementation of our national environmental laws. But far beyond Washington, the credibility of EPA science is essential to State- and community-level local officials, as they respond to emergencies, and address concerns about environmental pollution. The success of their difficult decisions depends upon public trust, and the science that supports them. The EPA advisory committees we're discussing today make sure that the Agency does the right science, and gets the science right.

The advisory committees were established to provide the highest levels of independent scientific expertise and peer review. They allow the Agency to recruit the best and brightest to review, critique, and, ultimately, improve EPA science. Historically, as was mentioned, appointment to an EPA advisory board was seen as a great honor, a recognition that you're among the Nation's best in science. The advisory committee process provides important oversight and transparency so essential to developing public trust. I can speak from my own experience at the EPA overseeing a major, and controversial study on the impacts of hydraulic fracturing on drinking water. The Science Advisory Board assembled an outstanding committee of experts, provided an extensive review, including public participation, and their review improved both the science and clarity of the report, and ultimately advanced our knowledge of the impacts of fracking on our waters.

Today we face unprecedented environmental challenges. Most urgently, the broad environmental health and social impacts of climate change are upon us, but let me list a few other examples. PFAs, or Teflon-related contaminants in our water and food, risks from cancer from widely used pesticides, like Roundup, lead in our aging drinking water infrastructure, harmful algal blooms, hazardous exposures from wildfires, and health risks to fence-line communities from industrial chemical discharges. These are not obscure science projects. They're real life health issues facing vir-

tually every community across our Nation. Decisions regarding these issues will require a strong scientific leadership from EPA, and the guidance of knowledgeable and balanced advisory boards.

Despite increasing demand on EPA science, the current Administration has made major changes, as we've heard, to threaten the quality, capacity, and balance of the Science Advisory Boards. Also, the recent Presidential executive order to eliminate committees presents a yet unknown, but additional troubling threat to EPA. I defer to my colleagues to present more details on those committees, but I would like to close with some observations about the state of science at EPA.

EPA science is in trouble. During the past 2 years, we've witnessed a profound shift in the priorities of the Agency. The fundamental mission of protecting health and the environment has given way to a focus on deregulation. How else can you explain the rollbacks that we've seen that may result in thousands of increased deaths and illnesses each year? Sadly, the rollbacks of science-based policies have been accompanied by a dismantling of the scientific infrastructure by the current political appointees. Science has become collateral damage in their assault on our environmental health regulations. I've attached a table to my testimony that we may project on the screen here that provides an overview of the many actions that have undermined science. First, the reversal of science-based policies, interference with peer review, cuts to research—both internal and external—limiting the scientific studies supporting regulatory decisions, and finally, revising the very methods so well peer reviewed and accepted to assess health risks and benefits. These actions, left unchecked, will have lasting impacts not only on EPA, but the future of our environment, and the health of all Americans.

Thank you for this opportunity to speak with you today.

[The prepared statement of Dr. Burke follows:]

Testimony of Thomas A. Burke, PhD, MPH  
Jacob I and Irene B. Fabrikant Professor and Chair in Health Risk and Society  
Director, Risk Sciences and Public Policy Institute  
Johns Hopkins University  
Bloomberg School of Public Health

U.S. House of Representatives  
Committee on Science, Space, and Technology  
Subcommittee on Investigations and Oversight Environment and  
Subcommittee on Environment

Hearing on “EPA Advisory Committees: How Science Should Inform Decisions”

July 16, 2019



Thank you for the opportunity to address the Subcommittees on Investigations and Oversight, and Environment. I am Dr. Thomas Burke, Professor at the Johns Hopkins University Bloomberg School of Public Health. I am also Director of Johns Hopkins Risk Science and Public Policy Institute. I speak today as an individual, informed by a career devoted to public health and protecting our environment. As such, these views do not necessarily represent those of the Johns Hopkins University or Johns Hopkins Health System. Before joining the Hopkins faculty, I worked as a state official, serving as Director of Science and Research for the New Jersey Department of Environmental Protection and then as Deputy Commissioner of Health for New Jersey. I have also been a member of both the EPA Science Advisory Board (SAB) and the EPA Board of Scientific Counselors, and served on numerous committees of the National Academies of Science, Engineering and Medicine. Perhaps most relevant to today's topic, from January 2015 to January 2017 I served as the EPA Science Advisor and Deputy Assistant Administrator for the Office of Research and Development.

#### **The Important Role of Science Advisory Committees at EPA**

Science has been called the "backbone" of EPA. Credible and transparent science is essential to the EPA mission and the implementation of our national laws. Far beyond Washington, the credibility of EPA science is essential at the state and community level as public health officials respond to concerns about the drinking water safety and air pollution, or respond to emergencies from chemical releases or harmful algal blooms. The success of these difficult decisions depends upon public trust in the science that supports them. The Advisory Committees of EPA, particularly the Science Advisory

Board, Clean Air Scientific Advisory Committee and the Board of Scientific Counselors have a key role in making sure the Agency does the right science - and gets the science right.

The Advisory Committees have been essential to the credibility and defensibility of EPA actions. They were established and structured to provide EPA with the highest level of independent scientific expertise and peer review. They allow the Agency to recruit the best and the brightest and to include multiple scientific disciplines to review, critique and improve the science that guides EPA decisions. An open nominations process casts a broad net, and there is extensive review of candidates to evaluate their scientific accomplishments and expertise, in addition to an evaluation of any potential conflicts of interest. Historically, appointment to the EPA Science Advisory Board was seen as a great honor, recognition as being among the nation's best.

In addition to expertise and peer review, the Advisory Committee process also provides important oversight and transparency that is essential to developing public understanding and trust in science based decisions. For example, the SAB review process posts all reports and supporting information, is open to the public, and includes opportunities for public and stakeholder comment. I can speak from my own experience at the EPA Office of Research and Development overseeing the major nationwide study *Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States*.<sup>(1)</sup> The SAB assembled an outstanding committee of experts, provided an extensive and inclusive review, and included public participation and about 100,000 public comments. The review improved both the science and clarity of the report, which advanced our knowledge of the potential impacts

of fracking on our drinking water.

In summary, the SAB and other advisory committees provide essential support to the mission of EPA and have played an important role in assuring the quality of the science that has been the foundation of our nation's great environmental health progress of the past 40 years.

#### **Today's Environmental Health Challenges**

The environmental health challenges facing our nation have never been greater. Most urgently, the broad health, economic, and social impacts of climate change are upon us and require unprecedented collaboration across the sciences to mitigate the causes, adapt to changes, and build resilient communities. Let me list a few other examples:

- PFAS (Teflon related) contaminants in our water and food
- The impacts of fracking on our health and environment
- The risks of cancer from widely used pesticides like Roundup
- Lead in our aging drinking water systems
- Harmful algal blooms
- Hazardous exposures from wildfires
- Illness and mortality related to particulate air pollution
- Health risks to fence line communities from industrial chemical emissions

These are not obscure science projects; they are real life health issues facing virtually every community across our Nation. Decisions regarding these issues have high stakes for the public and for the polluters. These decisions will require strong scientific leadership from EPA and the guidance of knowledgeable and balanced advisory boards.

#### **Threats to the Science Advisory Process**

Despite the increasing demands upon EPA science, the current Administration has made

major changes that threaten the quality, capacity and balance of the science advisory boards. Starting with Scott Pruitt's dismissal of several members of the Board of Scientific Counselors, the Administrator then moved to dismiss several members of the SAB and CASAC. He issued a directive that barred any member receiving support from EPA grants.(2) The stated purpose of this directive was to strengthen independence, although no similar restriction was imposed for members receiving support from EPA regulated industries. This restriction not only led to the dismissal of several members, but remains as a barrier to the inclusion of the leading researchers who have received competitive grants in the fields most relevant to the EPA mission.

A recent Presidential Executive Order presents an additional threat to the EPA Science Advisory Committees. (3) This order requires each agency to terminate at least one third of their federal advisory committees by September 30, 2019. While the specific committees to be eliminated have not yet been named, the potential impacts on the transparency and credibility of EPA science are troubling.

#### **Dismantling Science at EPA**

While our focus today has been the EPA Science Advisory Committees, I would like to close with some observations about the state of EPA science. My former role as Agency Science Advisor has provided me with a unique perspective on this. During the past two years we have witnessed a profound shift in the priorities at the Agency. The fundamental mission of protecting health and the environment has given way to a focus on deregulation. How else can you explain rollbacks that result in thousands of increased deaths each year? (4) Sadly, the rollbacks of science-based policies have been

accompanied by a dismantling of the science infrastructure of EPA by the current political appointees. Science has become collateral damage in the assault on our environmental health regulations. The attached table provides an overview of the actions that have undermined science including: reversal of science based policies, interference with peer review, cuts to research both internal and external, limiting the scientific studies supporting regulatory decisions, and revising the methods of assessing health risks and benefits. These actions, left unchecked, will have lasting impacts not only on the EPA, but also on the future of our environment and the health of all Americans.

Thank you for this opportunity to speak with you today.

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## Deregulation: Dismantling Science at EPA

### Rolled back, rescinded or revised Policies and Rules

- Paris Climate Accord
- Clean Power Plan
- Waters of the U.S.
- Chlorpyrifos ban reversal

### Interference with Scientific Peer Review

- Dismissal of Board of Scientific Councilors
- Science Advisory Board changes
- Clean Air Science Advisory realignment
- White House Order to reduce Federal Advisory Committees

### Research cuts

- Climate Change Research
- Chemical Safety and Sustainability
- Science and Technology budget
- Elimination of Science to Achieve Results Program

### Limiting the Evidence Base

- “Transparency” Rule to restrict scientific studies supporting regulation
- Exclusion of historical epidemiologic data
- Narrow focus of evidence reviews and exposure assessments for chemical hazards

### Revising Scientific Methods

- Less protective risk assessment methods
- Promoting threshold assumption for “safe” level of chemical exposures
- Revision of guidelines for cancer and non cancer effects
- Limited scope of benefit cost analysis

**Thomas A. Burke, Johns Hopkins University Bloomberg School of Public Health**

Thomas A. Burke, PhD, MPH, is the Jacob I and Irene B. Fabrikant Professor and Chair in Health Risk and Society at Johns Hopkins University Bloomberg School of Public Health, Department of Health Policy and Management. He holds joint appointments in the Department of Environmental Health Sciences and the School of Medicine Department of Oncology. He is also Director of the Johns Hopkins Risk Sciences and Public Policy Institute. Dr. Burke was nominated by President Barack Obama to serve as EPA Assistant Administrator for the Office of Research and Development. From January 2015 until January 2017 Dr. Burke was the EPA Science Advisor and Deputy Assistant Administrator for Research and Development. His research interests include the health impacts of climate change, evaluation of population exposures to environmental pollutants, assessment and communication of environmental risks, and application of epidemiology and health risk assessment to public policy. Before joining the University faculty, Dr. Burke was Deputy Commissioner of Health for the State of New Jersey and Director of Science and Research for the New Jersey Department of Environmental Protection. In New Jersey, he worked to reduce the impact of environmental contaminants on health, from coastal water quality to inner city air pollution. He directed initiatives that influenced the development of national programs, such as Superfund, the Safe Drinking Water Act, and the Toxics Release Inventory. Dr. Burke is currently Chair of the National Academies of Sciences, Engineering and Medicine Environmental Health Matters Initiative. He served as a member of the National Academy of Sciences Board on Environmental Studies and Toxicology, and also chaired the Academies Committee on Improving Risk Analysis that produced the report *Science and Decisions*. He is a Fellow of the Society for Risk Analysis and a lifetime National Associate of the National Academies. Dr. Burke received his BS from St. Peter's College, his MPH from the University of Texas and his PhD in epidemiology from the University of Pennsylvania.

Chairwoman SHERRILL. Thank you. Next we have Dr. Swackhamer.

**TESTIMONY OF DR. DEBORAH SWACKHAMER,  
PROFESSOR EMERITA, HUMPHREY SCHOOL  
OF PUBLIC AFFAIRS, UNIVERSITY OF MINNESOTA**

Dr. SWACKHAMER. Good afternoon, Chairwoman Sherrill, Chair Fletcher, Ranking Members Norman and Marshall, Chairwoman Johnson, and Committee Members. My name is Deborah Swackhamer, and I'm a Professor Emerita from the University of Minnesota. I previously served as Chair of the EPA chartered Science Advisory Board, and Chair of the EPA BOSC. I speak to you today as an environmental sciences and policy expert, and as a private citizen, and not on behalf of the U.S. EPA. My perspectives and statements are mine alone.

To start, I want to underscore two important points that I elaborate on in my written testimony. First, environmental threats are very complex and multi-disciplinary, thus strong multi-disciplinary science is essential for EPA to meet its mission. The second point, external, independent expert science advice is critical to ensure that EPA is supported by the best multi-disciplinary science. When the external science advisory role is diminished or tarnished by a lack of independence, the integrity of the science used by EPA is also diminished and tarnished, and this leads to weak environmental protection.

Now let me speak to BOSC specifically. EPA and ORD (Office of Research and Development) science would be diminished without an effective BOSC. BOSC advises the Assistant Administrator of the ORD on what the scope and direction of internal research should be, and to ensure the highest quality of the research being conducted. Such ongoing review allows for mid-course corrections, and infusion of new and innovative ideas. ORD is a relatively small enterprise, and thus BOSC plays an important role in keeping it on point. ORD targets its research programs to fill in the gaps that external research doesn't fill. BOSC helps identify those gaps, identify duplication, identify potential external partnerships to maximize effectiveness, and advises on emerging issues that EPA research should get a jump start on. Without BOSC, ORD runs the risk of getting isolated from outside research advances, being unnecessarily redundant and wasteful, and it could easily fall behind in focusing on timely issues.

Interference in the process of appointing BOSC members can be highly disruptive to the ability of BOSC to assist ORD. In April 2017, the members of BOSC who had served one of their two allowed terms were assured by senior ORD staff that their appointments would be renewed for a second term. One week later the Administrator's Office reversed this recommendation, and announced that none of these members' terms would be renewed. The reasons given to the media created the perception that the intent of the Administrator's Office was to remove independent research scientists, and replace them with people having a vested interest in the regulatory actions of EPA. In June 2017, all of the members of the five BOSC subcommittees who were up for second term also had their memberships terminated.



Regardless of the motive, it meant that BOSC was stripped of the vast majority of its members, and scheduled meetings, and thus it could not provide timely advice to ORD on a number of important pending matters, one being recommendations on how to reprioritize research programs as a result of budget cuts. The other was the review of the next edition of ORD's strategic research plans. It took 6 months to repopulate BOSC, and another year to get them up and running. The new BOSC just had their first executive committee meeting last month, 2 years after those non-renewals. The action on the part of EPA resulted in significant disruption of the iterative and ongoing process of external scientific advice provided to ORD, important time lost while EPA research and planning proceeded without the benefit of BOSC advice. It should be noted that the Administrator took similar actions against the SAB and CASAC.

Interference with science advisory boards at EPA is consistent with a broader pattern of science misuse by the Agency. Why would the Administrator's Office interfere with science advisory committees? The aggressive changes made to the advisory committee eligibility and composition are unprecedented at EPA. It is my concern that they are populating the committees with a significant number of members who have a vested interest in EPA actions and regulations, thus co-opting the committees in order to support the overall direction of the Agency to deregulate fossil fuel and other industries, and loosen environmental protections, rather than provide independent advice based on solid science. The EPA administration has demonstrated a pattern of cherry picking scientific evidence, of ignoring rigorous scientific consensus, or simply politicizing science to justify its actions.

While regulations can be affected by politics, science never should be. Interference with the Science Advisory Committees is a direct attack on the integrity of science, and leads to an erosion of the scientific underpinning of environmental regulations. Thank you.

[The prepared statement of Dr. Swackhamer follows:]

**House Subcommittee on Investigations and Oversight  
and  
House Subcommittee on the Environment  
Committee on Science, Space, and Technology, U.S. House of Representatives  
Room 2318 Rayburn House Office Building**

**“EPA Advisory Committees: How Science Should Inform Decisions”  
July 16, 2019**

**Written Testimony submitted by Deborah L. Swackhamer, Ph.D.  
Professor Emerita, University of Minnesota**

My name is Deborah Swackhamer, and I am a Professor Emerita from the University of Minnesota, in Minneapolis and Saint Paul, where I held appointments in Environmental Health Sciences in the School of Public Health, and in Science, Technology, and Public Policy in the Humphrey School of Public Affairs. I also co-directed the Water Resources Center in Minnesota. I am trained as an environmental chemist, with an emphasis on understanding toxic chemical movement in the environment and human exposures. I served as Chair of the U.S. Environmental Protection Agency (EPA) Science Advisory Board from 2008-2012, and served as Chair of the EPA's Board of Scientific Counselors from 2015-2017. I continue to hold a Special Government Employee (SGE) appointment at EPA, but currently do not serve on any committees. I speak to you today as an environmental sciences and policy expert, and as a private citizen, and not on behalf of the U.S. EPA. My perspectives and statements are mine alone.

**Key points of this testimony**

- 1) Strong multidisciplinary science is essential for EPA to meet its mission.
- 2) External, independent expert science advice is critical to ensure that EPA is supported by the best science.
- 3) EPA and ORD science would be diminished without an effective BOSC.
- 4) Interference with scientific advisory boards at EPA will lead to the loss of scientific integrity at the agency, and is consistent with a broader pattern of science misuse at the agency.

**Strong multidisciplinary science is essential for EPA to meet its mission.** The EPA is charged with protecting human health and the environment. This widely encompassing mandate is highly complicated. The many issues affecting human health require understanding pollutant sources to air, water, and soil; the movement of pollutants through air, water, and soil; the exposures of these pollutants to people through breathing, eating, drinking and through the skin; then understanding the impacts to human health at the cellular, genetic, metabolic, and organ levels; and finally

the outcomes of these impacts such as illness, reproductive disorders, various diseases, cancer, etc. There are hundreds of known pollutants, and thousands of potential pollutants. While EPA regulates individual pollutants, we know that there are all kinds of interactions (environmentally and toxicologically) that increase the actual complexity of this in an exponential manner. This complexity requires many diverse fields of scientific expertise be brought to bear to help achieve EPA's mandate: environmental engineering; air and water pollutant modeling; water resource expertise; environmental biology, microbiology, and chemistry; exposure science; ecology; and human, wildlife, and aquatic toxicology. However, since people live in communities, and pollution generally correlates inversely with economic health, understanding solutions for pollution also requires expertise in economics, geography, sociology, community planning, vulnerable populations, and environmental justice.

**External expert science advice is critical to ensure that EPA is supported by the best science.** The Congress passed the Federal Advisory Committee Act (FACA) in 1972 in recognition of the need for Federal agencies to get expert science advice for these highly complex problems such as environmental protection. In doing so, they formalized a consistent and transparent process for agencies to follow when establishing these committees to ensure independence of the advice, public access to the advice, and accountability and transparency of the agency's use of science.

The EPA is a science-based regulatory agency. To meet its mandate it must use the most current, robust, and accepted scientific evidence available. It is understood that effective environmental policy must be based in strong science, and that without strong science environmental policy is weakened and ineffective. For EPA to meet its mandate, it is essential that it use the best scientific evidence to guide its policies and decision-making. Advice from external, independent scientific experts are key to achieving this goal.

The role of advisory committees is generally two-fold. The first role is to provide external, objective advice to EPA. They are the independent eyes looking in from outside, able to examine scientific evidence, make constructive recommendations, and provide peer review. The second role is to provide the EPA with access to an expanded pool of expertise. The EPA does not have the resources to have all the many facets of environmental science covered by agency staff, and thus having access to leaders in environmental research from outside the agency is a huge advantage to informing their own research priorities (e.g. BOSC) or reviewing their scientific evidence for regulations (e.g. CASAC, SAB). Their peer review work also makes EPA more accountable to the public. Thus, if the external science advisory role is diminished or tarnished by a lack of independence, the integrity of the science used by EPA is also diminished and tarnished. And this leads to weak environmental protections and actions.

**EPA and ORD science would be diminished without an effective BOSC.** EPA conducts its own research on a number of topics, to be sure that the necessary science needed to understand environmental protection is available to them. The Board of Scientific Counselors (BOSC) was created by EPA in 1996 to specifically advise the

Assistant Administrator of the Office of Research and Development (ORD) on what the scope and direction of internal research should be, and to ensure the highest quality of the research being conducted. Such on-going review allows for mid-course corrections, infusion of new and innovative ideas, as well as constructive support for the research program.

ORD is a relatively small enterprise, and thus BOSC plays an important role in keeping it “on-point”. ORD targets its research programs to fill in the gaps that external research doesn’t fill, such as the research provided by universities and other research laboratories. For example, it develops tools and models that the State environmental agencies can use to help implement the Clean Water Act or Safe Drinking Water Act – something basic research laboratories might not do. BOSC helps identify those gaps, identify where research might be duplicated elsewhere, identify potential external partnerships to maximize effectiveness, and advises on emerging issues that EPA research should get a jump-start on. Without BOSC, ORD runs the risk of getting isolated from outside research advances, being unnecessarily redundant and wasteful, and it could easily fall behind in focusing on timely issues.

Interference in the process of appointing BOSC members can be highly disruptive to the ability of BOSC to assist and advise ORD. On April 28, 2017 the members of BOSC who had served one of their allowed two terms were assured by senior ORD staff that their appointments would be renewed for a second term. On May 4, one week later, the Administrator’s Office reversed this recommendation and announced that none of these members’ terms would be renewed. The reasons given to the media for this decision were that “*The Administrator believes we should have people on this board who understand the impact of regulations on the regulated community*” (New York Times) and “...*(the Administrator) is considering new applicants, including those who may work for chemical and fossil fuel companies...*” (Associated Press). This created the perception that the intent of the Administrator’s Office was to remove independent research scientists and replace them with people having a vested interest in the regulatory actions of EPA. On June 19, 2017, all of the members of the five BOSC subcommittees who were up for a second term also had their memberships terminated. Regardless of the motive, it meant that BOSC was stripped of the vast majority of its members, all its future scheduled meetings were canceled, and thus it could not provide timely advice to ORD on a number of important pending matters – one being recommendations on how to absorb proposed budget cuts, and reprioritize research programs as a result; the other was the review of the next edition of strategic research plans for the 6 research areas in ORD. I was removed as Chair of BOSC on October 31, 2017. It took from June until November 2017 to repopulate BOSC. The newly reconstituted BOSC had their first Executive Committee meeting in early June 2019 – nearly 2 years to the day after the non-renewals. This action on the part of EPA resulted in significant disruption of the iterative and on-going process of external scientific advice provided to ORD, important time lost while EPA research and planning proceeded without the benefit of BOSC advice.

It should be noted that the Administrator took similar actions against the SAB and CASAC. Second term appointments were denied to members, and the committees were reconstituted

to create biased, non-independent committees. In addition to time lost, the politicization of these committees greatly diminishes their ability to provide robust and independent scientific advice to the agency.

**Interference with scientific advisory boards at EPA will lead to the loss of scientific integrity at the agency, and is consistent with a broader pattern of science misuse by the agency.** Why would the EPA Administrator's Office interfere with the science advisory committees? The aggressive changes made to the advisory committee eligibility and composition are unprecedented at EPA. It is my concern that they are populating the committees (especially SAB and CASAC) with a significant number of members who have a vested interest in EPA actions and regulations, thus co-opting the committees in order to support the overall direction of the agency to de-regulate fossil fuel and other industries and loosen environmental protections, rather than provide independent advice based on solid science. The EPA administration has demonstrated a pattern of selectively cherry-picking scientific evidence, of ignoring rigorous scientific evidence, or simply politicizing science to justify its actions. While regulations can be affected by politics, science never should be. The interference with the independence and composition of the science advisory committees is a direct attack on the integrity of science, and leads to an erosion of the scientific underpinning of agency regulations. Ultimately this may result in weakened environmental protections, degradation in our country's environmental condition, and an erosion in the health and well-being of our communities.

**Deborah L. Swackhamer, PhD**  
**Professor Emerita, University of Minnesota**

Dr. Deborah L. Swackhamer is Professor Emerita at the University of Minnesota in Science, Technology, and Public Policy in the Humphrey School of Public Affairs and Environmental Health Sciences in the School of Public Health. She also directed the University of Minnesota Water Resources Center from 2002 until 2014. She received a BA in Chemistry from Grinnell College, IA and an MS and PhD from the University of Wisconsin-Madison in Water Chemistry and Limnology & Oceanography, respectively. After two years post-doctoral research in Chemistry and Public & Environmental Affairs at Indiana University, she joined the Minnesota faculty in 1987. She officially retired from the University in 2015, and continues to work informally with researchers and decision makers on water resource policy.

In 2012 Dr. Swackhamer completed a 4 year term as Chair of the Science Advisory Board of the US Environmental Protection Agency, and served as a member of the Science Advisory Board of the International Joint Commission of the US and Canada from 2000-2013. She served as Chair of the US EPA Board of Scientific Counselors from 2015-2017. She served as President of the National Institutes of Water Resources in 2011-2012. She is a member of the National Academy of Sciences Board of Environmental Science and Toxicology, and a member of the Steering Committee of the Environmental Health Matters Initiative.

Dr. Swackhamer received the prestigious Founders Award from the Society of Environmental Toxicology and Chemistry for lifetime achievement in environmental sciences in 2009. She is a lifetime Fellow in the Royal Society of Chemistry in the UK. In 2014 she was named an Inaugural Fellow of the international Society of Environmental Toxicology and Chemistry. She received the Warren A. Hall Medal from the Universities Council on Water Resources in 2017 for her lifetime achievements in water resources research and education.

Chairwoman SHERRILL. Thank you. And, finally, we have Dr. Samet.

**TESTIMONY OF DR. JONATHAN SAMET,  
DEAN, COLORADO SCHOOL OF PUBLIC HEALTH**

Dr. SAMET. Good afternoon. Chairwoman Sherrill, Chair Fletcher, Ranking Members Norman and Marshall, Subcommittee Members, thank you for the opportunity to speak with the Subcommittee today. I'm Jonathan Samet, a pulmonary physician and epidemiologist, and presently Dean and Professor at the Colorado School of Public Health. Today I testify as an individual. Much of my testimony relates to the Clean Air Scientific Advisory Committee—in my jargon I will hereafter be saying CASAC—and I would emphasize that the S is for scientific. It was created, as noted, under the 1977 amendments to the *Clean Air Act*. My comments are based on serving on multiple advisory committees across a 40-year career, including serving as a consultant member for CASAC in 1995–96, when our current fine particle standard was implemented, and later chairing CASAC.

During that period, the transition to the current approach for development and review of the National Ambient Air Quality Standards, or NAQS, was developed. That process is shown here. You will notice that it begins on that side, with science, and ends on the other side, with the possible promulgation of the new National Ambient Air Quality Standard. Along the way there are a number of steps. First, the development of the Integrated Science Assessment, that brings together what we know about the harms from air pollution; the Risk and Exposure Analysis, which explores how different changes to the NAQS might benefit public health; and finally, a public—a policy analysis that is brought to the Administrator as the basis for decisionmaking. CASAC provides review of each of these documents through often multiple cycles of revision as they are brought to the point where they are ready as a base—to be the basis for decisionmaking.

My main points. An effective approach from moving from scientific findings to possible revisions of the NAQS has been in place for a decade, this latest process. The role of CASAC is well-defined and pivotal. Given the scope of the documents reviewed, the seven chartered members specified in the 1977 amendments have generally been augmented by 12 to 15, or more, additional panel members to do their job. For example, the current ISA (Integrated Science Assessment) for particulate matters—matter is 1,800 pages in length. The breadth of its science cannot be covered by seven people alone. CASAC's ability to provide in-depth scientific review has now been limited by the exclusion of EPA-funded researchers, often the most knowledgeable in relationship to the NAQS pollutants. This follows the 2017 rule on committee membership.

With the currently ongoing review of the documents related to airborne particles, CASAC has been crippled by the 2018 dismissal of the additional panel members added to complement the seven chartered members. The resulting gap in expertise has been acknowledged by the chartered CASAC, which has requested restoration of the same, or a similar panel. Under the current CASAC chair, untested changes in review approaches have been introduced

that have been disruptive to established CASAC processes. Such changes need careful evaluation by CASAC and the SAB. As described in detail in my testimony, these changes to CASAC membership and functioning are symptomatic of threats to the paradigm of moving from a scientific foundation to possible revisions of the National Ambient Air Quality Standards. Such threats include reduced EPA funding for needed research on these air pollution—air pollutants, and the potential exclusion of key studies, particularly epidemiological studies, through the proposed transparency rule.

In summary, over more than 40 years, CASAC has functioned effectively in providing guidance to the EPA as it has considered whether and how to revise the National Ambient Air Quality Standards. Leading researchers, experts in air quality management, and practitioners have served on it. The hundreds of panel members have contributed thousands of hours to benefit public health. Like others, I'm proud to have contributed to CASAC. The integrity of CASAC, and its pivotal role in guiding the EPA, need to be maintained. Thank you.

[The prepared statement of Dr. Samet follows:]



**Testimony to the House Committee on Science, Space, & Technology**  
**Subcommittee on Investigations and Oversight & Subcommittee on Environment**

July 16, 2019

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### Introduction

I am Jonathan M. Samet, MD, MS, currently Dean and Professor at the Colorado School of Public Health. My professional background includes training in medicine with specialization in internal medicine and subspecialization in pulmonary disease and also in epidemiology, a core public health research and practice discipline. Over my 40-year career, I have carried out a broad array of studies on the environment and health, including many directed at indoor and outdoor air pollution, some providing critical evidence related to airborne particulate matter and ozone.<sup>1-4</sup> I have also commented on the necessity of maintaining scientific evidence as the foundation for environmental protection.<sup>5</sup> Today, I am testifying as an individual and not representing any institution or organization.

As a consequence of my research, I have been a member of numerous national and international committees concerned with the translation of scientific evidence into policy, including serving on various committees of the Environmental Protection Agency's (EPA) Science Advisory Board. With regard to the reviews carried out by the Clean Air Scientific Advisory Committee or CASAC, I was one of the Consultants to the Committee for the review of the Criteria Document and Staff Paper that led to the 1997 PM<sub>2.5</sub> National Ambient Air Quality Standard (NAAQS). I chaired CASAC from 2008 through 2012 and, while in this role, I led the review carried out for the PM NAAQS. During that review, the transition to the current suite of documents related to the NAAQS review process was completed, resulting in the Integrated Science Assessment (ISA), the Risk and Exposure Assessment (REA), and the Policy Assessment (PA) (Figure 1). I provided guidance to the EPA staff concerning frameworks for assembling and evaluating evidence, drawing on my experience as editor and author for the reports of the Surgeon General on smoking and health and various committees of the National Academies of Science, Engineering and Medicine that I had chaired. Of these committees, the Congressionally-requested Committee on Research Priorities for Airborne Particulate Matter of the National Research Council is particularly relevant, as the committee was tasked to identify the most critical scientific uncertainties around PM following promulgation of the 1997 PM<sub>2.5</sub> NAAQS and charged with developing a research agenda addressing these uncertainties, and to track progress in resolving these uncertainties.<sup>6,7</sup>

These comments offer my views on CASAC and the NAAQS review process and on the changes to this now decade-old process that have been affected during the past two years of the current administration. These changes are reflective of a far-reaching strategy of reducing the impact of scientific evidence at the Environmental Protection Agency (EPA) that is systematic and engineered to disconnect decision-making from scientific evidence, long the basis for agency actions to protect human and environmental health.

### CASAC's independent and deliberative input in the NAAQS review process

The CASAC was created under the 1977 Amendments to the Clean Air Act with the following purpose: "The Clean Air Scientific Advisory Committee (CASAC) provides independent advice to the EPA Administrator on the technical bases for EPA's National Ambient Air Quality Standards" (<https://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/CASAC>). Additionally, "...CASAC also addresses research related to air quality, sources of air pollution, and the strategies to attain and maintain air quality standards and to prevent significant deterioration of air quality." The NAAQS are evidence-based standards. With regard to the NAAQS, the Clean Air Act states: "National primary ambient air quality standards, prescribed under subsection (a) of this section shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such

primary standards may be revised in the same manner as promulgated.” “Criteria” refers to evidence and the pollutants for which NAAQS are promulgated often referred to as “criteria pollutants” as a result. Thus, within the Clean Air Act, there is an explicit connection of the NAAQS to scientific evidence.

Since my term on CASAC ended, the EPA’s approach for assembling and interpreting evidence with review from CASAC has proved effective. The approach is well-established as is the role of CASAC (Figure 1); it provides a transparent record of the concerns raised during the review, summarized in a letter to the Administrator; and changes in response to review are documented with a rationale provided. The scope of the documents reviewed and the breadth of the scientific evidence has necessitated the augmentation of the seven Chartered CASAC members, i.e., the members specified under the Act, with additional panelists and several cycles of revision and review of each consecutive document have been needed. The practice of expanding the panel beyond the Chartered CASAC members is long-standing. The span of scientific expertise needed cannot be captured with the seven members of the Chartered CASAC.

For example, CASAC is currently reviewing the draft ISA for Particulate Matter, which totals almost 1900 pages. Its 13 chapters cover an enormous array of topics: sources, chemistry, concentrations, exposures, and dosimetry; adverse health effects, ranging from reproductive outcomes to total mortality, as assessed with toxicological and epidemiological approaches; and welfare effects. The ISA integrates this information into those findings that are relevant to potential revision of the NAAQS. To have at least one expert on each of the major topics, an expansion of the review panel beyond the seven Chartered CASAC members is mandatory. The panel for the 2009 Clean Air Scientific Advisory Committee for Particulate Matter NAAQS is provided as Table 1; it includes 23 members, 16 in addition to the Chartered members.

The sequence of the documents is consistent with usual risk assessment approaches: the Integrated Science Assessment (ISA) is concerned with hazard identification, providing an assessment of the strength of evidence for causation and a suite of adverse outcomes for consideration in the Risk/Exposure Assessment (REA), which quantitatively examines how exposure and risk would vary with various scenarios related to changing the NAAQS. The ISA’s approach to making judgments as to the causal nature of associations of a criteria pollutant with health outcomes draws on widely used approaches, embedded within various EPA guidelines and used by other entities, e.g., the Centers for Disease Control and Prevention in evaluating the evidence on smoking and health. The REA considers selected health outcomes and assesses the burden of disease attributable to PM at current levels and levels that would prevail under various scenarios associated with changes in the NAAQS. The REA is a critical step in moving from the ISA and its identification of hazard to the Policy Assessment (PA), which guides the Administrator’s decision-making.

The role of CASAC in this process is clear. It provides scientific review for all of the documents that bring the scientific evidence and policy options to the EPA Administrator. The CASAC comments are typically extensive, responding to key questions posed by EPA staff; major comments are summarized in a letter to the Administrator and the comments of individual panel members are provided. An example for the previous review of the ISA for Particulate Matter can be found at: [https://yosemite.epa.gov/sab/sabproduct.nsf/73ACCA834AB44A10852575BD0064346B/\\$File/EPA-CASAC-09-008-unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/73ACCA834AB44A10852575BD0064346B/$File/EPA-CASAC-09-008-unsigned.pdf). This process has been in place for about a decade, undergoing small refinements. Generally, there is agreement that it has proved a workable approach to the complex task of moving from myriad scientific papers to the evidence that is most critical for possible revisions to the NAAQS.

### **The Changing Role of CASAC and the NAAQS Review Process in the Current Administration**

Sweeping changes can be identified in the role of CASAC in the NAAQS review process; these can be summarized as follows:

- Changes in the criteria for membership on EPA Scientific Advisory Board committees, which apply to CASAC. In particular, researchers funded by the EPA are now excluded.
- An accelerated schedule for the review process was adopted, potentially limiting CASAC input and evaluation of EPA responses to comments.
- In the case of the CASAC panel to review the ISA for Particulate Matter, the additional panel members beyond the seven Chartered CASAC members were dismissed, before the review began.
- The current CASAC chair introduced an idiosyncratic approach to evidence evaluation and synthesis that deviates sharply from the state-of-practice and from the Integrated Review Plan (<https://www3.epa.gov/ttn/naaqs/standards/pm/data/201612-final-integrated-review-plan.pdf>) under which the ISA had been developed. The two CASAC meetings held to date were diverted from scientific review considerations to process considerations as a result.

The net result of these changes in approach is clear: the scope and quality of the CASAC review are threatened. The seven Chartered CASAC members do not include either an epidemiologist or a statistician, both critical areas for the NAAQS review process. The need for expanded expertise has been recognized by CASAC, calling for reappointment of the dismissed panel members or a comparable set of experts in the April 11, 2019 letter from Chair Cox to Administrator Wheeler ([https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthCASAC/6CBCBBC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf)). I am concerned that the new requirements for membership on Science Advisory Board committees will be a barrier to recruitment of some knowledgeable experts. In the case of CASAC, appointment as a Chartered member has been viewed as an honor for members of the scientific and public health communities; that honor has been tarnished in the current EPA.

I have been particularly concerned by the changes introduced by the current CASAC chair around evaluation and synthesis of evidence, a critical role for the ISA and REA. I have provided public comments in that regard at both CASAC meetings on the ISA for Particulate Matter. The 2016 Integrated Review Plan describes how the sequence of documents for Particulate Matter will be developed and reviewed, along with setting out the methodologies that will be used. With the initial review, the CASAC Chair forcefully introduced different considerations related to how the evidence should be evaluated, particularly affecting the epidemiological studies that have been critical to guiding the NAAQS for Particulate Matter. As noted in my comments to CASAC, the chair's alternatives to the established approaches are untested in practice. Any major modifications to the EPA's methodologies should have a full vetting and appropriate review by the Science Advisory Board.

### **The CASAC Changes Reflect a Broader Pattern of Removing Science from EPA Actions**

Since its founding, the EPA has been a science-based agency in formulating policies and regulations; some of the scientific evidence comes from its Office of Research and Development, some from its extramural research program—the Science to Achieve Results (STAR) Program, and some from research funded by diverse non-EPA sources. The laws underlying its authorities draw specific connections to scientific evidence. The foundational role of science in EPA actions is threatened; the example of the NAAQS and the role of CASAC is illustrative.

As its starting point (Figure 1), the NAAQS process begins with the peer-reviewed evidence. Now, the generation of new knowledge on air pollution and health is threatened by reduced funding for intramural and extramural research. The STAR Program has been drastically reduced and EPA is no longer supporting the NIEHS/EPA Children's Environmental Health and Disease Prevention Research Centers, or Children's Centers. These centers have carried out research on such topics as air pollution and asthma, and the consequences of environmental pollution for child health more generally. Also threatening the evidence that can be considered is the 2018 rule, *Strengthening Transparency in Regulatory Science*, which calls for access to data and also to the code underlying analyses. Such transparency has become state-of-practice in some fields as part of the move to assure "rigor and reproducibility." However, the logistics, processes, and funding for such data sharing have yet to be addressed. And, the Transparency Rule may preclude consideration of some pivotal epidemiological studies for which data sharing may be impracticable because of privacy and confidentiality considerations. In a rule-making context, data access could also lead to conflicting findings from the same data sets if skilled analysts seek to push results towards or away from the null.

Moving through the process in Figure 1, as mentioned above, the composition of advisory groups, like CASAC has now been altered through the policy initially advanced by former EPA Administrator Pruitt with broad implications. The policy excludes EPA funded scientists from Science Advisory Board membership while easing restrictions on membership in the EPA committees by industry scientists. A net result could be a shift in the balance of committees from having the most knowledgeable participants to including more with potential bias and conflict-of-interest, whether disclosed or undisclosed. With CASAC, as noted, the seven Chartered members cannot provide the in-depth, multidisciplinary review that is needed.

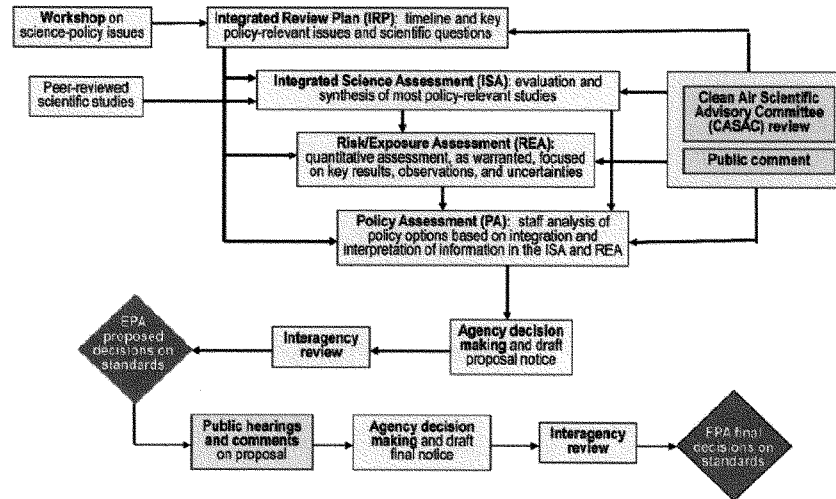
Finally, with CASAC in particular, the current chair has disrupted established processes for evidence evaluation and review by attempting to impose an untested alternative. Concern has also been raised with regard to the systematic review process being used for the Toxic Substances Control Act.<sup>8</sup> The concerns related to a methodology that did not reflect the state-of-practice and that could exclude relevant studies.

Separation of decision-making from its scientific foundation leaves openings for interference at the political level. Figure 2 provides a general schema for the pathway from research to actions that are intended to protect the environment and human and ecosystem health. The NAAQS review process represents a specific example of such a process and my testimony touches on how several steps have been altered in the current administration. In the general schema (Figure 2), agency actions also reach to considerations of dose-response relationships and cost-benefit analysis.

From the outset, this administration did not grasp the cross-cutting role of science in the activities of the agencies.<sup>9</sup> Beyond this general lack of understanding, the EPA became the focus of the concerted attack described in this testimony. Severing the close connection of science with the EPA's actions threatens its core mission—"the protection of human health and the environment".

**Figure 1.** The NAAQS Review Process and the CASAC Role

Schematic of the key steps in review of the National Ambient Air Quality Standards



Source: U.S. EPA. Preamble to the Integrated Science Assessments (ISA). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-15/067, 2015.

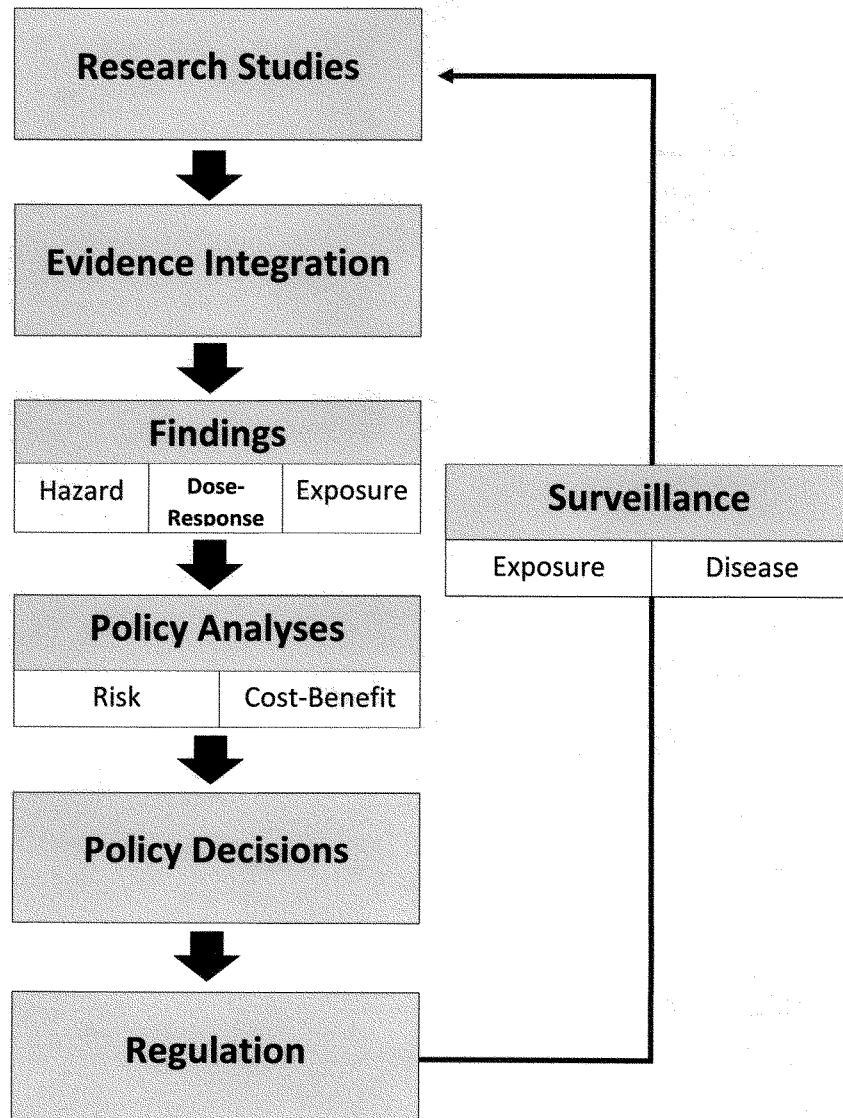
**Figure 2.** Path from Research to Action to Protect the Environment and Human Health

Table 1. Panel Members for Clean Air Scientific Advisory Committee for Particulate Matter NAAQS, 2009

## Clean Air Scientific Advisory Committee for Particulate Matter NAAQS

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### CHAIRPERSON

Dr. Jonathan Samet, Department of Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA

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### MEMBERS

Dr. Lowell Ashbaugh, Crocker Nuclear Lab, University of California, Davis, CA

Dr. Ed Avol, Department of Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA

Dr. Joseph Brain\*, Department of Environmental Health, Harvard School of Public Health, Harvard University, Boston, MA

Dr. Wayne Cascio, Brody School of Medicine, East Carolina University, Greenville, NC

Dr. Ellis B. Cowling\*, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

Dr. James Crapo\*, Department of Medicine, National Jewish Medical and Research Center, Denver, CO

Dr. Douglas Crawford-Brown, Department of Environmental Sciences and Engineering, University of North Carolina at Chapel Hill, Chapel Hill, NC

Dr. H. Christopher Frey\*, Department of Civil, Construction and Environmental Engineering, College of Engineering, North Carolina State University, Raleigh, NC

Dr. David Grantz, Botany and Plant Sciences and Air Pollution Research Center, Riverside Campus and Kearney Agricultural Center, University of California, Parlier, CA

Dr. Joseph Helble, Thayer School of Engineering, Dartmouth College, Hanover, NH

Dr. Rogene Henderson\*\*, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Philip Hopke, Department of Chemical Engineering, Clarkson University, Potsdam, NY

Dr. Donna Kenski\*, Lake Michigan Air Directors Consortium, Rosemont, IL

Dr. Morton Lippmann, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

Dr. Helen Suh MacIntosh, Environmental Health, School of Public Health, Harvard University, Boston, MA

Dr. William Malm, National Park Service Air Resources Division, Cooperative Institute for Research in the Atmosphere, Colorado State University, Fort Collins, CO

Mr. Charles Thomas (Tom) Moore, Jr., Western Regional Air Partnership, Western Governors' Association, Fort Collins, CO



Dr. Robert F. Phalen, Center for Occupation & Environment Health, College of Medicine, Department of Community and Environmental Medicine, Air Pollution Health Effects Laboratory, University of California Irvine, Irvine, CA

Dr. Kent Pinkerton, Center for Health and the Environment, University of California, Davis, CA

Mr. Richard L. Poirot, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

Dr. Armistead (Ted) Russell\*, Department of Civil and Environmental Engineering, Georgia Institute of Technology, Atlanta, GA

Dr. Frank Speizer, Channing Laboratory, Harvard Medical School, Boston, MA

Dr. Sverre Vedal, Department of Environmental and Occupational Health Sciences, School of Public Health and Community Medicine, University of Washington, Seattle, WA

\*Members of the statutory Clean Air Scientific Advisory Committee (CASAC) appointed by the EPA Administrator.

\*\*As immediate past CASAC Chair, Dr. Henderson is invited to participate in CASAC advisory activities for FY 2009.

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**SCIENCE ADVISORY BOARD STAFF**

Dr. Holly Stallworth, Economist and Designated Federal Officer, Clean Air Scientific Advisory Committee, Environmental Economics Advisory Committee, Washington, D.C.

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9. Lewis M. *The Fifth Risk*. New York, NY: W. W. Norton & Company, Inc.; 2018.

**Appendices:**

**A. COMMENTS CONCERNING EPA’S INTEGRATED SCIENCE ASSESSMENT (ISA)  
FOR PARTICULATE MATTER (EXTERNAL REVIEW DRAFT-OCTOBER 2018)**

CASAC ISA Particulate Matter Comment by Dr. Jonathan Samet, submitted  
December 11, 2018

**B. COMMENTS CONCERNING EPA’S INTEGRATED SCIENCE ASSESSMENT (ISA)  
FOR PARTICULATE MATTER (EXTERNAL REVIEW DRAFT-OCTOBER 2018)**

CASAC ISA Particulate Matter Comment by Dr. Jonathan Samet, submitted March  
27, 2019

**Appendix A**

COMMENTS CONCERNING EPA'S INTEGRATED SCIENCE ASSESSMENT (ISA) FOR  
PARTICULATE MATTER (EXTERNAL REVIEW DRAFT-OCTOBER 2018)

Prepared by:

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Dean and Professor  
Colorado School of Public Health  
Aurora, Colorado  
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Submitted December 11, 2018

### **Background**

I write these comments from the professional perspective of being a pulmonary physician and epidemiological researcher who has carried out research on the health effects of indoor and outdoor air pollution for decades. My research has used the full range of epidemiological methods to assess associations of air pollution with health. As a consequence of my research background, I have been a member of numerous national and international committees concerned with the translation of scientific evidence into policy, including serving on various committees of the Environmental Protection Agency's (EPA) Science Advisory Board. With regard to Particulate Matter (PM), I was one of the Consultants to the Clean Air Scientific Advisory Committee (CASAC) for the review of the Criteria Document and Staff Paper that led to the 1997 PM<sub>2.5</sub> National Ambient Air Quality Standard (NAAQS). I chaired CASAC from 2008 through 2012 and, while in this role, I led the reviews carried out for the PM NAAQS. During that review, the transition to the current suite of documents related to the NAAQS review process was completed, resulting in the Integrated Science Assessment (ISA), the Risk and Exposure Assessment (REA), and the Policy Assessment (PA). I provided guidance to the EPA staff concerning frameworks for assembling and evaluating evidence, drawing on my experience as editor and author for the reports of the Surgeon General on smoking and health and various committees of the National Academies of Science, Engineering and Medicine that I chaired. Of these committees, the Committee on Research Priorities for Airborne Particulate Matter is particularly relevant, as the committee was tasked to identify the most critical scientific uncertainties around PM following the PM<sub>2.5</sub> NAAQS, to develop a research agenda addressing these uncertainties, and to track progress in resolving these uncertainties.

Since my term on CASAC ended, the EPA's approach for assembling and interpreting evidence with review from CASAC has proved effective. The approach is well-established (Figure 1); provides a transparent record of the concerns raised during the review, summarized in a letter to the Administrator; and changes in response to review are documented with a rationale provided. The scope of the documents reviewed and the breadth of the scientific evidence has necessitated the augmentation of the seven Chartered CASAC members with additional panelists and several cycles of revision and review of each consecutive document have been needed. The practice of expanding the panel beyond the Chartered CASAC members is long-standing. For example, I attach a table taken from the June 13, 1996 Closure Letter on the Staff Paper from Dr. George Wolff, CASAC Chair, to Administrator Browner ([Link to Letter](#)). This informative table lists the 21 panel members and their expertise, reflecting the broad range of disciplines required for comprehensive review of the lengthy documents assembled for reconsidering a NAAQS (Table 1). That scope cannot be captured with the seven members of the Chartered CASAC.

The sequence of the documents is consistent with usual risk assessment approaches: the ISA is concerned with hazard identification, providing an assessment of the strength of evidence for causation and a suite of outcomes for consideration in the REA. The approach to making judgments as to the causal nature of associations of PM with health outcomes draws on widely used approaches, embedded within various EPA guidelines and used by other entities, e.g., the

Centers for Disease Control and Prevention in evaluating the evidence on smoking and health. The REA considers selected health outcomes and assesses the burden of disease attributable to PM at current levels and levels that would prevail under various scenarios associated with changes in the NAAQS. The REA is a critical step in moving from the ISA and its identification of hazard to the PA, which guides the Administrator's decision-making.

This process has been in place for about a decade, undergoing small refinements. Generally, there is agreement that it has proved a workable approach to the complex task of moving from myriad scientific papers to the evidence that is most critical for possible revisions to the NAAQS. The Appendix to these comments includes a letter from seven former Chartered CASAC members, supporting the current approach and offering concern about not expanding beyond these seven individuals.

#### **The Current ISA Review**

Over two days, December 12 and 13, the charter CASAC members face the task of reviewing the draft PM ISA, numbering 1881 pages and occupying 19.4 megabytes. It was first released on October 23, allowing approximately 6 weeks for review by CASAC and the public. The CASAC has five general charge questions stemming from the "Back to Basics Process for Review of the National Ambient Air Quality Standards" and an additional eight, more specific, albeit challenging, questions. Examining the agenda, setting aside the time for administrative matters, presentations, and public comments, approximately 11 hours remain for the committee to do its work, including a writing session. The CASAC members will likely continue to refine their comments following the meeting, but this schedule for reviewing an enormous document cannot support the needed in-depth review.

With deference to the CASAC members, this mandated approach can at best result in a more superficial review and more cursory comments than achieved with the prior approach. As a first item on its agenda, CASAC should question the EPA staff on the new review approach and, specifically, how the consequences of this abbreviated process will be evaluated. Such questioning is justifiable, given how the review process has been altered and the implications of a hurried evaluation. The import of this first testing of the new review process needs to be fully understood.

#### **The Current ISA**

As noted, the current ISA is lengthy, reflecting the enormity of the literature. Quoting the ISA (P-10, line 18): "This ISA evaluates relevant scientific literature since the 2009 PM ISA...". Over that time period, the growth of the literature on PM and health alone has been substantial (Table 2). This table provides article counts from broad searches conducted on December 10, 2018 on topics relevant to this ISA. The scope of the literature available and considered is enormous with 2656 references cited in the first draft ISA.

Consider Chapter 5, *Respiratory Effects*, for example. This 340 page chapter covers a broad set of outcomes that are critically relevant to public health; the relevant literature covers particle characteristics and dosimetry, and findings from mechanistic, toxicological and epidemiological research. It covers not only PM<sub>2.5</sub>, but also PM<sub>10-2.5</sub> and ultrafine particles (UFP) across an array of health outcomes. There are 425 citations. The various lines of evidence are considered for each outcome and synthesized following the principles laid out in the Preface of the ISA. The ISA's findings reaffirm those of the 2009 ISA, without advancing conclusions with regard to the strength of evidence.

The CASAC review of this chapter should include panel members with expertise in lung toxicology, mechanisms of lung injury and epidemiology. Given the breadth of the outcomes considered, more focused expertise in some areas, e.g., asthma, is warranted. And, reviewers will likely need to examine some of the critical studies cited to assure that they have been correctly represented or to address study-specific concerns.

#### **Are Refinements Needed?**

Inevitably, any process for gathering, reviewing, and synthesizing evidence can be improved as experience is gained. While I have been supportive of the ISA as a format for gathering and reviewing evidence, new and more efficient approaches may be needed, particularly for PM and ozone, given the scope of the relevant literature. In the case of PM, by 2009, substantial evidence causally linked PM to a number of short-term and long-term adverse effects. These became the basis for the REA, an analysis supporting the PA and ultimately the Administrator's decision on NAAQS revision. When adverse effects of major public health concern have well documented causal links to PM, should the emerging literature be reviewed exhaustively? Could screening approaches be used to limit the number of comprehensive reviews considered in the ISA?

The REA remains a key step in developing evidence-based guidance for the Administrator. It would best be maintained as a free-standing document.

#### **Conclusions and Recommendations**

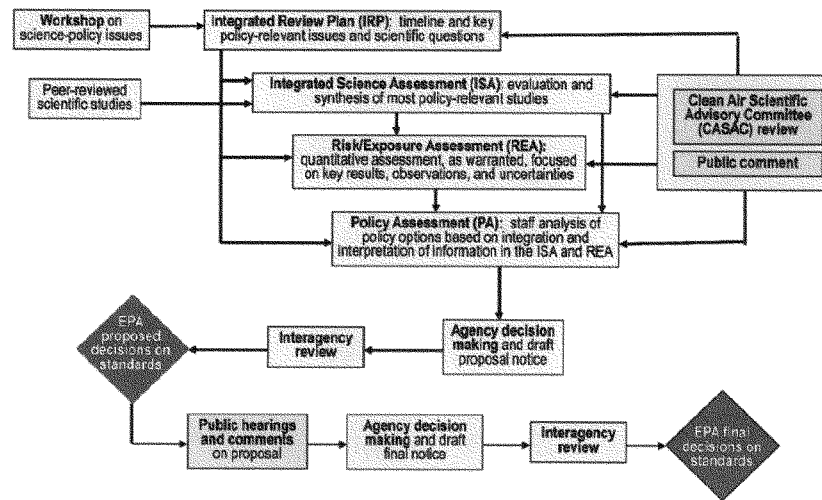
My comments concerning the formidable, if not impossible challenge, posed by review of the draft PM ISA have been echoed by others. Thus, with regard to the process for this review of the PM ISA, I recommend the following:

1. CASAC should provide its assessment of the feasibility and effectiveness of this accelerated review process, coinciding with not appointing consultant members to the PM panel. This first application of a new process should be closely scrutinized for its consequences.

2. The Science Advisory Board should undertake its own evaluation of the sweeping changes made to its review processes for the PM NAAQS and the consequences for the quality of its work.
3. The EPA staff need to continue to provide a written response to CASAC's principal comments; such documentation is critical if CASAC has only a single review meeting.
4. The size of the draft PM ISA contributes to the complexity of review, even without the changes to the review processes. The ISA was intended to be briefer and more integrative than the previous Criteria Documents. In that regard, the ISA has succeeded, but this approach to evidence gathering, evaluation, and synthesis is challenged by the enormity of the literature. Discussion is warranted as to how to scope the literature relevant to updating a NAAQS and to produce a sufficiently informative, but smaller document.



Figure 1. Schematic of the key steps in review of the National Ambient Air Quality Standards



U.S. EPA (U.S. Environmental Protection Agency). (2015). Preamble to the Integrated Science Assessments [EPA Report]. (EPA/600/R-15/067). Research Triangle Park, NC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment—RTP Division. <https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244>.

Table 1. Summary of CASAC Panel Members Recommendations (all units  $\mu\text{g}/\text{m}^3$ ), 1996

		PM <sub>2.5</sub> 24-hr	PM <sub>2.5</sub> Annual	PM <sub>10</sub> 24-hr	PM <sub>10</sub> Annual
Current NAAQS		N/A	N/A	150	50
EPA Staff Recommendation		18 - 65	12.5 - 20	150 <sup>13</sup>	40 - 50
Name	Discipline				
Ayres	M.D.	yes <sup>2</sup>	yes <sup>2</sup>	150	50
Hopke	Atmos. Sci.	20 - 50 <sup>3</sup>	20 - 30	no	40 - 50 <sup>4</sup>
Jacobson	Plant Biologist	yes <sup>2</sup>	yes <sup>2</sup>	150	50
Koutrakis	Atmos. Sci.	yes <sup>2,5,6</sup>	yes <sup>2,5,6</sup>	no	yes <sup>4</sup>
Lamitz	Statistician	no	25-30 <sup>7</sup>	no	yes <sup>2</sup>
Legge	Plant Biologist	75	no	150	40 - 50
Lippmann	Health Expert	20 - 50 <sup>3</sup>	15 - 20	no	40 - 50
Mauderly	Toxicologist	50	20	150	50
McClellan	Toxicologist	no <sup>9</sup>	no <sup>5</sup>	150	50
Menzel	Toxicologist	no	no	150	50
Middleton	Atmos. Sci.	yes <sup>2,3,12</sup>	yes <sup>2,5</sup>	150 <sup>3,13</sup>	50
Pierson	Atmos. Sci.	yes <sup>2,9</sup>	yes <sup>2,9</sup>	yes <sup>4</sup>	yes <sup>4</sup>
Price	Atmos. Sci./ State Official	yes <sup>3,10</sup>	yes <sup>10</sup>	no <sup>3,4</sup>	yes <sup>4</sup>
Shy	Epidemiologist	20 - 30	15 - 20	no	50
Samet <sup>1</sup>	Epidemiologist	yes <sup>2,11</sup>	no	150	yes <sup>2</sup>
Seigneur	Atmos. Sci.	yes <sup>3,5</sup>	no	150 <sup>13</sup>	50
Speizer <sup>1</sup>	Epidemiologist	20 - 50	no	no	40 - 50
Stolwijk	Epidemiologist	75 <sup>7</sup>	25-30 <sup>7</sup>	150	50
Uttell	M.D.	65	no	150	50
White	Atmos. Sci.	no	20	150	50
Wolff	Atmos. Sci.	75 <sup>3,7</sup>	no	150 <sup>3</sup>	50

<sup>1</sup> not present at meeting; recommendations based on written comments<sup>2</sup> declined to select a value or range<sup>3</sup> recommends a more robust 24-hr. form<sup>4</sup> prefers a PM standard rather than a PM standard 10-2.5 10<sup>5</sup> concerned upper range is too low based on national PM /PM ratio 2.5 10<sup>6</sup> leans towards high end of Staff recommended range<sup>7</sup> desires equivalent stringency as present PM standards 10<sup>8</sup> if EPA decides a PM NAAQS is required, the 24-hr. and annual standards 2.5 should be 75 and 25  $\mu\text{g}/\text{m}^3$ , respectively with a robust form<sup>9</sup> yes, but decision not based on epidemiological studies<sup>10</sup> low end of EPA's proposed range is inappropriate; desires levels selected to include areas for which there is broad public and technical agreement that they have PM pollution problems 2.5<sup>11</sup> only if EPA has confidence that reducing PM will indeed reduce the components 2.5 of particles responsible for their adverse effects<sup>12</sup> concerned lower end of range is too close to background<sup>13</sup> the annual standard may be sufficient; 24-hr level recommended if 24-hour standard retained

Table 2. PubMed Literature Search Results for Report Key Terms, 2009 – present

Search Term(s)	Number of Citations
Epidemiology and particulate matter	6639
Epidemiology AND particulate matter AND respiratory effects	1461
Epidemiology AND particulate matter AND respiratory health	1231
Epidemiology AND particulate matter AND cardiovascular disease	1406

APPENDIX

Andrew Wheeler  
 Acting Administrator  
 U.S. Environmental Protection Agency  
 1200 Pennsylvania Avenue NW, Washington, DC 20460

RE: Proposed changes to Clean Air Scientific Advisory Committee (CASAC) review process

December 10, 2018

Acting Administrator Wheeler:

We write as past members of the Clean Air Scientific Advisory Committee (CASAC) of the Science Advisory Board of the US Environmental Protection Agency (EPA) to express concern about the announced approach for CASAC review of the National Ambient Air Quality Standards (NAAQS), which eliminates the comprehensive peer review process that evaluates evidence related to the NAAQS and replaces the process with a single seven-person panel, comprised of the Charter CASAC members. Several of those signing this letter have served as Chair of CASAC (Samet, Frey, Hopke, Diez Roux), and we have expertise in the health effects of air pollution, coming from our research and patient care activities, as well as a range of disciplines pertinent to the NAAQS review. As a primary concern, we are united in suggesting that a seven-person panel cannot review and evaluate the documents prepared by the Agency in the process for consideration of revisions to the NAAQS. We are deeply concerned that eliminating the CASAC panels will lead to superficial reviews that will not have the needed scientific depth. The Charter CASAC, simply based on its number, cannot span the scope of science considered by the EPA as it guides the Administrator in assuring that the NAAQS will protect human health with an adequate margin of safety, as mandated by the Clean Air Act. Furthermore, for the current ozone and particulate matter reviews, the EPA is proposing a rushed schedule, which will reduce transparency, opportunity for public input, and the quality of the review.

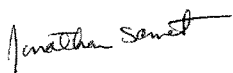
Those signing this letter are in agreement that the CASAC peer review process was not "broken"; quite to the contrary, an effective process had been established that led to high-quality and timely peer review that has directly informed NAAQS revisions. Scientific evidence has been the foundation for NAAQS revision and peer review is fundamental to the translation of scientific evidence into standards to protect the public health. The CASAC panels have typically included 14-15 members beyond the Charter CASAC to have the full range of expertise needed to cover the Integrated Science Assessment (ISA), Risk and Exposure Analysis (REA), and Policy Analysis (PA) documents. The range of topics to be covered includes atmospheric sciences, exposure sciences, toxicology, epidemiology and statistics, risk assessment, and

ecological and human welfare effects. For the most critical areas, such as epidemiology, several expert panel members have been included in the pollutant-specific review panels.

With these numbers and breadth of expertise, CASAC panels have provided comprehensive reviews that are then summarized by the CASAC Chair and approved by the Chartered CASAC before transmittal to the Administrator. CASAC has been augmented with additional expert scientists to form review panels for over three decades. The role of the Charter CASAC, and additional scientists added to complete pollutant-specific panels, is well specified in the series of documents developed by the EPA in support of NAAQS revision (see Figure 1 below from the 2013 ISA for Ozone). CASAC has recognized that the EPA documents need to be adequate for their intended purpose. In our experience, peer review by CASAC has resulted in substantial revisions by the EPA. In the past, CASAC typically provided two cycles of peer review per document, as each document was revised in response to CASAC comments.

We are deeply concerned that eliminating these levels of peer review and expertise will deprive the EPA of essential, independent scientific guidance that is needed to set NAAQS that are protective of human health. We request the opportunity to speak with the EPA's leadership on the process by which CASAC provides scientific input to the agency as the NAAQS are revised. Collectively, we have provided years of service to the agency on CASAC and its panels. We are hopeful that the tradition of assuring the best possible peer review will be maintained.

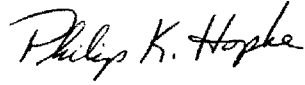
Sincerely,



Jonathan M. Samet, M.D., M.S.  
Dean and Professor  
Colorado School of Public Health  
CASAC Chair 2008-2012



H. Christopher Frey, Ph.D.  
Glenn E. Futrell Distinguished University Professor  
North Carolina State University  
CASAC Chair 2012-2015



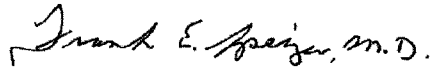
Philip K. Hopke  
Bayard D. Clarkson Distinguished Professor Emeritus, Clarkson University  
Adjunct Professor, Department of Public Health Sciences  
University of Rochester School of Medicine and Dentistry  
CASAC Chair 2000-2004



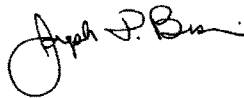
Ana V. Diez Roux, M.D. Ph.D.  
Dean and Distinguished University Professor of Epidemiology, School of Public Health  
Drexel University  
CASAC Chair 2015-2017



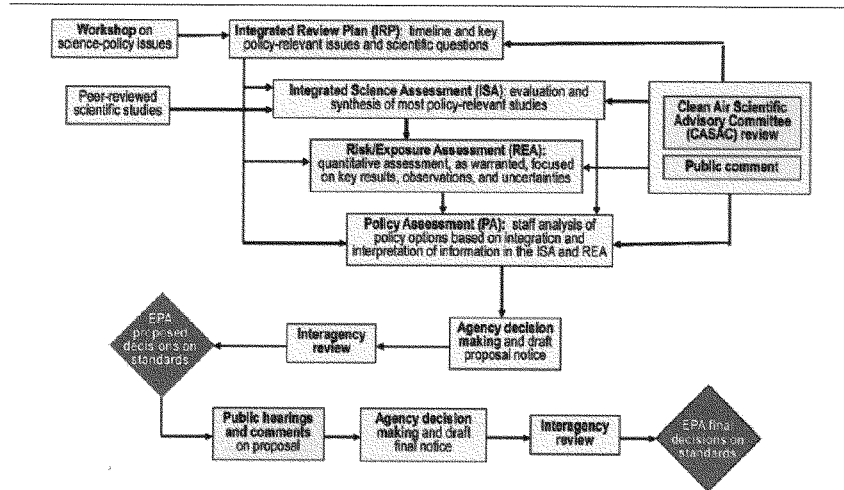
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Frank Speizer, M.D.  
Edward Kass Professor of Medicine  
Channing Laboratory  
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Joseph D. Brain, S. D. in Hyg.  
Cecil K. and Philip Drinker Professor of Environmental Physiology  
Harvard T.H. Chan School of Public Health



**Figure 1** Illustration of the key steps in the process of the review of National Ambient Air Quality Standards.



**Appendix B**

**COMMENTS CONCERNING EPA'S INTEGRATED SCIENCE ASSESSMENT (ISA) FOR  
PARTICULATE MATTER (EXTERNAL REVIEW DRAFT-OCTOBER 2018)**

Prepared by:

Jonathan M. Samet, MD, MS  
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Submitted March 27, 2019

### **Background**

Having provided comments at the December 12, 2018 meeting of the Clean Air Scientific Committee (CASAC) as it considered the first draft of *Integrated Science Assessment (ISA) for Particulate Matter (PM)*, I now offer comments on the processes used by CASAC in its review of the ISA. These earlier comments are appended. I elaborate my background at some length below because of its relevance to my comments.

I offer comments from the professional perspective of being a pulmonary physician and epidemiological researcher who has carried out research on the health effects of indoor and outdoor air pollution and other environmental agents for decades. As a consequence of that research, I have been a member of numerous national and international committees concerned with the translation of scientific evidence into policy, including serving on various committees of the Environmental Protection Agency's (EPA) Science Advisory Board. To reiterate the earlier description of my background, with regard to PM, I was one of the Consultants to the Clean Air Scientific Advisory Committee (CASAC) for the review of the Criteria Document and Staff Paper that led to the 1997 PM<sub>2.5</sub> National Ambient Air Quality Standard (NAAQS). I chaired CASAC from 2008 through 2012 and, while in this role, I led the reviews carried out for the PM NAAQS. During that review, the transition to the current suite of documents related to the NAAQS review process was completed, resulting in the Integrated Science Assessment (ISA), the Risk and Exposure Assessment (REA), and the Policy Assessment (PA). I provided guidance to the EPA staff concerning frameworks for assembling and evaluating evidence.

With regard to "accountability research", I chaired the first and second workshops on the topic for the Health Effects Institute (HEI), resulting in HEI Communications 11 and 15.

I have also been involved with providing guidance to EPA concerning revisions to the Integrated Risk Information System (IRIS), including incorporation of systematic review methodologies and judgments as to the strength of evidence. This guidance has come through three committees of the National Academies of Science, Engineering, and Medicine that I have chaired.

I have also participated in other activities involving evidence integration with the purpose of drawing causal conclusions. One long-standing model for weight-of-evidence approaches has been the reports of the Surgeon General on smoking and health; beginning with the landmark 1964 report, this series of reports, now numbering 36, has reached powerful conclusions on the causation of disease by active and passive smoking. As Senior Scientific Editor for the 2004 report, I led a recalibration of the methodology for causal inference applied in these reports, an approach then successfully used in a series of subsequent reports: the 2006 report on involuntary smoking, the 2012 report on youth, and the 50<sup>th</sup> anniversary 2014 report. More recently, I chaired the Working Group that revised the Preamble for the Monographs of the International Agency for Research on Cancer (IARC). That revision led to refinements to the IARC approach for evidence integration in order to better incorporate mechanistic evidence.

Since my term on CASAC ended, the EPA's now established approach for assembling and interpreting evidence with review from CASAC has proved effective. It has proved to be practicable in its implementation; it provides a transparent record of the concerns raised during the review, summarized in a letter to the Administrator; and changes in response to review are documented with a rationale provided; and its validity has not been questioned.

#### **The Current CASAC Review of the ISA**

Here, I complement my earlier comments, addressing the shift in approach for evidence assessment and inference that has been introduced with this review of the PM ISA. This shift was signaled by CASAC Chair, Dr. Tony Cox, in instructions to CASAC provided in advance of the December 12-13 meeting. In addition to making assignments related to charge questions, the memo directed the attention of the CASAC panel to a series of methodological and technical issues concerned with data analysis and interpretation of models, as well as to aspects of causal inference. The issues were posed as questions, representing additions to the charge questions provided by the EPA. Parallel comments were provided by Dr. Cox in the compendium of individual, pre-meeting comments dated December 10, 2018.

The final review comments submitted to EPA are extensive, providing useful comments on some issues, but pervasively, questions are raised concerning process that echo the earlier submissions, including the letter from Dr. Cox to the CASAC panel, the preliminary comments, and the letter submitted by Dr. Cox to Dr. John Vandenberg dated December 17, 2018. The intent is clear: to force a revision of the processes in place for the five-year review of the NAAQS. In its comments on the draft ISA, CASAC indicates that it does not find responsiveness to the methodological concerns raised in Dr. Cox's letter to Dr. Vandenberg.

Here, I do not offer a specific critique of the points raised by CASAC around methodologies for evidence identification and review, interpretation of models, and causal inference and classification of strength of evidence. My principal points are directed at process:

- I concur that methods for utilization of evidence in decision-making processes should not be static and that CASAC could usefully provide guidance on making changes in the approach used by EPA in meeting its charge for five-year reassessments of the NAAQS. Such changes should be measured and not disruptive as the EPA carries out the challenging task of reviewing the burgeoning evidence on PM (or other pollutants) on the timeline mandated by the Clean Air Act. If new approaches are to be adopted, then modifications cannot be made so far into the development of the ISA, as in this instance.
- The comments are described as "consensus" comments. Has there been sufficient discussion among CASAC members to assure that the comments do reflect a "consensus" view?
- Throughout EPA, evidence is the starting point for policy and regulations. A variety of approaches are used in evidence translation processes; the in-place processes for

NAAQS review have been considered exemplary and changes to them have sufficiently broad implications to merit in-depth review by the Science Advisory Board.

- And, if a change in a process that has proved functional through multiple NAAQS reviews is to be made, the methodology should be transitioned to an approach that is known to work. The questions posed to Dr. Vandenberg and the comments about process raised by CASAC appear to directly reflect the writings and formulations of Dr. Cox. Several publications cited in these documents appear to be the foundation for the suggested shifts in approach. These include:
  - Cox Jr, Louis Anthony Tony, and Douglas A. Popken. "Has reducing fine particulate matter and ozone caused reduced mortality rates in the United States?" *Annals of epidemiology* 25.3 (2015): 162-173. (13 citations)
  - Cox Jr, Louis Anthony. "Do causal concentration-response functions exist? A critical review of associational and causal relations between fine particulate matter and mortality." *Critical reviews in toxicology* 47.7 (2017): 609-637. (10 citations)
  - Cox, Louis, et al. "Applying nonparametric methods to analyses of short-term fine particulate matter exposure and hospital admissions for cardiovascular diseases among older adults." *International journal of environmental research and public health* 14.9 (2017): 1051. (3 citations)
  - Cox, Louis Anthony Tony. "Effects of exposure estimation errors on estimated exposure-response relations for PM<sub>2.5</sub>." *Environmental research* 164 (2018): 636-646. (0 citations)
  - Cox Jr, Louis Anthony. "Modernizing the Bradford Hill criteria for assessing causal relationships in observational data." *Critical reviews in toxicology* 48.8 (2018): 682-712. (0 citations)

I note that these papers were published from 2015 to 2018. To date, using Google Scholar, I find few citations by others, the hallmark of peer recognition and of scientific significance. These papers have had insufficient time to be considered by the scientific community in-depth. The approach and underlying methods proposed by CASAC cannot be considered the current state-of-practice.

Papers by others are cited, but publication dates are also recent. These references point to future directions around estimation of effects, but cannot be considered as redefining the state-of-practice.

- While I served as Chair of CASAC, apparently in response to stakeholder concerns, panel members were asked not to participate in discussions of their own work because of the potential for perceived or actual conflict-of-interest. Does that restriction remain in force? If so, the chair's advocacy for his own work should be considered as inappropriate.

- A close read of the CASAC comments shows abundant points of criticism, but steps 1-8, listed on pages 8 and 9 do not offer a framework that represents a sufficiently well-specified system for EPA to move forward.
- Many of the CASAC comments directed at the ISA, would be more appropriately raised when CASAC considers the draft Health Risk and Exposure Assessment (HREA). For that analysis, considerations related to model construction and assumptions, forms of concentration-response relationships and potential confounding are critical. In fact, the CASAC comments conflate the broader and holistic processes used to assess weight-of-evidence overall with the emerging techniques for estimation of “causal effects” from the data from particular studies.
- Are changes in methodology for NAAQS review within the mandate of CASAC? CASAC is an *advisory* committee and its mandate under the Clean Air Act is to provide guidance to the EPA. While there is no proscription on CASAC’s taking a more active role, the approach taken with this ISA represents a substantial departure from prior CASAC panels.
- I was surprised to find comments about prior documents and CASAC reviews (e.g., lines 16-18, page 1). First, the present CASAC was not charged with reviewing prior documents, but the latest draft ISA; and second, what is the basis for this statement? Is this statement the view of the full panel? A further example can be found in Dr. Cox’s comments on pages A-14 to A-15, which offer an opinion, without evidential analysis, on the conduct of prior reviews and even on the expertise of prior CASAC panels.
- I concur with the sensible recommendation to expand the panel with consultants as originally planned. As I have commented previously the seven members of the chartered CASAC cannot hold the breadth of expertise needed to review this 1,881 page draft. As one outcome of this meeting, CASAC should identify the additional expertise needed, including at the least an experienced environmental epidemiologist, an expert in exposure sciences, and an environmental statistician.
- As a starting point for any substantive changes to the NAAQS review methodology, CASAC should consider requesting consultation with the full SAB and move towards workshops that would provide a proper venue for in-depth discussions. The issues considered here do not lend themselves to teleconferences. Solicitation of a report from the National Academies of Science, Engineering and Medicine is an alternative to the SAB.

Bottom line: the NAAQS review is on a very tight timetable. CASAC has already been crippled by the restriction of the reviewers to the seven chartered members. Of the extensive comments provided by CASAC, many are useful, but a new draft ISA cannot be built around a still unspecified and untested framework for evidence evaluation and integration.

Clean Air Act Amendments of 1977 (42 U.S.C. § 7409(d)(2))  
The Clean Air Scientific Advisory Committee

(A) The Administrator shall 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.

(B) Not later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 7408 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 7408 of this title and subsection (b) of this section.

(C) Such committee shall also (i) 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, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) 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.

**Jonathan Samet, M.D., M.S.**  
**Dean and Professor**  
**Colorado School of Public Health**

**Jonathan M. Samet**, a pulmonary physician and epidemiologist, is Dean of the Colorado School of Public Health and Professor in the departments of Epidemiology and Environmental & Occupational Health. Dr. Samet received a Bachelor's degree in Chemistry and Physics from Harvard College, an M.D. degree from the University of Rochester, School of Medicine and Dentistry, and a Master of Science degree in Epidemiology from the Harvard School of Public Health. His research has focused on the health risks of inhaled pollutants—particles and ozone in outdoor air and indoor pollutants including secondhand smoke and radon. He has also investigated the occurrence and causes of cancer and respiratory diseases, emphasizing the risks of active and passive smoking. He has served on and chaired numerous committees of the National Academies of Science, Engineering and Medicine and also chaired the EPA's Clean Air Scientific Advisory Committee and the FDA's Tobacco Products Scientific Advisory Committee. He chaired the working group of the International Agency for Research on Cancer that classified Radiofrequency Electromagnetic Radiation as a possible carcinogen and also chaired the Biological Effects of Ionizing Radiation (BEIR) VI Committee of the National Academies. Dr. Samet has served as editor and author for Reports of the Surgeon General on Smoking and Health since 1984, receiving the Surgeon General's Medallion in 1990 and 2006 for these contributions. He received the 2004 Prince Mahidol Award for Global Health awarded by the King of Thailand, the Edward Livingston Trudeau Medal from the American Thoracic Society/American Lung Association, the Luther L. Terry Award for Distinguished Career from the American Cancer Society, and the Fries Prize for Health. He was elected to the National Academy of Medicine in 1997 and received the Academy's David M. Rall Medal for his contributions in 2015.

Chairwoman SHERRILL. Thank you. And, as the Chair, I would like to thank all of our panel for hewing so closely to the time limit. Next we'll begin our first round of questions, and I'm going to recognize myself for 5 minutes.

My first question is for Dr. Burke. In your testimony you note that being appointed to the EPA Science Advisory Board has traditionally considered an honor reserved for the best scientists in our Nation. I'm concerned that following former Administrator Pruitt's directive, which bars EPA grant recipients from serving on advisory committees, this is no longer the case. So in your experience, both as a scientist, and as the former Deputy Assistant Administrator for EPA's Office of Research and Development, how competitive are the EPA grants?

Dr. BURKE. Thank you for that question. The EPA grants, which are unfortunately now few and far between, as we've seen the reduction in the Science to Achieve Results Program at ORD, were incredibly competitive, and they were reviewed independently from the Agency by experts, and ranked, just as we have a review system at the National Institute of Health (NIH). They're very competitive, awarded to the best and brightest in the field. And, therefore, receiving those grants meant a certain degree of recognition out through academic science, but also in the general environmental science community, just as being appointed to the SAB would be seen as that recognition. So they're very competitive.

What you have, when you omit those folks from the talent pool of our Nation's most prestigious advisory board, is a skewing that eliminates the best minds. What other area of science would you omit the best minds at the start, and not consider the potential conflicts of interest of people who may have direct financial interest, or have received compensation from companies that have a very big vested interest in the subject at hand.

Chairwoman SHERRILL. And speaking of conflicts of interest, what do you think about the justification for the order that precludes them from participating because of a conflict of interest?

Dr. BURKE. The—I'm—to clarify the question, the order that precludes the—

Chairwoman SHERRILL. Grant recipient.

Dr. BURKE. That conflict of interest—financial conflict of interest is something that is very important. However, these grant processes are—imagine if we did that from peer reviewing of the NIH grants. This is something we deal with in science. It's very clear to see if there's a direct conflict, and those grant recipients don't financially benefit directly from the regulatory decision down the line. This is a convoluted process, and it's skewed to eliminate, I think, unfortunately, many of the great independent scientific experts in our academic community, while not offering similar protections from others.

Chairwoman SHERRILL. Thank you. And then my next question, industry representatives and consultants are notably not included in the directive claiming to strengthen independence of Science Advisory Committees, so it's certainly important that these boards consist of diverse perspectives. But this double standard seems absurd on its face, and it's especially concerning considering GAO's finding that appointees' financial disclosure forms have not been



properly handled. So, Mr. Gomez, can you please remind me of what the GAO found regarding the Ethics Office's review of financial disclosures?

Mr. GOMEZ. Sure. So we did an audit of the financial disclosure forms, and so we audited 74 different firms for special government employees and the committees, and in that review we did find that there were 17 of those forms that had not been signed and dated, so there was really a lack of assurance that those folks—that EPA had done the review, and that those folks were free of conflicts. So one of the things that we did is we recommended that the Agency strengthen the oversight of the ethics review program to do, for example, regular checks, and oversight, and spot checks to ensure that its ethics review program is working well.

Chairwoman SHERRILL. And, Dr. Burke, in light of the 2017 directive, could those on the payroll of regulated industry be considered to have “a conflict of interest,” at least as significant as EPA grant recipients?

Dr. BURKE. One would certainly think so. If you're sitting on that board, and a matter of perhaps the toxicity of a product from the industry that you work for is being considered, that could represent the appearance of a conflict of interest, or perhaps a direct financial conflict of interest. So that has to be carefully considered in the forms in the ethics review. And we all have received training from the Agency. It's mandatory before you're appointed to go through the training, to understand and report those apparent conflicts. We have in science, both at the National Academy and through major science advisory boards, ways to work around that, and to prevent those conflicts, and they need to be enforced.

Chairwoman SHERRILL. Thank you. My time has expired, so now I'm going to recognize Mr. Norman for 5 minutes.

Mr. NORMAN. Thank you, Chairwoman Sherrill, and I want to thank each of the panelists for taking the time to come. Mr. Gomez, do you agree that any legislative action requiring Federal Advisory Committee should require the membership of the advisory committee to be fairly balanced, in terms of the points of views represented, and the functions to be performed by the Advisory Committee?

Mr. GOMEZ. So generally, sir, the charters for each committee spell out, you know, the composition, the membership. Sometimes Congress may actually dictate, you know, whether folks should come from a particular interest. So what we did is we looked at, for each committee, what was the charter stating, also what are the—any directives, or legislative direction, and most of the committees do have that charge of bringing balance and—to the committee membership.

Now, in a lot of the committees that we looked at, there isn't really a percentage that says X number should be this, and Y number should be that. It is really at—left up to the staff at EPA to decide what is it that the committee needs—or what is it that the office needs, and they usually try to get that into the advisory committees.

Mr. NORMAN. So the answer would be yes, you think the views should represent the whole committee?

Mr. GOMEZ. That's usually what's spelled out in the charter for each of the committees—

Mr. NORMAN. OK.

Mr. GOMEZ [continuing]. Yes, that there should be balanced representation, however that's defined.

Mr. NORMAN. All right. I'm sure you know this, but there's a direct quote from Public Law 92-463, better known as the *Federal Advisory Committee Act, FACA*. With your answer in mind, do you think that if one stakeholder group make up over 80 percent of a single advisory committee that that would be fairly unbalanced?

Mr. GOMEZ. So, again, in our audit we were looking at what process the EPA has in place, and whether EPA followed its process. Our audit wasn't looking at whether the representation or the composition of the committee was balanced or unbalanced, so we don't have an opinion about what the balance should be. Our audit was a process audit to look at, hey, did EPA—does EPA have a process in place, what is it, and did they adhere to that process?

Mr. NORMAN. So yes or no?

Mr. GOMEZ. Well, we don't have an opinion on that, sir.

Mr. NORMAN. OK. According to your report, at one point, in 2010, academics made up 80 percent of the Science Advisory Board. You know, I don't have anything against academics, but if that 82 percent of members were from industry, I think we'd all point to a pretty big problem. So help me understand. I know academics are world leaders in the field, but wouldn't it be beneficial to have different perspectives, at least more than 18 percent of membership, from consultants and non-governmental organizations (NGOs)?

Mr. GOMEZ. Again, we don't have an opinion on what the make-up of the committee should be. You know, that's something that comes from EPA, in determining what is it that they need, representation, and if there's any direction, either legislative direction, or direction from the charters.

Mr. NORMAN. OK. I get that you don't have an opinion on it, but wouldn't it make sense to have different perspectives from these other groups, other than academia?

Mr. GOMEZ. I think so. I mean, I think that's what a lot of the committees call for. They want independent scientific advice from a variety of viewpoints, yes.

Mr. NORMAN. OK. Thank you. And last, Mr. Gomez, this GAO report was made public yesterday, at 1:35 p.m., just barely over 24 hours before the gavel today. As far as I'm aware, none of the minority Members on this Committee were offered a chance to review a draft copy, but the majority was able to send out a summary of the full report just 3 minutes later. Did you provide the majority with a draft copy of this report before the hearing?

Mr. GOMEZ. We did not, sir.

Mr. NORMAN. Then how else could the majority have obtained a copy of this report?

Mr. GOMEZ. So I think the majority maybe can speak where they obtained the copy of the report, so—we—so the report was for Senate staff, Senate requestors, and so the, you know, whoever requests the report can give it to whoever they decide, so—

Mr. NORMAN. But you didn't provide it?

Mr. GOMEZ. No.

Mr. NORMAN. OK. Thank you. Appreciate it. I yield back.

Chairwoman SHERRILL. And next the Chair will recognize Chairwoman Fletcher, 5 minutes.

Chairwoman FLETCHER. Thank you, Chairwoman Sherrill. Speaking of the GAO report that was released yesterday. It did highlight a couple of areas of concern in the EPA's process for appointing members to advisory committees. First, as discussed, that the Agency didn't follow its own internal appointment process for two major scientific advisory committees, the CASAC and SAB. In EPA's response to the GAO's report, they stated that the process the Agency used for appointments to SAB and CASAC was more rigorous than the membership grid procedure that is standard for all other committees, and requested GAO remove its first findings from the report entirely. However, it's interesting to note that this supposedly more rigorous process was not utilized for other committees. Mr. Gomez, did you find any evidence that EPA used in-person briefings for other advisory committees, perhaps in addition to the prepared membership grids?

Mr. GOMEZ. We're not aware of that. So for the—it's only for the two committees that we found, where they deviated from the process. So we're not aware that this was also done for the other committees.

Chairwoman FLETCHER. And if you found that it was only done for these two committees, how did EPA justify its use of this supposedly improved procedure for only two of its committees?

Mr. GOMEZ. I mean, that's a good question. They didn't justify it to us, except that the explanation was just that they deviated, and came up with an alternative process. We don't understand why—or why they also didn't follow their established process.

Chairwoman FLETCHER. So what is GAO's assessment of the procedure used for SAB and CASAC appointments, and the elimination of the membership grid?

Mr. GOMEZ. So, again, we looked at what the Agency is required to follow, according to their Handbook, and we lay out those procedures, and one of those key steps was that they develop these grids that, you know, has relative qualifications, and it's also the staff's recommendation for the best qualified staff. And so we don't understand why EPA didn't follow that for these two committees. It's not clear to us why, and so we don't have an explanation.

Chairwoman FLETCHER. Did EPA indicate to you that this new examination, more rigorous examination of candidates, was going to become incorporated into the Agency's Handbook?

Mr. GOMEZ. We asked that question, and we did not get a response as to whether this new alternative process is going to be a new procedure in their Handbook.

Chairwoman FLETCHER. OK. Thank you. And one last question on this particular topic, is it unusual for agencies to request findings be removed from draft reports? What information would agencies need to provide to you to compel GAO to change its report findings?

Mr. GOMEZ. Sure. So we have a standard practice of giving agencies our draft reports because we want their reaction, right? We want them to review what we have to make sure it's accurate. And so they generally will provide us comments, and sometimes it hap-

pens that we disagree, right? We disagree, and we generally want to have data and information because, you know, we are data driven, so we want to assess the data, if there's additional data. In this case, we didn't get any additional data from EPA to allow us to make any additional assessment. So sometimes it happens, and, as you noted, it's recorded in the report.

Chairwoman FLETCHER. Thank you. One additional topic I want to touch on, the GAO also found that 23 percent of the Advisory Committee members appointed as special government employees (SGEs) did not receive a signature from an ethics official on their SGE filing form, which ensures an employee's compliance with Federal ethics rules. Are you able to comment on the nature of the SGE ethics forms that remain unsigned?

Mr. GOMEZ. So that's a good question, and I think we can provide for the record, like, where those forms were. I do know that some of those forms were for members of the SAB, but we can give you a listing of the committees that those pertain to.

Chairwoman FLETCHER. Thank you, we would like to see those. Will the GAO be conducting any additional research into the individuals who had not yet received signature on their ethics forms?

Mr. GOMEZ. Not additional reviews, no.

Chairwoman FLETCHER. And have you seen this occur in other instances during your tenure at GAO? Is this a common occurrence, or an unusual occurrence?

Mr. GOMEZ. So I'd have to get back to you on that, because I want to doublecheck to see if there have been other audits that we've done at other agencies, where we're looking at their ethics program, and to see whether, in fact, we found similar findings. So we can check to see if there are other audits we've done governmentwide, or other agencies, but I'm not aware at this moment.

Chairwoman FLETCHER. Well, can I take it from your answer, that this is something that you have to research and go back and look at, that this isn't a common or routine occurrence, that you would expect for so many ethics forms to be missing, a quarter of them?

Mr. GOMEZ. Again, I don't know what—how it's at other agencies, whether—I mean, this was, for us, a finding that rose to the level of us making a recommendation, because we saw so many forms that hadn't been properly reviewed, signed, and dated, and so that concerns us, because we want to make sure that EPA has a good process in place to ensure that they are doing ethics reviews on a timely basis, again, to ensure that there are no conflicts of interest. So we thought it was important enough that it rose to the level of a recommendation that we made to EPA. EPA has agreed with our recommendation, and, as I understand it, they've already taken steps to improve that process.

Chairwoman FLETCHER. OK. Thank you, Mr. Gomez. We'll look forward to receiving the additional information from you, and I have gone over my time, so, Madam Chairwoman, I yield back.

Chairwoman SHERRILL. Thank you. The Chair now recognizes Ranking Member Marshall for 5 minutes.

Mr. MARSHALL. Yes, thank you so much. I'll keep with Mr. Gomez for a second. Want to continue to talk about this alternative process of evaluating candidates. Did you feel that what they did

do in these two instances was as rigorous as the prescribed Handbook procedure?

Mr. GOMEZ. Well, sir—so we didn't have an opportunity, because we didn't get any data on what EPA did, so EPA just told us that they had briefings with senior management, where they discussed the advantages and disadvantages, or plus and minuses, of candidates. But for all the other committees that we viewed, you know, we had those grids, those documents. We were able to see these—this is how the committee nominated folks, and this is who they viewed was most qualified. For EPA, we weren't able to see that, so we weren't able to make that assessment.

Mr. MARSHALL. In those two, but in the other 20 committees, from a broad, holistic perspective, did you think the EPA was doing a satisfactory job in their advisory board appointments?

Mr. GOMEZ. Yes, sir.

Mr. MARSHALL. OK. Maybe go back to everybody left, the witnesses, do you feel there's any two committees that EPA could eliminate, Dr. Samet?

Dr. SAMET. I would actually probably defer to my colleague, Dr. Burke, who has a broad perspective on the various committees. And, given the broad—breadth of EPA science, its multidisciplinary, I suspect that there's a rather lean set of committees, but I would defer to Dr. Burke on this.

Dr. BURKE. There are, I think, 18, 18, and 22 committees at EPA, and they represent a tremendous amount of different interests. For instance, there's a Committee on Environmental Justice, there's a—

Mr. MARSHALL. I'm sorry, it's kind of a yes or no. Do you think there's some that could be eliminated?

Dr. BURKE. I would think that, as has been mandated by the executive order, to carefully study and understand the criteria would be necessary before saying they should be eliminated, so—

Mr. MARSHALL. But they could be absorbed, or combined, or something like that?

Dr. BURKE. I would really defer to the process on that. I can't say. I found them to be tremendously influential and important, and particularly important to the business community, as—

Mr. MARSHALL. And there is a process that if they're declared essential, we can bypass that. I'll go back to Mr. Gomez. Looking at your charts on just the proportion of academic members in a committee, your SAB report, 22 academic members, and there's five industry members, about an eighth of it is industry. What is an ideal ration of academic to non-academic, and how do you get there?

Mr. GOMEZ. Again, that's a good question, and I think that that's driven, as I mentioned earlier, by the charter of the committee, and whatever the needs are of EPA, to make those determinations. Again, we were not looking at what's the proper composition. That wasn't our focus. Our focus, again, was a process audit, to look at what's the process, did EPA follow the process, and if not, you know, what is it they can do to improve it?

Mr. MARSHALL. Yes. I mean, I kind of look at things through healthcare, since I'm a physician, and I think of recommendations for pap smears and mammograms, and the academic folks telling us you only need a pap smear every 3 years, young women don't

need mammograms, but I was the person down there with the experience, trying to tell a woman why she didn't need that pap smear, or didn't need a mammogram, and really I thought it was in her best interest to get it. And I really think that there's a great place for people from industry, and non-academics. And I guess I would almost take exception that people on the committees are the best and the highest qualified, with my experience in medicine is the brightest, the greatest, were so busy, so popular, had such a long waiting list, they didn't have time to do some of these committees. So I think it's a different pool of people that are even available to have the time, and really think that we should keep really emphasizing non-academic members on some of these committees. So, with that, I'll yield back the remainder of my time.

Chairwoman SHERRILL. Thank you. And next the Chair recognizes Representative Lamb for 5 minutes.

Mr. LAMB. Thank you, Madam Chairwoman. Dr. Burke, I just wanted to ask you kind of a series of questions with pretty short answers, if you don't mind. You have appointments at Hopkins in both Environmental Health and Oncology, is that right?

Dr. BURKE. Yes.

Mr. LAMB. And is that because, over time, we've learned that there can be a link between industrial activity, and what that puts into the environment, and rates of cancer among people that work there, or people that live near wherever that site is?

Dr. BURKE. Yes. I've devoted my career to that kind of science.

Mr. LAMB. So could we actually say, in some sense, your job has to do with trying to prevent cancer in people that live near these places? You're studying the effect that it has in the hope that maybe at some point we can do things to prevent people from getting cancer?

Dr. BURKE. I think that's what epidemiologists strive for, not just for cancer, but for all environmentally related diseases.

Mr. LAMB. Right. And in doing that, do you employ something called the scientific method?

Dr. BURKE. Yes.

Mr. LAMB. And there's different ways to describe that, but I remember, at least from being in school, that the scientific method is a process that we've constructed over the years, where maybe first you observe, and then you measure things, and then you might do experiments, and then you construct a hypothesis, but then you continue to change that and refine it as you learn more. Is that, like, a fair general description of the scientific method?

Dr. BURKE. Absolutely.

Mr. LAMB. OK. Now, when you start out on any scientific problem, and you want to employ the scientific method, is it important that you try to eliminate, or put to the side, any biases that you might have about the problem before you start it?

Dr. BURKE. I think it's important from the start to the finish of scientific work to try and understand biases, and to put them forth, and to deal with them throughout the process.

Mr. LAMB. Yes. And that's actually—would you say that's kind of what separates a real scientist from, say, an advocate, or even, like, a politician like me?

Dr. BURKE. I'm so glad you mentioned that, because we're getting our signals mixed here today between stakeholder comment and scientific peer review. I agree that stakeholders have an enormous role to play in policy decisions, but with scientific peer review, it's about expertise, and the right disciplines at the table.

Mr. LAMB. Thank you. Yes, I thought the use of the word stakeholder was a little bit odd as well, because if you have someone, for example, like you, who has chosen to devote their career to trying to prevent people from getting cancer, it doesn't really seem to me like you have a stake, other than just what's good for society. So I don't know that that's the best word to use to describe your role in the process. And I thought your list was great of the most challenging and pressing environmental problems right now, because I think you had eight on there. Of those eight, seven of them pretty directly impact people in western Pennsylvania, where I'm from, every single day, just due to our history, and the economic activity that we have right now.

So just to pick one, you mentioned the report that you worked on about the impact of fracking on drinking water, and western Pennsylvania is more or less the capital of hydraulic fracturing, at least in the northeast. I have lots of constituents that live near drilling sites, that have family members that live near drilling sites. We have well pads at our airport, which, you know, a lot of people in our region go through all the time. So the main thing that we all want to know is that when we turn on the tap in our houses, or you drink water from the fountain at the airport, whatever it is, that there's a pretty good chance you're not being poisoned, or being exposed to something that can give you cancer. And we know that none of us are ever going to know that for sure. I don't know exactly where every well pad is, or how it's influencing, but you want to have some trust there, right? We always say a cop on the beat. I mean, that's a fair analogy, right, the idea that you guys are neutrally investigating for the good of the public about these questions, right?

Dr. BURKE. Yes.

Mr. LAMB. So that report that you did while you were at EPA, and you used the Science Advisory Board as part of that, would that be part of that process, kind of, of being the cop on the beat to protect the public, and the water that they drink, in a place like mine?

Dr. BURKE. I might use a different analogy. We weren't cops. It wasn't a regulatory report. It was trying to do public health to understand a fundamental question, are the activities related to fracking impacting our water resources, particularly our drinking water resources, because that was the burning question.

Mr. LAMB. Yes, it's a good point. You're kind of doing the part of the cop's—I'm a former prosecutor, which is why I use that analogy, but you're doing the part of the cop's job that actually comes first, which is just that basic act of observing, and measuring, and recording what happened.

Dr. BURKE. Right.

Mr. LAMB. Before we decide who we need to arrest or prosecute, what exactly happened here is a question of fact. And so, doing that report, you had to use the scientific method, again, in order

to determine what might be happening to our drinking water, right?

Dr. BURKE. Yes, sir.

Mr. LAMB. And wouldn't it be fair to say that to learn about our drinking water using the scientific method, to write a scientific report, it would've been a good idea to have actual scientists involved in that process, right?

Chairwoman SHERRILL. And if you could answer quickly? The gentleman's time has expired.

Dr. BURKE. Yes. And they were, and it was a very rigorous—

Mr. LAMB. And that's what you were trying to do. Thank you. I'm sorry I went over my time. And, as you noted, I'm sure we'll continue to explain, there are lots of ways that the industry has input into this process along the way, because, as you noted, you were not making the regulation. You were finding out what happened, and what could be happening, to our drinking water, and I thank you to that. I yield back, Madam Chairwoman.

Chairwoman SHERRILL. Thank you. And now the Chair recognizes Representative Babin for 5 minutes.

Mr. BABIN. Thank you very much, Madam Chair, and thank you, witnesses, for being here today. Mr. Gomez, are EPA ethics officials, are they career staffers?

Mr. GOMEZ. Yes, sir.

Mr. BABIN. OK. So, from your finding and recommendation, you're saying that EPA career officials, however many in number they may be, are not doing their job? Is that what you're saying?

Mr. GOMEZ. So our finding was that, yes, I mean, we found cases, 17 cases, where the financial disclosure forms had not been signed and dated, so really there was no assurance that someone had reviewed them. We also did find cases where, you know, forms weren't reviewed and signed within the allowed time, 60 days, and so the explanation that we got from EPA was that they were short staffed in that office, and so, since then, they've added additional people, and they have noted that they're doing a more regular review to make sure that the folks that are sometimes the designated folks to review those forms are doing it in the right way, and within the right amount of time.

Mr. BABIN. OK. Thank you. And then, as the Ranking Member on the Space Subcommittee, I have the pleasure of hearing from NASA witnesses on almost a weekly basis, and yet it seems it's not very often that someone brings up criticism of their advisory boards, especially any that may be as large as the EPA Science Advisory Board. Is it fair to say that the Federal Advisory Committees at NASA would share the same essential to best science outlook as EPA's committees? Dr. Burke?

Dr. BURKE. Yes. I would hope that all the agencies—I'm sorry.

Mr. BABIN. OK.

Dr. BURKE. I would hope that all agencies depend upon Federal advisory committees that do bring the kind of expertise they need, especially science agencies like NASA, like Agriculture, like EPA.

Mr. BABIN. OK. And anybody else want to take a stab at that? OK. All right. And along with the two Ranking Members here today, I have my concerns on the scope of this hearing. NASA has some crucial advisory committees. Department of Energy has some



crucial advisory committees, and so does the National Science Foundation. The list goes on. Science informs decisions at agencies other than the EPA, and I think this hearing could've been a chance to hear from all of them, instead of repeating this show at the Full Committee level in a couple of weeks. And, with that, I yield back, Madam Chair. Thank you.

Chairwoman SHERRILL. Thank you. The Chair now recognizes Representative McAdams for 5 minutes. Is he here? He's not here, so we will go on to Representative Wexton for 5 minutes.

Ms. WEXTON. Thank you, Madam Chair, and thank you to the witnesses for appearing today. Much has been said, both today and over the past 2-1/2 years by observers of EPA's actions, about the danger of politicizing these boards, and filling them with unqualified appointees, climate deniers, and a high number of individuals who are financially dependent on regulated industries. In its report, the GAO pointed to BOSC as a committee with unusually high turnover—71 percent of those on BOSC on January 19, 2017, were no longer serving on the Board 15 months later. This mass exodus of individuals who are aware of the specific purpose and functioning of BOSC is concerning. Dr. Swackhamer, why is it important that these advisory boards include a number of individual members with experience advising the Agency? Why do we need to make sure we do that?

Dr. SWACKHAMER. Thank you for that question. I think it's always important not just for BOSC, but for lots of these advisory committees, to have some expertise from previous generations of these boards, you know, previous iterations of these boards, to carry forth understanding of what's going on before them, the depth of some of these issues. Some of these issues take more than 2 or 3 years to actually get through, and so you need a certain number of people on the committee that understand that context. They provide a lot of context.

The other thing is that EPA is actually a very complicated Agency, and to understand the science that's being done at EPA actually takes quite a while to figure out who's doing what, how it's—how it connects to the regulatory mission of EPA. It's a complicated—often it's called a Byzantine Agency. And so, you know, it probably took me, you know, a full year of being on BOSC, before I was chair, to even understand how it all worked. And so you kind of come in as a freshman, and you learn the ropes. And so then to lose, you know, 80 percent, 70 percent of that expertise in one fell swoop was devastating. And, of course, it then took months to even bring in new people. But now the new BOSC is considerably made up of freshmen.

Ms. WEXTON. And that impacts their effectiveness as an advisory committee, would you agree?

Dr. SWACKHAMER. I think it just means that their learning curve—they're still on a learning curve, instead of being at the top of that learning curve, and they're not benefiting from having enough people on that committee who can kind of bring them up to speed, and provide that expertise.

Ms. WEXTON. Very good. Thank you. Dr. Samet, thank you for your thorough overview of CASAC's role in developing adequately protective standards for the health and safety of Americans. It con-

cerns me that the Administration that is so bent on diluting science's role in regulatory decisions is now responsible for creating these important standards. In particular, the EPA has cut expert subpanels on particulate matter and ozone, but it seems they are still planning on completing the regulatory process by the end of next year. Dr. Samet, is EPA permitted to raise the allowable threshold of a pollutant?

Dr. SAMET. The *Clean Air Act* requires that the Administrator set a standard that is protecting the public health, with an adequate margin of safety, for the National Ambient Air Quality standard pollutants. In that context, given the lengthy record of evidence review and findings that the standards are either protective, or, in the case of particulate matter and ozone, in fact, there's concern that we cannot achieve standards that will provide that protection with an adequate margin of safety, it would be difficult for me to see how a true science-based review would lead to the possibility of raising the standards. It certainly is a concerning possibility, but, given the mandate—strong public health mandate of the *Clean Air Act*, I would hope that the possibility to which you refer would never take place.

Ms. WEXTON. So does it appear to you that the EPA is setting the stage for weakening the standards for ozone and particulate matter, from what you have observed?

Dr. SAMET. The questions that will come to the Administrator would be whether the NAQS for either ozone or PM needs to be revised. The science processes that would lead to that decision have typically been looked at as—the possibility of lowering the standard values. Perhaps one of the threats could be that evidence that has been viewed in the past is supporting evidence of harm, and the need to reduce the standards, would be set aside under some of the approaches for evidence evaluation and inclusion or exclusion, i.e. the transparency rule, as an example, which probably most threatens epidemiological evidence.

Ms. WEXTON. And, in your view as a pulmonary physician and as an epidemiologist, would it be scientifically justifiable for the EPA to weaken the standards for ozone and particulate matter at this time?

Dr. SAMET. From my—

Chairwoman SHERRILL. And, again, if you could just go quickly? The gentlewoman's time's expired.

Dr. SAMET. OK. From my own perspective, the evidence, particularly the epidemiological evidence, indicates ongoing risk at current levels of exposure.

Ms. WEXTON. Thank you. Thank you, Madam Chair, for your indulgence. Yield—

Chairwoman SHERRILL. Thank you. And now the Chair recognizes Representative Baird for 5 minutes.

Mr. BAIRD. Thank you, Chairwomen Sherrill and Fletcher, and Ranking Members Norman and Marshall, and I really want to thank the witnesses for being here today. And my question goes to each of you, or all of you, and it has to do with the fact that all of you are very familiar with the Science Advisory Board, but the National Academies have a similar process in putting together their panels. Do you think the SAB, or other advisory committees,

could mimic parts of that National Academy process, and if so, what would be the benefits of doing that? And, Mr. Gomez, you can start—or, no, I see Mr. Samet's ready to go.

Dr. SAMET. Thank you. I'll speak to this as a more than 20-year member of the National Academy of Medicine, previously the Institute of Medicine. I'm quite familiar with those processes. There the committees are addressing particularly charged questions, and assuring that both there's a balance of scientific views on whatever the matter may be, and that there is no conflict of interests. In a sense, the process is somewhat akin to that of the Agency in picking the scientific disciplines that need to be represented to provide guidance to the Agency. There are certainly, at the National Academies, considerations of potential conflicts of interest and ethics. A potential conflict alone might not be the basis for exclusion of someone from a panel. It's typically a balance of scientific views on matters that are sometimes complex, that it is an underlying principle.

Dr. SWACKHAMER. I can just agree with that, that I'm—I have been on many National Academy committees. I currently serve on two of their committees, and have been involved with the EPA science advisory advice for more than a decade. And I would say that the number one criteria from both of those bodies, organizations, is to make sure that, at the table, you have the right array of expertise, and the right perspectives. And so, on committees for the National Academy, as well as committees at EPA, you always have some industry perspective, some NGO perspective, some State perspective, hopefully some Native American perspective. You have community perspective and urban perspective, you have—on all the sciences as well. And so the number one driving parameter is making sure you have the right science at the table.

Dr. BURKE. And I would just add the Academy goes to great measures before each study to evaluate potential financial conflict of interest, even the appearance of conflict of interest, and every member of a committee continually updates that information. And so, yes, the Academy process is a great model, and in the past I think the EPA Science Advisory Board, and other scientific committees, tried to imitate, and use those good provisions that have helped us prevent bias and conflict.

Mr. GOMEZ. So GAO also works directly with a number of National Academy of Science panels and committees. Sometimes we convene our own expert panels with the help of the National Academies. So what I would just say, that whether it's a National Academies panel, or an EPA advisory committee, that the selection process is transparent, is well-documented, so that people can see what's taking place.

Mr. BAIRD. So thank you, and I yield back my time.

Chairwoman SHERRILL. Thank you. Next, the Chair recognizes Representative Beyer for 5 minutes.

Mr. BEYER. Thank you, Madam Chair, very much, and thank you all very much for being with us, Dr. Swackhamer with us again. I remember when you came to testify before us in 2017. That was the day we were shocked to learn that, on the day of the hearing, an EPA political appointee attempted to alter your testimony, encourage you to mislead the Committee on important facts, despite

the fact that you were invited to testify as an independent scientist, and that you had actually cleared your participation with the EPA Ethics Office ahead of time. So we were aghast. My colleagues and I referred this to the EPA Inspector General, but we have not yet heard of the final judgment. Have you been contacted and had discussions with the Inspector General along the way?

Dr. SWACKHAMER. I have not.

Mr. BEYER. That is not the answer I was expecting, but I'm stunned, and I think we will follow up with that again. So you have no sense of when the Inspector General is prepared to do a final report on this?

Dr. SWACKHAMER. No, I do not.

Mr. BEYER. Did you experience any pressure from the EPA today?

Dr. SWACKHAMER. No. Once again, because I continue to hold a special government employee appointment at EPA, I did clear my participation here with the Ethics Office at EPA.

Mr. BEYER. So there's progress from 2 years ago, that you at least weren't pressured this time, right, so—

Dr. SWACKHAMER. Right.

Mr. BEYER. Dr. Burke, you wrote, among other things, that the advisory committees were established and structured to provide EPA with the highest level of independent scientific expertise and peer review, emphasis on the word independent, be able to recruit the best and brightest, and elsewhere the AP was quoted as saying that the Administrator's Office was attempting to remove independent research scientists, and replace them with people having a vested interest in the regulatory actions.

My friend from South Carolina talked earlier about—asked a question about fair and balanced—that's a fun phrase—and was somehow arguing that 80 percent academics would make it unfairly balanced. Can someone who is paid by the industry, that has a strong profit motivation, whose interests are dominated by shareholder value, ever be expected to come to something like that without an industry agenda? And can they ever be expected fairly to come with an independent scientific agenda when they're being paid by an industry to represent them?

Dr. BURKE. Let me speak from experience. I've been in this role a long time as a regulator and as a scientist, and in my long experience in environmental protection. When the industry folks come and present their science, it very rarely comes down on the side of protecting public health, and pointing out to an agency, perhaps, that they have a hazard there. Rather, it's to push back on public health measures, whether it's a level for cleanup, a standard that you're setting. So, sure, it's in the interest of an industry to protect their business interests, and you expect that. That's a source of bias. We have to control that.

Somebody getting their paycheck to work for that industry, would that be a potential conflict of interest? Yes, and that should be made clear, and it should be balanced in the process. On the other hand, when you need expertise, like we did for the fracking report, where else to go but the oil and gas industry to get the best engineers, and the people who understand the process? So you have

to be able to tap that industry expertise and genius, but also balance the biases.

Mr. BEYER. OK. As a small businessperson, our family business has been selling cars, I have often gotten upset when somebody's promoting a Chevrolet when we don't represent that product, you know? And as 5 years on this Committee, I've so often seen the industry representatives come specifically to talk about why we are trying to regulate their industry too much, why it's too high a standard for ozone, or the like.

Dr. Samet, one of the other things that showed up here was the old discussion we had, where in this Trump era revisions, if a scientist got an EPA grant, they weren't allowed to serve on the Scientific Advisory Boards, but there was no such restriction on the industry scientists. Doesn't this asymmetry strike you as remarkable?

Dr. SAMET. The asymmetry is concerning. And, again, people get grants, as Dr. Burke pointed out, because they're able to compete for funding at the highest level, and to lose that large pool of expertise potentially harms the review process.

Mr. BEYER. I agree. Thank you. Madam Chair, I yield back.

Chairwoman SHERRILL. Thank you. And the Chair recognizes Representative Tonko for 5 minutes.

Mr. TONKO. Thank you, Madam Chair, and thank you to our witnesses for today's hearing on what is an increasingly important topic, and it's great to hear your perspectives. Credible independent science and evidence should shape Federal policy without the distorting effects of inappropriate political interference or conflicts of interest. Science advisory boards are staffed by the top experts in their field. These are the people who understand the science best, and can be trusted to help ensure that our air is clean, that our water is safe to drink, and that toxic chemicals aren't released into our environment to harm our families and communities.

Rather than listening to and respecting science, the Trump Administration is focused on removing as many of these scientific experts as they can off of America's Federal science advisory boards. As these credible independent scientists are being pushed out, the Administration's political leaders are working to replace them with industry advocates, and for-profit consultants. As a result, admittedly unqualified people are now in positions where they are reviewing issues they don't fully understand. In fact, many of these replacements are consultants on a corporate payroll, with many real conflicts of interest. These board positions are critical for safeguarding the public health and safety of millions of Americans. We need to know that the people who serve on these boards are working toward the best interests of the American people, and not sacrificing public good for the private gain of their employer.

So we must ask ourselves, why would the Trump Administration shut out the scientists and experts who know these issues best? We sounded the alarms when these actions were first proposed. Our fears have now been realized, that this Administration continues clearing out scientific experts to make room for non-experts bought and paid for by private industry. This is shameful, and all of us will pay the price.

So, Dr. Samet, on April 11, 2019, the chartered CASAC issued a letter to Administrator Wheeler, accompanying its review of the draft Integrated Science Assessment, or the ISA, of particulate matter. In the letter they state that they are not equipped to provide a comprehensive review, lacking, amongst other specialties, an epidemiologist and a statistician. Administrator Wheeler has yet to respond to this recommendation. A, in your experience as CASAC chair, is this type of letterprecedented?

Dr. SAMET. To ask for additional expertise beyond the seven chartered members was never necessary because the panels were always supplemented by the array of experts that was needed. I won't bore you with all the details of the 1,800 pages of the ISA, except to say that a broad group of scientists is needed to review it, well beyond the expertise of any seven people, and when CASAC wisely requested restoration of the panel, or a similar group, they did the right thing.

Mr. TONKO. And what is your perspective on the reinstatement of the PM and ozone panels?

Dr. SAMET. I think that CASAC will be unable to do its job, remembering that this is only the first of three documents that they need to look at, without having additional expertise, particularly in epidemiology, which has been critical to both the PM and ozone standards, and in statistics, to go through the complicated analyses that are done to pull out the results to show the risks.

Mr. TONKO. And what do you think is the consequence of Administrator Wheeler ignoring this request, and accepting the review submitted by a panel that admits it is unqualified?

Dr. SAMET. Well, I use the word crippled. The CASAC is, in fact, crippled, and I think that is a fair description. If you look at the comments, they are lengthy. They try to do their job, and, in doing so, they recognize that they could not do it the way they should.

Mr. TONKO. And can CASAC's review of the PM ISA be considered actionable, given that they have identified deficiencies in their capabilities to conduct what would be a thorough review?

Dr. SAMET. CASAC has requested revisions to the PM ISA, and once done, they will certainly need the broad range of expertise they've called for to do their job.

Mr. TONKO. Thank you. And, Dr. Burke, in your testimony you touch upon how the Advisory Committee process is one that prioritizes and ensures transparency in the Agency's scientific decisionmaking. Why is transparency so vital, so important?

Dr. BURKE. I think trust is vital to any successful policy. Transparency in the process of science, inclusion of broad peer review, public comment, is really essential to the way we build our policies in this country.

Mr. TONKO. And do you anticipate that the June executive order cutting FACA committees will impact agencies' transparency to—

Dr. BURKE. I am very concerned about representativeness and feedback during the development of policy if we lose an enormous amount of our advisory committees, yes.

Mr. TONKO. Do any of our other witnesses care to comment on the executive order?

Chairwoman SHERRILL. And if you could be quick? The gentleman's time has expired.

Dr. SWACKHAMER. Since BOSC has been identified as one of those discretionary committees not established by Congress, but by the administrators themselves some time ago, in 1996, I would be—I think it would be a tremendous loss to EPA, and to the Office of Research and Development, if they lost the expertise and the advice of BOSC.

Mr. TONKO. Thank you very much. And, Madam Chair, I yield back.

Chairwoman SHERRILL. Thank you. At this point, before we bring the hearing to a close, I want to thank our witnesses for testifying here today. The record will remain open for 2 weeks for additional statements from the Members, and for any additional questions the Committee may ask of the witnesses. The witnesses are excused, and the hearing is now adjourned.

[Whereupon, at 4:05 p.m., the Subcommittees were adjourned.]





## Appendix I

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### ANSWERS TO POST-HEARING QUESTIONS

## ANSWERS TO POST-HEARING QUESTIONS

*Responses by Mr. J. Alfredo Gomez*

U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.  
Washington, DC 20548

August 15, 2019

The Honorable Mikie Sherrill  
Chairwoman  
Subcommittee on Investigations and Oversight  
Committee on Science, Space, and Technology  
House of Representatives

The Honorable Lizzie Fletcher  
Chair  
Subcommittee on Environment  
Committee on Science, Space, and Technology  
House of Representatives

**Question for the Record for Hearing on *EPA Advisory Committees: How Science Should Inform Decisions***

Subsequent to your July 16, 2019, joint hearing on *EPA Advisory Committees: How Science Should Inform Decisions*, you requested that GAO provide additional information for the hearing's record. Specifically, you asked that GAO describe additional ways that public health could be negatively impacted if the U.S. Environmental Protection Agency (EPA) continues to weaken its advisory boards.

GAO's response to your question is that federal advisory committees play an important role at EPA by providing advice that helps the agency develop regulations, accredit laboratories, and manage research programs, among other activities. For example, the Clean Air Scientific Advisory Committee is responsible for reviewing national ambient air-quality standards, among other topics. EPA notes in its *Federal Advisory Committee Handbook*—which documents the agency's process for appointing members to serve on advisory committees—that having the best people who represent key interests and balanced viewpoints enables EPA's advisory committees to provide EPA with recommendations that the agency can rely on as it works to fulfill its mission. Accordingly, we continue to believe that for future committee appointments, EPA should (1) follow a key step in its appointment process to document staff rationales for proposed membership and (2) evaluate the quality of financial disclosure reviews for those committees members who are expected to provide their best judgment free from conflicts of interest and are required by federal regulations to disclose their financial interests.

If you or your staff members have any questions about this report, please contact me at (202) 512-3851 or [gomezj@gao.gov](mailto:gomezj@gao.gov).

Sincerely yours,

A handwritten signature in black ink that reads "Alfredo Gomez". The signature is written in a cursive style with a large, stylized "A" and "G".

J. Alfredo Gomez  
Director  
Natural Resources and Environment

cc: [Caitlin.Buchanan@mail.house.gov](mailto:Caitlin.Buchanan@mail.house.gov)  
[Harrisrr@gao.gov](mailto:Harrisrr@gao.gov)  
[Koenenm@gao.gov](mailto:Koenenm@gao.gov)  
[Thompsonjd@gao.gov](mailto:Thompsonjd@gao.gov)

*Responses by Dr. Thomas A. Burke*

Responses to Questions for the Record

Thomas A. Burke, PhD, MPH

Johns Hopkins University Bloomberg School of Public Health

- **Submitted by: Representative Eddie Bernice Johnson (D-TX)**

- In a June 2018 letter to former Administrator Pruitt, the EPA SAB wrote that they felt the "Strengthening Transparency in Regulatory Science" proposed rule merited review by the SAB, as the proposed rule had not been reviewed by the SAB prior to publication in the federal register. At the SAB meeting last month, the Board voted to complete an expansive review of the rule on accelerated timeline. Administrator Wheeler has confirmed that the agency is moving forward with finalizing the rule by the end of this calendar year.

- a. **Dr. Burke**, how surprised was you that the SAB had not reviewed a rule with such wide-spread potential implications to the use of science at the agency? Is this typical for regulatory actions?

**Answer:** Yes I was very surprised and disappointed that this proposed rule, which has such major implications for national public health and environmental policies, was not reviewed by the SAB. Given the current questions about the SAB appointment process and membership, and the far-reaching impacts of this rule, I feel it is appropriate to have a thorough and transparent review by the National Academies of Science.

- b. How long would a review of such a proposed rule generally take? Would the SAB have adequate time to complete a thorough review of the rule and provide recommendations to the Administrator prior to publication of the final rule?

**Answer:** A thorough review of the rule would require an understanding of the costs and feasibility of implementation, the impacts on the scientific evidence base for agency decisions and policies, as well as an examination of case examples to assess the implications for existing national environmental policies, from clean air to safe drinking water. The timing of this type of review is dependent upon by the data the Agency is able to provide to the reviewers. In this case it appears that there has been very little actual assessment by the Agency of the feasibility and impacts of this rule on the scientific evidence that is essential to its mission and statutory mandates to protect health and environment. This review cannot be an uninformed rush job. I estimate the review time should be consistent with the timeframe of many NAS consensus review studies – one and a half to two years.

- At an earlier hearing this Congress of these two subcommittees, my colleague Chair Fletcher asked Dr. Jennifer Orme-Zavaleta, the Acting EPA Science Advisor, about the Office of Science Advisor's role in the development of the agency's "Strengthening Transparency in Regulatory Science" proposed rule. She responded that the OSA had not been consulted prior to the publication of the proposed rule in the federal register.

a. **Dr. Burke**, as a former EPA Science Advisor, how unusual is it that the Office of Science Advisor was not consulted on this type of rulemaking?

**Answer:** I have no information or understanding of the role of the Science Advisor under Administrator Wheeler. However, I can respond based upon my own experience in the role. In the previous Administration the Science Advisor would most certainly be consulted and actively involved in the development and evaluation of the scientific implications of such a potentially influential rule.

b. Under your tenure as Science Advisor, how often was the OSA consulted in the rulemaking process, and at what stage were the scientific implications of potential rules taken into consideration?

**Answer:** I was very fortunate to serve during the Obama administration under leadership of Administrator Gina McCarthy. During that time science was truly considered the backbone of EPA and the science of OSA and the Office of Research and Development was viewed as supportive and essential to the programs and policies throughout the Agency. In my experience the science and evaluation of the scientific evidence must be the starting point of rulemaking, not an afterthought.

c. Given that the proposed "Transparency" rule was not reviewed by *either* the SAB or the Office of Science Advisor, prior to its publication in the federal register, what concerns do you have about this proposed rule?

**Answer:** As I stated in my written statement and oral testimony, I fear this rule is a thinly veiled attempt to undermine the scientific evidence base that has been the foundation of our Nation's progress in protecting public health and our environment.

**Submitted by: Representative Suzanne Bonamici (D-OR)**

- The EPA has proposed rulemaking to block access to good science by limiting the scope of research that the EPA can consider in making decisions. The "Strengthening Transparency in Regulatory Science," or the so-called "secret science" proposed rule would force the EPA to ignore valuable information discovered during their research if it contains confidential privacy-related health information. This proposed rule would have chilling consequences for the EPA and every person who benefits from clean air and clean water. Representative Tonko and I testified at the EPA in opposition to the proposed rule last summer.

But former Administrator Scott Pruitt also stacked the Science Advisory Board, which was charged with a limited consultation, rather than review of the proposed rule, with industry representatives in lieu of scientists and independent academics. Given the membership of the Board, we must do more to defend science.

- a. **Dr. Burke**, during your tenure at the EPA and as a member of the Science Advisory Board, did you encounter any efforts by EPA Administrators to limit the scope of the Board's review of proposed regulatory action? How does the membership of the Science Advisory Board affect public confidence in the integrity of the review process?

**Answer:** During my service as a member of the SAB, which includes multiple Administrations, I did not encounter any interference by EPA Administrators to interfere with or limit the scope of science reviews. During my time at the Agency I am confident that the Administrator respected the independence of the Board and did not limit the scope of reviews.

It is essential that the SAB have the expertise to provide high-level expert peer review on our most challenging environmental and public health issues. The Board must also be vetted to assure independence and protect against conflict of interest. The credibility of the Board depends upon this. Current questions concerning the membership of the SAB undoubtedly have a negative effect on public confidence in the integrity of the review process, and ultimately on the credibility of EPA.

**Submitted by: Representative Ben McAdams (D-UT)**

- This GAO report is troubling, given the lack of scientific input now on these boards meant to inform vital public health decisions.
  - a. **This is for the panel,** can you all describe what other ways we might see negative impacts to our public health if the EPA continues to weaken their advisory boards?

**Answer:** Weakening of the Advisory Boards reduces the transparency of agency decisions, undermines the quality and credibility of science essential to public health decision making, and perhaps most importantly erodes public trust in the credibility of the Agency. Public trust is essential to our public health efforts. It is also essential to our communities and businesses. EPA decisions impact lives, from safe drinking water to emergency response in time of disasters. For all of us, the quality of our environment determines the quality of our lives. The success of EPA depends upon strong science, and we depend on a strong EPA.

*Responses by Dr. Deborah Swackhamer*

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY  
 SUBCOMMITTEE ON INVESTIGATIONS & OVERSIGHT  
 SUBCOMMITTEE ON ENVIRONMENT

*EPA Advisory Committees: How Science Should Inform Decisions*

**Questions for the Record to:**

Dr. Deborah Swackhamer  
 Professor Emerita  
 Humphrey School of Public Affairs  
 University of Minnesota

**Submitted by: Representative Eddie Bernice Johnson (D-TX)**

- In a June 2018 letter to former Administrator Pruitt, the EPA SAB wrote that they felt the "Strengthening Transparency in Regulatory Science" proposed rule merited review by the SAB, as the proposed rule had not been reviewed by the SAB prior to publication in the federal register. At the SAB meeting last month, the Board voted to complete an expansive review of the rule on accelerated timeline. Administrator Wheeler has confirmed that the agency is moving forward with finalizing the rule by the end of this calendar year.
  - a. **Dr. Swackhamer**, how surprised were you that the SAB had not reviewed a rule with such wide-spread potential implications to the use of science at the agency? Is this typical for regulatory actions?

The "Strengthening Transparency in Regulatory Science" proposed rule is central to what evidence, what research studies, reports and publications can be used by EPA to inform their regulations. The proposed rule would restrict this use to scientific studies where all background data collected in the study was also fully made public, which would eliminate the use of epidemiological studies that provide confidentiality to individuals that participated in the study to protect their personal and health data. Since the most rigorous evidence in justifying regulations is often such epidemiological studies, this could eliminate the use of important scientific information **critical** to making the best possible regulations. Thus this rule has the potential to greatly disrupt and significantly weaken the ability of EPA to protect human health.

The potentially large impact of this rule makes it an obvious candidate for SAB review. There are potential unintended and unforeseen consequences to this rule that could be identified and explored by the SAB. In addition, the SAB could identify ways the rule could be improved to allow review of confidential data in a controlled manner (for instance, a small internal panel) to allow the use of a given study yet still provide assurances of the raw data quality. It is a travesty that the Administrator would not make use of the intellectual resources of the SAB at his disposal in crafting this important rule.

- b. How long would a review of such a proposed rule generally take? Would the SAB have adequate time to complete a thorough review of the rule and provide recommendations to the Administrator prior to publication of the final rule?

I do not see how the SAB can provide meaningful advice to the Administrator before the rule is finalized. The SAB is subject to the rules of FACA, and these do not allow the board to move quickly for such reviews. The selection and approvals of subcommittee members, Federal Register announcements, logistics and planning activities, and advance scheduling for each meeting or



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teleconference take many weeks; such a review might entail 1-2 meetings and 1-2 teleconferences. Thus even a streamlined Board activity might take a year to complete, then another month or two to be reviewed and approved by the full SAB. A discussion of the rule, with no formal written recommendations, could take place more quickly, but the full SAB does not meet very often (only met once so far under this administration).

- At an earlier hearing this Congress of these two subcommittees, my colleague Chair Fletcher asked Dr. Jennifer Orme-Zavaleta, the Acting EPA Science Advisor, about the Office of Science Advisor's role in the development of the agency's "Strengthening Transparency in Regulatory Science" proposed rule. She responded that the OSA had not been consulted prior to the publication of the proposed rule in the federal register.
  - a. **Dr. Swackhamer**, given that the proposed "Transparency" rule was not reviewed by *either* the SAB or the Office of Science Advisor, prior to its publication in the federal register, what concerns do you have about this proposed rule?

I am dismayed that this rule was not reviewed by the Office of the Science Advisor (OSA) prior to its publication in draft form. This seems to be disingenuous on the part of the Administrator, and shows disrespect for the OSA and disregard for scientific advice in general. As noted above, my concern with this rule is that it would exclude the use of published epidemiological studies that have been through rigorous peer-review that provide critical, and in most cases, the most rigorous evidence to set air, water, and soil standards to protect public health. Thus I am concerned that this rule will hinder EPA's ability to meet its primary mission. The fact that the OSA and the SAB were not consulted indicates that concerns for scientific integrity in rule making are not motivating this rule, but rather political ones are motivating this change.

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**Questions for the Record to:**

Dr. Deborah Swackhamer

Professor Emerita

Humphrey School of Public Affairs

**Submitted by: Representative Conor Lamb (D-PA)**

- As I remember from school, the scientific method is a process that we've constructed over the years wherein we observe, then measure, then experiment, and we refine our hypotheses as we learn more about the subject. And as scientists start on a scientific problem, it's important that they eliminate, or put to the side, any biases that might exist about the problem. That's what separates a real scientist from an advocate, or even from an elected official like me.

I've found the use of the word "stakeholder" odd in the context of this hearing on scientific advisory committees. In particular, the criticism of the committees' composition being weighted towards academics seems misplaced.

- a. **Dr. Swackhamer**, can you please discuss how the stakeholder comment period differs from the scientific review process conducted by scientific advisory committees?

Members of science advisory committees should **not** be characterized as "stakeholders".

Designated subcommittees of the science advisory committees produce draft reports of their recommendations and findings on a given issue that has been put before them. The full science advisory committees review the subcommittee draft reports and edit as needed prior to submitting the final report to the Administrator (or Assistant Administrator of the Office of Research and Development in the case of BOSC). As part of this review process, and as a part of all meetings, public comments are solicited and time in all meetings is set aside to hear them. Written comments are provided to each member. These oral and written comments are taken into consideration before final approval of any report.

The public comments are usually from individuals who represent a given vested interest in the subject matter; in other words, stakeholders. They are, by definition, not objective or independent in their views, as their purpose is to defend a certain perspective that supports the interests of the organization or company that they speak for. Their views may or may not be scientifically based. Thus stakeholder comments are fundamentally different from the deliberations of the scientific advisory committees.

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**Questions for the Record to:**

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- b. How does the role of a science advisor differ from that of a stakeholder?

The scientific advisory committees at EPA are meant to convene the highest quality scientific experts from relevant disciplines to provide objective, external advice to the Administrator (or Assistant Administrator). The objectivity is **essential** to the integrity of the scientific advice being offered. Any conflicts of interest and biases are declared and may cause the recusal of a committee member for a given deliberation. The members should not function as stakeholders, even if they are employed by industry or another regulated party. They are expected to bring their expertise and perspectives to deliberations, but not defend vested interests or function as stakeholders.

These committees do not have equal numbers of people with different perspectives because they are not equally available. The staff tries to have as broad a range of perspectives as possible. For example, there are fewer industry scientists who can participate independently of the financial interests of their employer than there are academic scientists. However, the different perspectives of academia, industry, state government, foundations, non-governmental organizations, and tribes are sought to serve on EPA's advisory committees.

**Questions for the Record to:**

Dr. Deborah Swackhamer

Professor Emerita

Humphrey School of Public Affairs

**Submitted by: Representative Ben McAdams (D-UT)**

- This GAO report is troubling, given the lack of scientific input now on these boards meant to inform vital public health decisions.
  - a. **This is for the panel**, can you all describe what other ways we might see negative impacts to our public health if the EPA continues to weaken their advisory boards?

As the advisory board integrity weakens, so does the integrity of their advice and work products. If there are not the appropriate blend of qualified experts, or members that can act independently of vested interests, then the advice given is tainted, biased, and not able to inform the EPA in the manner it was intended. The rigorous peer review process breaks down, and the regulations resulting from a flawed review are likely not protective of public health.

Another outcome is the failure to provide any advice at all. An example of this is the determination by CASAC that they did not have the appropriate expertise to do their Congressionally-directed mandate to review and recommend the NAAQS particulate matter standard, as described in detail in Dr. Jon Samet's testimony.

All of this leads to a collective weakening and erosion of the regulations for minimizing pollutant impacts on people and nature. It also leads to a general cynicism and lack of faith in the regulatory process, and the role of government to protect public health and the environment.

While a change in administration can mitigate the trend in deregulation and restore the integrity of the science advisory boards, the loss in trust by the public in the scientific validity and integrity of the EPA will last much longer.

*Responses by Dr. Jonathan Samet*

Congress of the United States  
House of Representatives  
Committee on Science, Space, and Technology  
Subcommittee on Investigations & Oversight, and Subcommittee on Environment  
July 16, 2019 Joint Hearing “EPA Advisory Committees: How Science Should Inform Decisions”

## Responses to Questions for the Record

Jonathan M. Samet, MD, MS  
Dean and Professor, Colorado School of Public Health

**Representative Eddie Bernice Johnson:**

- At an earlier hearing this Congress of these two subcommittees, my colleague Chair Fletcher asked Dr. Jennifer Orme-Zavaleta, the Acting EPA Scientific Advisor, about the Office of Science Advisor’s role in the development of the agency’s “Strengthening Transparency in Regulatory Science” proposed rule. She responded that the OSA had not been consulted prior to the publication of the proposed rule in the federal register.
- a. **Dr. Samet**, given that the proposed “Transparency” rule was not reviewed by *either* the SAB or the Office of the Science Advisor, prior to its publication in the federal register, what concerns do you have about this proposed rule?

**Dr. Samet response:**

*On first reading, a call for “transparency” and access to data from pivotal studies in decision-making seems reasonable and consistent with a broad call in the scientific community for data access and “rigor and reproducibility” of research. However, a deeper reading leads to multiple concerns, particularly around epidemiological studies, those involving data collected from and about people and populations. In particular, data in epidemiological studies, which often do provide the “pivotal” findings for environmental agents, have often been collected with assurances of the privacy and confidentiality of data. Given the historical span of some studies, e.g., the Harvard Six Cities Study, participants were enrolled, informed consent obtained, and data collected long before today’s push for data sharing began. The underlying ethical implications of the Transparency Rule have not been adequately explored.*

*The Transparency Rule needs further input from experts, such as the SAB or the Office of the Science Advisor, to address the approaches to models, modeling, and assessment of dose-response relationships. The language is ambiguous and lacks the specificity needed to implement the Transparency Rule.*

*Also lacking is sufficient consideration of the mechanisms and costs of sharing data, which could pose a substantial burden for the broad community of researchers holding data relevant to decision-making by the EPA. Data-sharing involves more than posting a data set; meticulous documentation is needed and inevitably users will have questions that need to be addressed by the original investigators.*

**Dr. Samet response continued:**

*Given the breadth of expertise of the SAB, review of the Transparency Rule by that group would have provided valuable input for formulating an approach to assuring the quality, rigor, and reproducibility of key analyses.*

**Representative Ben McAdams:**

- I am particularly troubled by the Clean Air Scientific Advisory Committee cutting expert subpanels on particulate matter and ozone pollution. Ozone related deaths in the Salt Lake Valley have been on the rise, and as recent as 2017, there were 26 related ozone deaths. **Dr. Samet**, in your opening testimony you provided an overview of CASAC's role in developing adequate standards for health and safety of Americans.
  - a. With the EPA diluting and diminishing science's role in air quality monitoring, can you speak to the negative health impacts we could anticipate seeing if the EPA is permitted to raise the allowable threshold for a pollutant, like say ozone?

**Dr. Samet response:**

*Under the Clean Air Act, the Administrator has a duty to propose National Ambient Air Quality Standards (NAAQS) that protect public health with "an adequate margin of safety." Meeting that responsibility has been challenged by high-quality epidemiological research showing adverse health effects at outdoor concentrations below current standards for both airborne particulate matter and ozone. To guide the Administrator, the EPA carries out risk analyses directed at various scenarios of changes to the NAAQS; such analyses for airborne particles and ozone show that even with lowering of the NAAQS for these pollutants, a residual pollution-related disease burden would remain. The answer to the question is thus clear: any relaxing of the existing NAAQS would lead to an increase in the burden of pollution-caused ill health in the United States.*

**Dr. Samet**, in your opening testimony you provided an overview of CASAC's role in developing adequate standards for health and safety of Americans.

- b. What other impacts might we see with the EPA weakening ozone and particulate matter standards?

**Dr. Samet response:**

*Beyond health impacts, welfare effects, e.g., visibility are also considered for the pollutants covered by the NAAQS. For both particulate matter and ozone, visibility could be reduced if standards were relaxed. There are also potential implications for the control of greenhouse gas emissions, since reduction of both ozone and particulate matter concentrations will involve tighter control of combustion sources and hydrocarbon releases, e.g., methane, a greenhouse gas.*

**Representative Ben McAdams continued:**

- **Dr. Samet**, I frequently hear from my constituents that air quality is their number one issue. When I was Salt Lake County Mayor it was one of my biggest public health concerns. We not only have large problems with ozone on the ground, but particulate matter from pollution and compounded is the natural inversion effect, which make visibility in the Valley impossible some days. Current, CASAC lacks an epidemiologist and a statistician.
  - a. Why are specialties like this so important to CASAC and a thorough NAAQS review process?

**Dr. Samet response:**

*CASAC is charged with providing guidance to EPA on a broad range of research findings coming from multiple lines of investigation. Epidemiological studies often figure prominently in that mix and they may provide key information for decision-making around causation of adverse effects and concentration-response relationships. They may also involve complex analyses and use of models, particularly to estimate how risk varies with exposure. Quantitative methods are critical to translating from such research to analyses that support decision-making.*

*Epidemiology and biostatistics are the core disciplines for reviewing such research. While the Clean Air Act does not specifically specify that the Chartered members include either an epidemiologist or a biostatistician, review panels for the NAAQS have always included both disciplines. The current membership of CASAC thus has a critical gap in its expertise and with the dismissal of the consultant panel members, CASAC is hindered in carrying out its scientific review responsibilities.*

- **Dr. Samet**, I frequently hear from my constituents that air quality is their number one issue. When I was Salt Lake County Mayor it was one of my biggest public health concerns. We not only have large problems with ozone on the ground, but particulate matter from pollution and compounded is the natural inversion effect, which make visibility in the Valley impossible some days. Current, CASAC lacks an epidemiologist and a statistician.
  - b. How are places like Salt Lake, which already experiences poor air quality, negatively affected by a lack of specialties like epidemiology?

**Dr. Samet response:**

*Salt Lake, like other polluted areas, is best served by evidence-based NAAQS that meet the public health mandate of the Clean Air Act. We have extensive scientific evidence available on the risks of air pollution. We can best use that evidence to protect public health in Salt Lake and elsewhere by having the full range of expertise needed to guide EPA as it considers revisions to the NAAQS.*

*This GAO report is troubling, given the lack of scientific input now on these boards meant to inform vital public health decisions.*

**Representative Ben McAdams continued:**

- This GAO report is troubling, given the lack of scientific input now on these boards meant to inform vital public health decisions.
  - a. **This is for the panel,** can you all describe what other ways we might see negative impacts to our public health if the EPA continues to weaken their advisory boards?

**Dr. Samet response:**

*EPA has long been a science-based agency. As such, it relies on guidance from diverse advisory boards covering the broad range of science relevant to its mission. These boards assist EPA in determining what research needs to be done, in evaluating the quality of the research, and in translating from the resulting scientific evidence to policy and regulatory decisions. Any weakening of the advisory boards in their number and the quality of their members could have sweeping consequences. The advisory boards are critical to this science-based agency.*

**Representative Suzanne Bonamici**

- The National Ambient Air Quality Standards, or NAAQS, were established under the Clean Air Act to regulate criteria pollutants that have significant negative effects on human health. Congress made sure that public health was the driving factor in setting the NAAQS by requiring the standards to be based on exclusively on scientific, health-based evidence.
  - a. **Dr. Samet,** in your testimony you mention that the “scope and quality of the CASAC review are threatened.” What are the implications of the elimination of the particulate matter and ozone review panels for CASAC’s work?

**Dr. Samet response:**

*Here, I focus on the particulate matter panel, since we have already seen the consequences as CASAC reviews the Integrated Science Assessment or ISA for particulate matter. Per my comments to CASAC, the committee’s seven members are challenged to cover this 1800+ page document that involves multiple scientific areas, some outside the expertise of any CASAC member. CASAC itself has recognized the problems coming from the dismissal of the additional panel members and the insufficient breadth of its expertise. Additionally, the process for reviewing the NAAQS for PM (and for ozone) is on a relatively accelerated schedule, given the planned completion of the process by 2020. With both the limitation of having only the 7 Chartered CASAC members and the time schedule, the rigor of the review of critical agency documents will inevitably be diminished.*



**Representative Suzanne Bonamici continued:**

- The National Ambient Air Quality Standards, or NAAQS, were established under the Clean Air Act to regulate criteria pollutants that have significant negative effects on human health. Congress made sure that public health was the driving factor in setting the NAAQS by requiring the standards to be based on exclusively on scientific, health-based evidence.
- b. How does the elimination of this expertise effect the EPA's ability to uphold its mission to protect public health?

**Dr. Samet response:**

*As a former chair of CASAC and a participant in diverse advisory committees for EPA, I have provided expertise to the agency, as have others, to support its mission of protecting public health. The agency has long-established practices involving external scientific experts that have proved essential for meeting its public health mission. The answer is clear—reducing that expertise threatens EPA's ability to fulfill its critical mission for the nation.*