

Testimony to the House Committee on Science, Space, & Technology

Subcommittee on Investigations and Oversight & Subcommittee on Environment

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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.

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.¹⁻⁴ I have also commented on the necessity of maintaining scientific evidence as the foundation for environmental protection.⁵ 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_{2.5} 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_{2.5} NAAQS and charged with developing a research agenda addressing these uncertainties, and to track progress in resolving these uncertainties.^{6,7}

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.

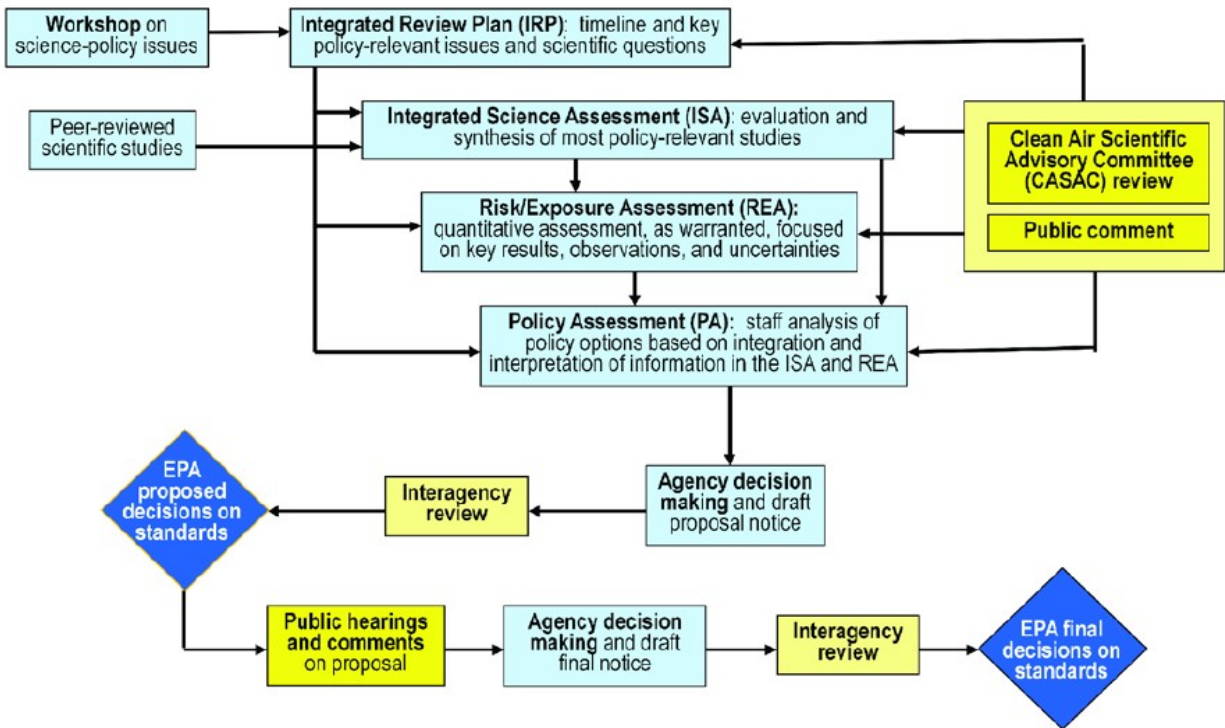
Finally, with CASAC in particular, the current chair has disrupted established processes for evidence evaluation and review by attempting to impose an untested alternative. Concern has also been raised with regard to the systematic review process being used for the Toxic Substances Control Act.⁸ The 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.⁹ 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".

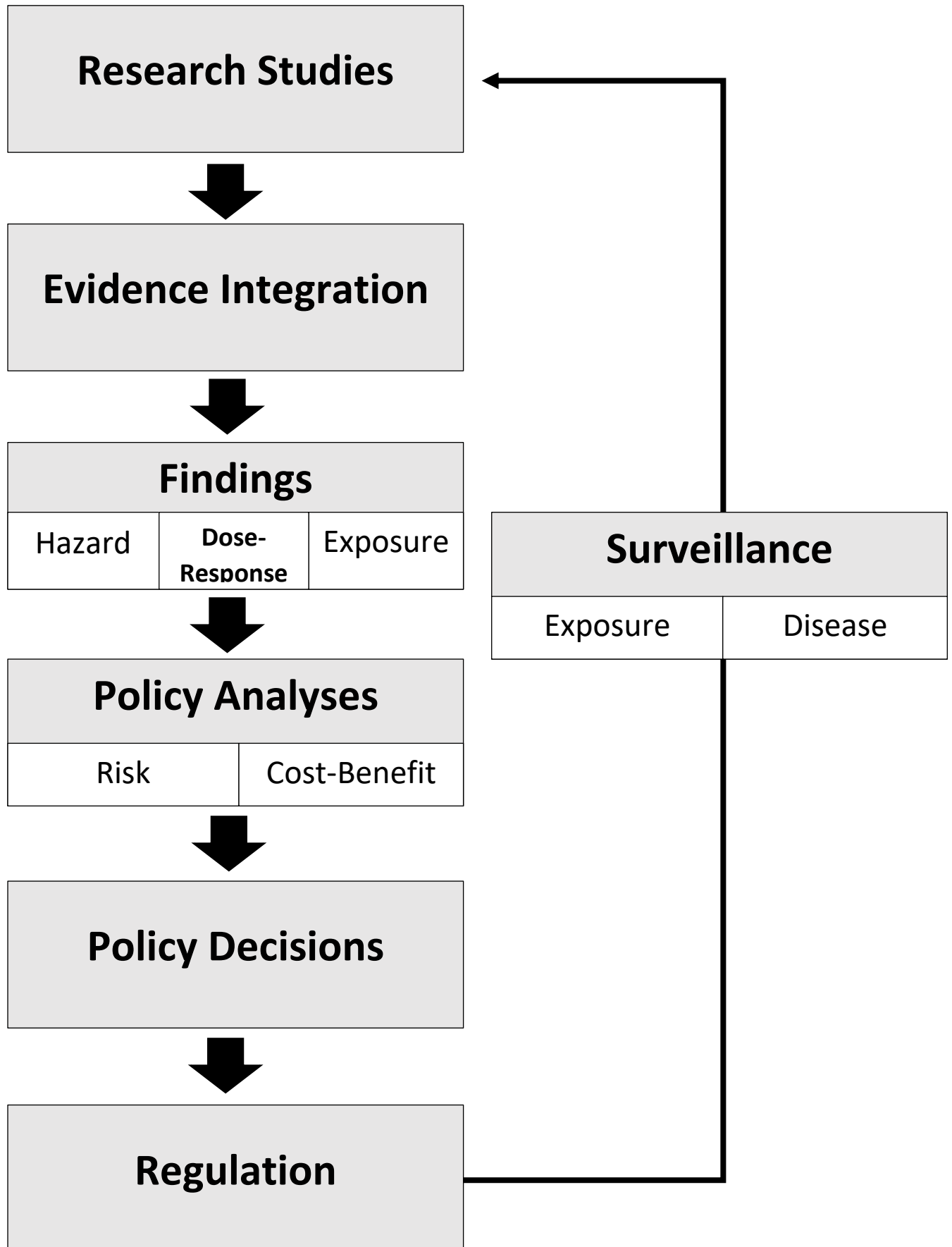
Figure 1. The NAAQS Review Process and the CASAC Role

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



Clean Air Scientific Advisory Committee for Particulate Matter NAAQS

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*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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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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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_{2.5} 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_{2.5} 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_{2.5}, but also PM_{10-2.5} 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.

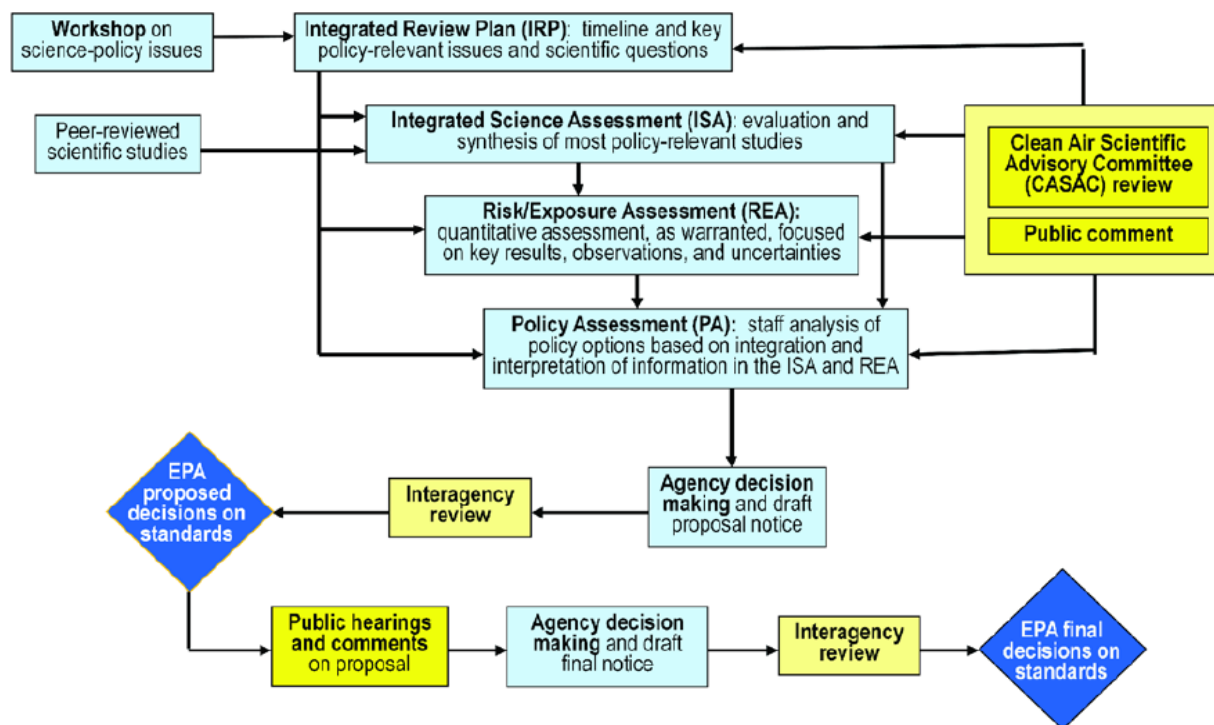
Conclusions and Recommendations

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 _{2.5} 24-hr	PM _{2.5} Annual	PM ₁₀ 24-hr	PM ₁₀ Annual
Current NAAQS		N/A	N/A	150	50
EPA Staff Recommendation		18 - 65	12.5 - 20	150 ¹³	40 - 50
Name	Discipline				
Ayres	M.D.	yes ²	yes ²	150	50
Hopke	Atmos. Sci.	20 - 50 ³	20 - 30	no	40 - 50 ⁴
Jacobson	Plant Biologist	yes ²	yes ²	150	50
Koutrakis	Atmos. Sci.	yes ^{2,5,6}	yes ^{2,5,6}	no	yes ⁴
Larntz	Statistician	no	25-30 ⁷	no	yes ²
Legge	Plant Biologist	≥ 75	no	150	40 - 50
Lippmann	Health Expert	20 - 50 ³	15 - 20	no	40 - 50
Mauderly	Toxicologist	50	20	150	50
McClellan	Toxicologist	no ⁸	no ⁸	150	50
Menzel	Toxicologist	no	no	150	50
Middleton	Atmos. Sci.	yes ^{2,3,12}	yes ^{2,5}	150 ^{3,13}	50
Pierson	Atmos. Sci.	yes ^{2,9}	yes ^{2,9}	yes ⁴	yes ⁴
Price	Atmos. Sci./ State Official	yes ^{3,10}	yes ¹⁰	no ^{3,4}	yes ⁴
Shy	Epidemiologist	20 - 30	15 - 20	no	50
Samet ¹	Epidemiologist	yes ^{2,11}	no	150	yes ²
Seigneur	Atmos. Sci.	yes ^{3,5}	no	150 ¹³	50
Speizer ¹	Epidemiologist	20 - 50	no	no	40 - 50
Stolwijk	Epidemiologist	75 ⁷	25-30 ⁷	150	50
Utell	M.D.	≥ 65	no	150	50
White	Atmos. Sci.	no	20	150	50
Wolff	Atmos. Sci.	≥ 75 ^{3,7}	no	150 ³	50

¹ not present at meeting; recommendations based on written comments

² declined to select a value or range

³ recommends a more robust 24-hr. form

⁴ prefers a PM standard rather than a PM standard 10-2.5 10

⁵ concerned upper range is too low based on national PM /PM ratio 2.5 10

⁶ leans towards high end of Staff recommended range

⁷ desires equivalent stringency as present PM standards 10

⁸ 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

⁹ yes, but decision not based on epidemiological studies

¹⁰ 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

¹¹ only if EPA has confidence that reducing PM will indeed reduce the components 2.5 of particles responsible for their adverse effects

¹² concerned lower end of range is too close to background

¹³ 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.

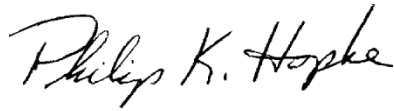
Sincerely,



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



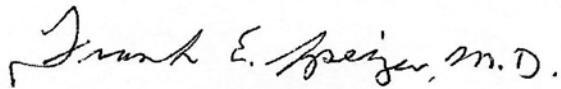
Ana V. Diez Roux, M.D. Ph.D.

Dean and Distinguished University Professor of Epidemiology, School of Public Health
Drexel University
CASAC Chair 2015-2017



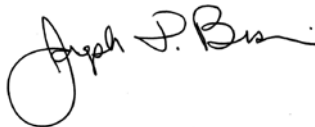
James D. Crapo, M.D.

Professor of Medicine, Department of Medicine
National Jewish Health
University of Colorado Denver



Frank Speizer, M.D.

Edward Kass Professor of Medicine
Channing Laboratory
Harvard Medical School



Joseph D. Brain, S. D. in Hyg.

Cecil K. and Philip Drinker Professor of Environmental Physiology
Harvard T.H. Chan School of Public Health

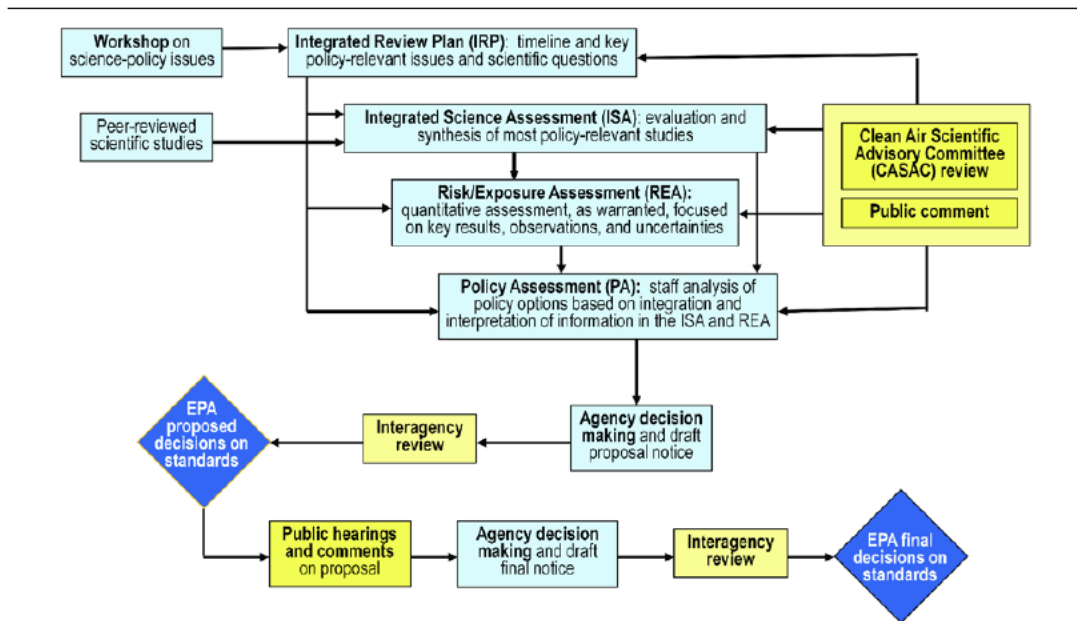


Figure 1 Illustration of the key steps in the process of the review of National Ambient Air Quality Standards.

Appendix B

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

Prepared by:

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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_{2.5} 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 50th 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_{2.5}." *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.