Summary Minutes of the
U.S. Environmental Protection Agency (EPA)
Chartered Clean Air Scientific Advisory Committee (CASAC)
Public Teleconference on Particulate Matter
March 28, 2019

Date and Time: Thursday, March 28, 2019, 11:00 AM – 3:00 PM ET

Location: Telephone and live audio webcast only

Purpose: To discuss the 03-07-19 Draft CASAC Review of the EPA's *Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft – October 2018).*[1]

Participants: Chartered CASAC Members (also see roster[2])
Dr. Tony Cox, Chair
Dr. James Boylan
Dr. Mark Frampton
Dr. Sabine Lange
Dr. Timothy Lewis
Dr. Corey Masuca
Dr. Steven Packham

Mr. Aaron Yeow, Designated Federal Officer (DFO)

Dr. John Vandenberg, EPA National Center for Environmental Assessment (NCEA)

Other Attendees (See Attachment A)

Convene Meeting and Review of Agenda

Mr. Aaron Yeow, DFO, opened the meeting. He noted that, as required under the Federal Advisory Committee Act (FACA), the CASAC's deliberations are held in public, with advanced notice given in the Federal Register.[3] He noted that there was a public comment period on the agenda for members of the public who had registered in advance with the SAB Staff Office to make oral comments. He stated there was also a clarifying public comment period noted on the agenda where members of the public could request an opportunity to make short clarifying comments providing new additional information to the CASAC. He noted that the CASAC had received written public comments, which were posted on the meeting webpage. He stated that committee member preliminary comments, the Draft CASAC report, and other meeting materials were also available on the meeting webpage. He indicated that after the December 12-13, 2018, meeting, there were a few follow-up questions from a CASAC member for the EPA and the public. The follow-up questions and responses have been posted on both the December 12-13 meeting webpage as well as the March 28 meeting webpage. He stated that the meeting minutes will be made publicly available after the meeting. He stated that the SAB Staff Office determined that there were no issues with conflict-of-interest nor any issues with an appearance of a loss of impartiality for any of the CASAC members.

He stated that the purpose of the public teleconference is for the CASAC to deliberate on the March 7 Draft CASAC PM ISA Report. The Draft CASAC report was developed after the December 12-13 meeting and was intended to assist in the CASAC deliberations. The Draft CASAC report did not need to be limited to only items that were discussed or agreed to at the December 12-13 meeting. FACA allows for the development of preparatory materials or position papers that will be deliberated in public by the CASAC, which is what the CASAC would do on the teleconference. The CASAC would now have public deliberations on the draft report and attempt to reach final advice and recommendations. The final CASAC report must reflect the final advice and recommendations that have been deliberated in public, so it is important for CASAC members to resolve all comments and/or issues with the draft CASAC report on the teleconference. He turned the meeting over to Dr. Tony Cox, Chair of the CASAC.

Dr. Tony Cox thanked the CASAC members for their preliminary comments on the draft CASAC report, thanked the public commenters, and thanked John Vandenberg and the EPA team for their hard work. He indicated that he has read many pieces that portray some of CASAC's recent work as a retreat from, or even a betrayal of, good science, and a pursuit of fringe ideas and impossible burdens of proof. He believed that nothing could be further from the truth and that CASAC members were all there to improve and strengthen the use of mainstream science in the ISA review process. He also stated that it was the CASAC's charge and duty to draw and state their own independent conclusions and to give the best possible scientific advice they can based on the material in the current Draft ISA, independent of what others think or like, or have stated in the past.

He went through the Agenda[4] and proposed going through the consensus responses for each chapter, starting with Chapters 2-13, then Chapter 1 and the Executive Summary, then the Letter to the Administrator.

Remarks from EPA

Dr. John Vandenberg, EPA NCEA, expressed the EPA's appreciation for the efforts by the CASAC and the public in providing comments on the Draft ISA. The Draft ISA was developed based on the Integrated Review Plan that was reviewed by the CASAC and the Draft ISA is consistent with the methods described in the Preamble, which was reviewed by many previous CASAC committees. He also thanked his staff for all of their hard work.

Public Comments on the Draft CASAC PM ISA Report

Mr. Yeow indicated that public commenters would speak in the order presented in the List of Registered Speakers[5] and presented some ground rules for the public comments period: comments would be limited to 3 minutes each; to please focus the oral comments on the Draft CASAC report; that input to the CASAC has the most impact if it provides specific scientific or technical information for CASAC to consider or if it relates to the clarity or accuracy of the technical information; and to please remain professional and civil, refraining from any personal attacks.

Chris Frey, North Carolina State University provided an oral statement referencing the 8 major findings and 44 recommendations provided in December 2018 from 17 members of the disbanded CASAC PM panel. The panel had also submitted written comments[6] on the Draft ISA and on process and scientific deficiencies of CASAC's draft letter and he indicated that he had also submitted written comments.[7] He indicated that CASAC's draft report mischaracterizes the Draft ISA. The Draft ISA is a comprehensive, systematic review that follows well-established principles and operational terminology. He indicated

that the CASAC should read the Integrated Review Plan and that the EPA should reinstate the CASAC PM Panel.

Gretchen Goldman, Union of Concerned Scientists, made an oral statement.[8] She indicated that the CASAC should follow the established causality framework described in the Preamble to the ISA and that it has evolved over the past decade, been endorsed by 11 prior CASACs and 138 experts, and has been deemed adequate in the courts. She stated that the Draft CASAC report upends this approach and that it would create an unattainable burden of proof and that it is not feasible or ethical to design and carry out population-level manipulative causation studies. She stated that this proposal is incompatible with the CASAC's charge to recommend PM NAAQS that protect public health with an adequate margin of safety. She also stated that the CASAC has significant gaps in expertise due to the dismissal of the PM panel.

Dan Greenbaum, Health Effects Institute (HEI), made an oral statement. He indicated that accountability studies can be useful in testing whether air quality actions actually result in pollution reductions and improved health (e.g. HEI studies in Southern California and Atlanta demonstrated improvements in both air quality and children and adult health; and their Irish coal ban study demonstrated a measurable reduction in respiratory mortality even after controlling for changing medical practice). He indicated that HEI would not suggest that all of their accountability studies be considered in the PM ISA, in part because several of them do not consider PM, and others are in locations and situations that are not relevant. Rather, they would suggest that the causality determination, while informed by accountability studies, must be based on the broadest set of evidence, including animal toxicology and human clinical studies, epidemiological panel studies, and epidemiological cohort studies. He stated that EPA has drawn on and needs to continue to draw on these diverse lines of evidence to fully consider causality. He stated that HEI views accountability studies as a valuable addition to that evidence base, but not as a substitute for this more comprehensive evaluation.

John Bachmann, Environmental Protection Network (EPN), presented an oral statement[9] and indicated that EPA has wholly ignored their previously stated concerns regarding the need to return the NAAQS review process to a sound, unbiased science and policy footing. He stated that the best and fastest way to restore credibility would be to reinstate the CASAC PM panel and that EPA and CASAC should reject half measures to add expertise. He stated that the preemptive rejection of the 2016 CASAC advice on weight-of-evidence approach described in the Integrated Review Plan (IRP) and suggestion for using hypothesis testing had blindsided EPA staff and is unreasonable at this stage of the NAAQS review process, nor is it supported by the current state of the science.

Lianne Sheppard, University of Washington, made an oral statement[10] and indicated that the Draft CASAC report lacked adherence to CASAC's mandate to provide independent review of draft documents for scientific quality and sound implementation of causal frameworks. She stated that CASAC should explain why it was providing advice inconsistent with CASAC advice on the IRP and how studies omitted from the ISA meet study inclusion criteria. She indicated if even a few members continue to call into question the causality determination for $PM_{2.5}$ effects on mortality, then the onus is on these CASAC members to also consider the evidence summarized in previous ISAs, and provide complete and specific rationale for why all those previous CASAC committees reached an incorrect conclusion.

Julie Goodman, Gradient, provided an oral statement[11] on behalf of Gradient, but noted that the American Petroleum Institute had provide funding for preparing comments. She indicated that several people have taken issue with CASAC's expertise, but setting aside the question regarding expertise,

CASAC has provided many valid critiques of several analyses in the Draft ISA, particularly with regard to evaluations of individual studies. She stated that the Draft ISA does not consider studies in a systematic, unbiased, or transparent manner, and lacks a detailed protocol and robust study quality evaluation. She found the draft CASAC report to be extremely thoughtful and thorough, and setting aside issues with CASAC's expertise and recommendations regarding causal methods, the EPA should consider CASAC's comments regarding the ISA review process and evaluation.

George Thurston, North American Chapter of the International Society of Environmental Epidemiology, made an oral statement[12] and indicated that the draft CASAC report inappropriately combed through the Draft ISA to identify any inconsistencies across specific studies instead of acknowledging the overall general agreement across various studies. He stated that the purported study-to-study inconsistencies are usually just plausible variations in the results across differing health outcomes, exposure populations, or locations considered. He indicated that CASAC should stay with EPA's well-established and effective weight-of-evidence approach. He urged EPA to reconvene the disbanded CASAC PM panel and noted that it should be comprised of its original members.

Corwin Zigler, The University of Texas at Austin, made an oral statement[13] and indicated that he specialized in the development and application of statistical and epidemiological methods for causal inference, focusing in particular on evaluating the health impacts of air pollution policy and exposure. With the weight of his expertise in causal inference methods, he wished to state his support for the causality framework used in the Draft ISA. He stated that the framework was useful in informing policy decisions and generally understood by most intended users of the Draft ISA. He indicated that there is a vast literature on causal inference methods, but that does not preclude the usefulness of the ISA causal framework for making causal determinations. He stated that most of the ISA causal framework is consistent with the relevant literature on causal inference methodology. He indicated that translating the scientific principles of causality from their roots in controlled experiments to the realities of observational, population-based studies is a large part of the disciplines of epidemiology and statistics, two areas, where CASAC specifically lacks relevant expertise. He echoed others' recommendations to reconvene a PM review panel and to include expertise in causal inference methodology, particularly in their application and interpretation amid the inherent challenges and uncertainties of population-based epidemiological research.

Albert Rizzo, American Lung Association, provided an oral statement,[14] indicating that the Draft CASAC report was troubling, and pointed to two comments on the first page of the report that he said were incorrect and should be removed: the claim that there is no comprehensive or systematic assessment of the science (despite nearly 1900 pages that examine in depth more than 2,000 studies); and that the ISA does not follow widely accepted scientific methods (despite following the process used by the National Academy of Sciences to determine causality). He urged the EPA to reconstitute the former CASAC PM panel.

Kevin Cromar, New York University, presented an oral statement on behalf of the American Thoracic Society (ATS).[15] He expressed thanks to the CASAC members for their hard work preparing comments on the Draft ISA. He stated that it was the professional opinion of ATS that the scientific studies contained in the Draft ISA are a good representation of adverse effects at the population-level, effectively characterize the mechanisms by which they occur, and provide a strong foundation to determine concentration-response (C-R) relationships. He noted that the CASAC report should be clear regarding consensus and non-consensus advice. ATS rejects the extreme viewpoints in the Draft CASAC report that the studies in the Draft ISA are unable to provide a factual basis for making causal determinations relevant to policymaking and the stated belief that causal determinations cannot be done

objectively and are merely a reflection of personal opinion. ATS also strongly urged EPA to reconvene the disbanded CASAC PM panel if another draft of the ISA is to be prepared.

Jonathan Samet, Colorado School of Public Health, made an oral statement. He indicated that he was a former Chair of CASAC and agreed 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, but that such changes should be measured and not disruptive. He noted that he had submitted written comments[16] and concurred with the recommendation to expand the panel with consultants as originally planned.

Bernard Goldstein, University of Pittsburgh Graduate School of Public Health, presented an oral statement. He indicated that his major points were that the number of studies considered to be suitable for inclusion in the Draft ISA continues to substantially increase, in contrast to the number of scientists involved in the CASAC review process; that the synthesis of this information follows standard methodological approaches; and that a single individual cannot provide a consensus. He stated that no seven experts could cover the health effects chapters, even if their expertise had been chosen to match the subjects of the chapters, and that there was a lack of epidemiological expertise on the CASAC. He stated that the current situation is one in which, if he were a member of CASAC, he would emphatically state his intention to resign unless the CASAC PM Panel, as formerly constituted, were restored and an open and transparent discussion were held. He would resign before allowing himself be part of a process in which a CASAC recommendation could well be made that does not uphold the legal standard to protect public health required by the Clean Air Act, makes it seem as if he claimed far more expertise than he had a right to do, and running the risk of forfeiting the respect of his peers in the scientific community.

Joel Schwartz, Harvard University, made an oral statement and indicated that the Draft ISA's approach of using epidemiology to estimate C-R relationships to use in health impact assessments is consistent with the recommendations of two National Academy of Science panels on risk assessment, which specifically endorsed such as approach; is consistent with the recommendations of the EPA Advisory Council on Clean Air Compliance Analysis; is consistent with the approach of the World Health Organization; and is consistent with the approach of the International Agency for Research on Cancer and many other scientific bodies. He indicated that, in contrast, the notion that it should be thrown out and all estimates be based on toxicology is completely inconsistent with the scientific consensus. He stated that the claim that measurement error makes epidemiology studies useless because they can overestimate effects is refuted by empirical data and that there is no empirical evidence supporting the assertion of CASAC that estimates could be biased upward, and therefore should not be used for risk assessment.

George Allen presented an oral statement,[17] indicating that he was a former member of CASAC, a member of the disbanded CASAC PM Panel, and that his comments did not necessarily reflect the views of his employer, Northeast States for Coordinated Air Use Management (NESCAUM) or NESCAUM member states. He stated that by redefining the causality framework, the CASAC has put EPA staff in a difficult situation. He also indicated that the CASAC should request that the CASAC PM Panel be restored and that the current Chartered CASAC is unqualified to perform the review alone in a manner that fulfills the Clean Air Act requirements, leaving the review vulnerable to legal challenges.

Roger McClellan was not on the teleconference to give an oral statement.

The CASAC members did not have any clarifying questions for public speakers. Dr. Cox thanked all the speakers as well as those who prepared written comments.

Discussion of Draft CASAC PM ISA Report

Discussion of Consensus Responses

Dr. Cox proposed going through the consensus responses to the charge questions for Chapters 2-13, then the Executive Summary and Chapter 1, then the Letter to the Administrator. Dr. Frampton proposed addressing two overarching issues first: the need for additional expertise, and how to express the need; and whether the causality framework was effective or need to be changed. The members agreed to spend the next 15 minutes to go through the consensus responses to the charge questions for Chapters 2-13.

The CASAC members agreed to add "UFP" to the sentence on page 13, line 27. Dr. Cox indicated that there currently was a "preamble" to Chapters 4-12, consisting of "General Comments" and "Causality Determination of Mortality from $PM_{2.5}$ Exposure." The members agreed to move the "General Comments" section (p. 18, line 26 – p. 19, line 4) and the "Causality Determination of Mortality from $PM_{2.5}$ Exposure" section (p. 19, line 6 – p. 21, line 15) to the front of the report, before the consensus response to the charge questions for the Executive Summary. The overall "Comments on Chapters 4-12" heading would then be deleted. The other members agreed with this. The members had no other comments on the consensus responses to the charge questions for Chapters 4, 5-11, 12, and 13.

Dr. Cox proposed discussing the response to the charge questions on Chapter 1 first, then the Executive Summary. He indicated that he was not proposing new standards of evidence or that manipulative causality should be the only criterion to be used. He stated that it seemed that there were two clusters of views of what good science is and how it should be used in the NAAQS process. The first view emphasizes authoritative expertise, time-tested tradition, and holistic expert judgement. The second view, to which he subscribes, rejects this as the best description of science. It emphasizes empirically testable predictive rules and generalizations; observations; and reproducible derivations of conclusions; using clear operational definitions. It allows for independent verification of reasoning leading up to conclusions. This approach considers that valid scientific conclusions must be drawn by applying empirically validated predictive rules and generalizations. In this view, holistic judgements can be valuable in formulating useful hypotheses and especially valuable in making empirically verifiable and potentially falsifiable predictions. Holistic judgements, no matter how great the expertise behind them, are not a substitute for science in this second sense of empirically validated predictive rules and derivations. This second view sees science as consisting of formulating and testing and modifying causal hypotheses based on the accuracy of their predictions and being explicit about how conclusions are derived, and not a holistic judgement. He stated that his goal was not to push for research he thought was important, or for philosophy of science. He indicated that, even if others viewed these two clusters differently, he wanted to preserve components of the second viewpoint in whatever the members come to consensus on. He stated that he had made a bad mistake by holding out this ideal of what science should be and then criticizing the current ISA for not adhering to that ideal. He thought that a much more useful approach is to make specific recommendations for what the ISA should do that it does not do now. Dr. Packham indicated that having rules for testing hypotheses was not out of the mainstream of science and was a huge part of many disciplines of science, including medical research and discovery of effectiveness of drugs. He stated that his position on science was that both of those approaches must be used and that he was very supportive of the idea of evaluating the ISA in terms of how well, how completely, and how effectively it utilizes evidence from both of those approaches to science. Dr. Frampton indicated that these are more general overarching comments and not necessarily specific to

Chapter 1 or the Executive Summary. Rather than ask EPA to address it in the Second Draft ISA, CASAC could ask them to add the concept that this approach exists and maybe advise them to have a workshop on these issues, vetting them through the scientific community, for consideration for future ISAs. He stated that to ask EPA in the Second Draft ISA to completely revise their approach to decision making would be paralyzing. Dr. Cox agreed and stated that he would love for the NAS to look at this.

Dr. Cox proposed removing whatever the members did not find important for the consensus response to the charge question for Chapter 1. He proposed the following edit to page 11, lines 5-11: "The CASAC finds that Chapter 1, similar to the Executive Summary, provides an effective summary of material from subsequent chapters." Then he proposed 5 points to add: 1) The CASAC recommends that Chapter 1 should explicitly list and apply systematic review criteria for inclusion of relevant studies and for evaluating, reconciling, synthesizing, and summarizing their results. 2) It should more clearly define the effects being described. Are they direct, indirect, total effects, or just association? 3) It should better characterize what is known about whether and under what conditions reducing PM2.5 alone would materially reduce human health risks. 4) It should characterize the uncertainty and sensitivity of its key conclusions with further information. 5) It should more fully address inconsistencies and discordant data in the available literature. Dr. Frampton indicated that he had issues with each of those. He stated that he agreed that more needs to be done in this ISA with regards to the quality of the studies, but was concerned that the term "systematic review" is suggestive of a meta-analysis approach, which is not what CASAC is recommending. He suggested using the phrase "systematic quality for study selection" or "systematic criteria for assessing study quality." There are criteria specified in the Preamble of the ISA, and although EPA does discuss how study quality would be assessed, the ISA does not discuss how the study quality assessment was used in the judgements that were made, or whether they were applied at all. There are enhancements that can be made to be more thorough and transparent about both the selection of studies and the assessment. The criteria for study selection were reasonable and it seemed that they were not eliminating studies based on quality criteria alone. But that was not explicitly stated and needs to be clarified. He did not think that this statement belonged in the Chapter 1 consensus response, and suggested that it was more of an overarching comment pertaining to the whole document. It was agreed that Dr. Frampton would craft a revised sentence or two to reflect this.

There was disagreement over point number 2. Dr. Frampton indicated that he did not think that the accountability approach was necessary to demonstrate causality. Dr. Cox stated that he completely agreed, but that whatever was being concluded in the ISA needed to be clear. Dr. Frampton indicated that just because there was not an accountability study should not mean that the observed effect was just an association. Dr. Packham did not think that the ISA was overstating conclusions and was clear in presenting their conclusions. The members agreed that this was more of a discussion of causality and not specific to Chapter 1, so they decided not to include point 2 as part of the Chapter 1 consensus response. For point number 3, they agreed that it was not specific to Chapter 1 and it would not be included in the Chapter 1 consensus response. For point number 4, Dr. Lange indicated that the other chapters did characterize uncertainty and sensitivity, but that they are not adequately characterized in Chapter 1. The members agreed that Dr. Cox will revise to make it clear that chapter 1 should convey the uncertainties and sensitivities of the key conclusions from the other chapters. For point number 5, Dr. Lange indicated that it is related to the point 4. Dr. Cox asked whether it would be useful to list examples. Dr. Lange indicated that examples were already listed in the consensus responses for Chapters 5-11. The members agreed to just refer to the consensus responses and individual comments. The remaining portion of the Chapter 1 consensus response (p. 11, line 13 – p. 13, line 17) would be deleted.

Dr. Cox proposed abridging the consensus response to the Executive Summary, revising page 5, lines 35-37 to the following: "The CASAC finds that the Executive Summary provides a concise and

accessible summary of many of the key findings and conclusions of the Draft ISA for a broad range of audiences. It does not accurately represent the totality of available high-quality scientific evidence." Dr. Cox proposed the next sentence to be: "The CASAC recommends that statements of key findings and conclusions should clearly distinguish between true and estimated PM exposure values." Dr. Frampton did not agree to adding that statement. He indicated that one can never really know true exposure. Dr. Lange indicated that what was being asked for was to add clarifying terms into the Executive Summary when describing exposures in the key findings and conclusions to indicate they are estimated exposures. Dr. Frampton stated that all exposures are estimated, so he did not really see the point in adding that statement. Dr. Cox indicated that many statements indicating adverse health effects occuring at certain exposure levels are highly misleading because those are estimated exposures with measurement exposure error, so it was important to be accurate for the sake of risk communication. The members agreed to recommend that EPA indicate when exposures being referred to are estimates.

Dr. Cox proposed adding the following statement, and then deleting most of the remaining portion of the Executive Summary response: "The CASAC recommends that statements of key findings and conclusions distinguish between effects of PM and effects of confounders (such as poverty and temperature), between individual and population risks, between observed changes and model-predicted changes in public health risks following changes in exposures; between assumptions and data on shapes of C-R functions; between results from the total body of scientific evidence and results from selected subsets of evidence; and between association and causation. The CASAC recommends the Executive Summary be revised to clarify these distinctions. It should explicitly discuss for each health effect whether ambient concentrations can or can not independently cause it." Regarding the portion of the statement on individual vs. population risk, Dr. Cox indicated that C-R function for a population may have a different slope than for each of the individuals in a population. Dr. Frampton indicated that was obvious. The members agreed not to include that statement. Regarding the portion of the statement on observed changes and model-predicted changes in public health risks, Dr. Frampton objected to it. Dr. Cox indicated that this referred to accountability studies. Dr. Frampton did not find that the statement was clear that it was referring to accountability studies. Dr. Cox stated that the issue was that in the ISA, there were many studies stating that a reduction in exposures resulted in a reduction in risk when, in reality, it is referring to modeled predictions, not observed changes. Dr. Frampton indicated that he did not recall that this was a major issue in the ISA and would need specifics on where in the ISA this occurred. Dr. Cox proposed creating a list of references where this was an issue and would send it out to the Committee after the meeting. Mr. Yeow indicated that since all deliberations had to be public, he needed to provide those references on the teleconference for the CASAC to agree to. He proposed to have the additional clarifying public comment period at 2:35 pm and for the members to stay on the teleconference for another hour after that so that they could finish deliberations on the draft report. If they could not finish deliberations, they would need to schedule another teleconference, which would lead to several months of delay. The CASAC members agreed to softening the language of the statement and to reflect that not all members agreed to the language: "Some members recommend EPA consider distinguishing…" The members also agreed to delete the remaining Executive Summary response (p. 5, lines 38 – p. 10, line 35).

Additional Clarifying Comments on the Draft CASAC PM ISA Report from EPA or the Public

Chris Frey, North Carolina State University, provided a clarifying comment and indicated that CASAC can provide advice to EPA on anything it wanted to, including process issues and strongly recommended that the CASAC recommend to the EPA to reinstate the CASAC PM Panel. He indicated that there was a difference between doing a scientific study and reviewing the current state of science. He urged the CASAC to give EPA a chance to provide their perspective on what the CASAC was deliberating, how

would they translate CASAC comments into practice. He indicated that he did not think the ISA should get into study quality, but rather policy-relevance.

Deborah Cory-Slechta, University of Rochester Medical Center, provided a clarifying comment underscoring the need for additional expertise on the CASAC. She pointed to one of the CASAC statements in the draft report that indicated that studies of early neurodevelopmental air pollution are not consistent. She pointed out that they were not consistent because they involve exposures at very different times of brain development or because the studies were carried out at different geographic locations. She stated that the studies were not inconsistent but that they were not being interpreted correctly. She indicated that this underscored the need for someone who understands the nervous system.

Gretchen Goldman, Union of Concerned Scientists, provided a clarifying comment indicating that in the discussion of the two different views of science there was some conflation between individual studies and review of existing studies. She stated that CASAC's charge with respect to the ISA is to look at the body of evidence and the strengths of the evidence that exists. With respect to the alternative framework, she wanted to clarify that on the Science piece, they were referencing and reacting to Dr. Cox's own words in the Draft CASAC Report as well as the discussions at the December 2018 CASAC meeting. She stated that Dr. Cox's proposal would indeed reject most of the key studies that EPA relies on for causal assessment on long-term PM exposure and mortality. She indicated that she welcomes accountability studies but that they cannot over rely on them in a context where they are using observational data to study an environmental risk.

Lianne Sheppard, University of Washington, provided a clarifying comment expressing her concern that CASAC does not have the expertise to do the job it tried to do, that the chair did not follow the suggestions of other CASAC members, that the CASAC has not asked for input from EPA, that CASAC did not adequately deliberate on key points of the draft report, that substantial changes to the report do not reflect the consensus of CASAC, and that the process was a travesty.

Seth Johnson, Earth Justice, provided a clarifying comment that nothing in the Clean Air Act (CAA) required looking at solely effects of PM alone without regard to how it might interact with other factors. He stated that the statutory text governing the ISA itself shows that it is not just the effects of PM alone that matters. He indicated that the Act says to the extent practical, the ISA shall include information on types of air pollution that may interact with the criteria pollutant to produce an adverse effect on public health or welfare. He stated that the Act says to the extent practical, the ISA shall include information on the factors that may alter the effects on public health or welfare of the criteria pollutant.

Dan Greenbaum, Health Effects Institute (HEI), provided a clarifying comment that they were pleased that accountability studies that they kicked off 10-15 years ago, at the request of EPA, were at the center of many of the discussions. He cautioned CASAC that although they have made much progress, it is not simple to do these studies. He stated that in many cases, actual observed measurements of exposure were very poor and misleading. He indicated that if carefully done, carefully vetted, carefully QA'd and QC'd, modeled estimates of exposure could actually be much better than measured exposures.

The CASAC members did not have any questions for the public commenters.

Discussion of Draft CASAC PM ISA Report (cont'd.)

Dr. Cox proposed jumping to the Letter to the Administrator, then the overarching issues. Dr. Frampton recommended covering the process issues first. The CASAC members all agreed to discuss the process issues for additional expertise and then the Letter to the Administrator. Dr. Cox indicated that the current language was to have access to additional expertise. The CASAC members agreed that they would recommend that EPA reappoint the previous PM panel or a panel with similar expertise as well as adding additional expertise. They also had discussion and agreed that they would like this panel to be formed in time for the review of the 2nd Draft ISA.

Discussion of Letter to the Administrator

On the first page of the Letter to the Administrator, Dr. Cox proposed revising the sentence on lines 32-35 and the members agreed to the following revision: "Overall the CASAC finds that the Draft ISA does not provide a sufficiently comprehensive, systematic assessment of the available science relevant to understanding the health impacts of exposure to particulate matter."

For the first bullet, the CASAC agreed to revising it to add that study quality was not systematically reviewed. The CASAC agreed to adding as the 2nd bullet, a statement regarding inadequate evidence for altered causal determinations. Dr. Cox proposed a new statement as the 3rd bullet: "For each effect, the ISA should make clear whether reducing ambient PM exposure alone is expected to reduce the risk of the effect. It should also discuss the extent to which this expectation has been tested and validated with available observational data." Dr. Frampton objected to that statement. There was some discussion and the CASAC then agreed to drop it. Dr. Cox proposed another bullet as the final bullet: "Clearer discussion of causality and causal biological mechanisms and pathways, specifically including pulmonary inflammation." The CASAC agreed to that. The CASAC members also agreed to delete the other bullets (first page of letter, line 40 – second page of letter, line 7).

There was disagreement over the statement that all key conclusions in the ISA should be supported by independently reproducible and verifiable derivations (second page of the letter, lines 9-12). After some discussion, the members agreed to revise the statement to reflect only some of the CASAC members agreeing with the statement and replacing "independently reproducible and verifiable derivations" with "explicit, and in principle, verifiable tests." The sentence on lines 10-12 would be deleted. The CASAC agreed to some revisions for clarity on lines 14-16. For the recommendation on lines 19-20, this would be replaced with the recommendation CASAC agreed to previously on the call regarding reappointing the previous PM panel or a panel with similar expertise. Dr. Frampton wanted to make sure that the recommendation was for a typical CASAC panel that reviewed agency documents, provided written comments, and participated in the review meeting. It was understood that this was the meaning of a CASAC panel and was what CASAC was recommending and that CASAC was recommending that the panel be formed in time for review of the 2nd Draft ISA. The members all agreed to stay on the call for another 30 minutes to an hour to complete the deliberations. The language in the Letter regarding the consensus responses to the charge questions for the chapters would reflect the revisions discussed and agreed to earlier on the call. Dr. Frampton asked whether the CASAC members really wanted to have a statement in the letter that some members are calling into question the causality determination between $PM_{2.5}$ and mortality. He indicated that there would need to be some compelling new evidence to call that determination into question, which he did not think existed. Dr. Cox indicated that he looked through the literature and was appalled that almost no studies control carefully for what he thought were the most important sources of confounding (lagged daily temperature extremes and poverty). Dr. Frampton did not want to argue the point, but just wanted to confirm that the CASAC was not in agreement over this

point. Dr. Packham indicated that he also did not agree with the EPA's causality determination for $PM_{2.5}$ and mortality, but for biological reasons. The CASAC agreed that they did not have consensus over this causality determination and agreed to leave the statement reflecting that in the letter.

Discussion of Overall Comments and Recommendations on the Integrated Science Assessment (ISA)

As discussed earlier on the call, the members agreed to move the "General Comments" section (p. 18, line 26 – p. 19, line 4) and the "Causality Determination of Mortality from $PM_{2.5}$ Exposure" section (p. 19, line 6 – p. 21, line 15) to a section at the front of the report, before the consensus response to the charge questions for the Executive Summary. The members agreed to delete the remaining portion of this section (p. 1, line 7 – p. 5, line 24).

Disposition of Draft CASAC PM ISA Report

The Chartered CASAC members all concurred with the report with the revisions discussed on the teleconference.

Summary and Next Steps

Mr. Yeow indicated that the report will be revised based on the discussions on the teleconference and would be emailed out to the CASAC members for their confirmation that the revisions reflect the discussions from the teleconference. It would then be transmitted to the Administrator.

The meeting was adjourned by Mr. Yeow at 4:40 pm.

Respectfully Submitted:	Certified as Accurate:
/s/	/s/
Mr. Aaron Yeow	Dr. Louis Anthony Cox, Jr.
Designated Federal Officer	Chair
EPA SAB Staff Office	CASAC

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by Committee members during the course of deliberations within the meeting. Such ideas, suggestions and deliberations do not necessarily reflect consensus advice from the Committee members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters or reports prepared and transmitted to the EPA Administrator following the public meetings.

Materials Cited

The following meeting materials are available on the CASAC website: https://yosemite.epa.gov/sab/sabproduct.nsf//MeetingCalCASAC/4F40665AD1DDCEF6852583A000645464?OpenDocument

[1] 03-07-19 Draft CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft – October 2018)
[2] Chartered CASAC Roster
[3] Federal Register Notice Announcing the Meeting
[4] Agenda
[5] List of Registered Public Speakers
[6] Written comments from 17 Members of the Disbanded CASAC PM Review Panel
[7] Written Comments from H. Christopher Frey, North Carolina State University
[8] Oral Statement from Gretchen Goldman, Union of Concerned Scientists
[9] Oral Statement from John Bachmann, Environmental Protection Network
[10] Oral Statement from Lianne Sheppard, University of Washington
[11] Oral Statement from Julie Goodman, Gradient
[12] Oral Statement from George Thurston, North American Chapter of the International Society of Environmental Epidemiology
[13] Oral Comments from Corwin Zigler, University of Texas at Austin
[14] Oral Statement from Albert Rizzo, American Lung Association
[15] Oral Statement from Kevin Cromar, on behalf of the American Thoracic Society
[16] Written Comments from Jonathan Samet, Colorado School of Public Health
[17] Oral Statement from George Allen

ATTACHMENT A – Other Attendees

Name	Affiliation
Allen, George	
Akers, Brad	
Allen, Phil	
Alman, Breanna	
Bachmann, John	Environmental Protection Network
Baer, Louis	Portland Cement Association
Becker, Michelle	USEPA
Billings, Paul	American Lung Association
Black, Hank	BirminghamWatch.org
Blake, Uni	American Petroleum Institute
Bloomer, Bryan	USEPA
Brown, James	USEPA
Brown, Marie	South Carolina DHEC
Buckley, Barbara	USEPA
Burkett, Jeff	Liberty Utilities
Butler, Craig	
Calma, Justine	
Cascio, Wayne	USEPA
Cashin, Michael	Minnestoa Power (ALLETE)
Chan, Elizabeth	USEPA
Chudow, Amanda	NYSDEC
Coffman, Evan	USEPA
Cone, Shane	DNREC
Copeland, Andrea	Phillips 66
Copley, Bruce	ExxonMobil Biomedical Sciences, Inc.
Corrales, Mark	USEPA
Cory-Slechta, Deborah	University of Rochester
Cromar, Kevin	New York University
Curtis, Holly	NESCAUM
Damberg, Rich	USEPA
Daniels, Rebecca	USEPA
Davidson, Kenneth	USEPA
Dolwick, Pat	USEPA
Dominici, Francesca	Harvard University
Dutton, Steven	USEPA
Enstrom, James	UCLA and Scientific Integrity Institute
Ewart, Gary	American Thoracic Society
Felker-Quinn, Emmi	USEPA

Name	Affiliation
Fine, Philip	South Coast Air Quality Management District
Fraiser, Lucy	
Frey, Betsy	Delaware DNREC/DAQ
Frey, H. Christopher	North Carolina State University
Frisby, Bradford	National Lime Association
Fritz, Patricia	NY State Department of Health
Fuller, Christine	Georgia State University
Gerhart, Seth	
Gledhill, Jonathan	Policy Navigation Group
Goldman, Gretchen	Union of Concerned Scientists
Goldstein, Bernard	University of Pittsburgh Graduate School of Public Health
Goodman, Julie	Gradient
Gorman, Teresa	LPI
Graham, John	
Greaver, Tara	USEPA
Greenbaum, Dan	Health Effects Institute
Hale, Zack	S&P Global Market Intelligence
Hansen, Michael	Gasp
Hantman, Irene	Verdant Law
Hassett-Sipple, Beth	USEPA
Herrick, Jeff	USEPA
Hersher, Rebecca	NPR
Hetes, Bob	USEPA
Hines, Erin	USEPA
Hogue, Cheryl	Chemical & Engineering News
Hotchkiss, Andrew	USEPA
Hoyer, Marion	USEPA
Hulse-Moyer, Laurie	Washington State Department of Ecology
Irby, Sebastian	
Isied, Margaret	
Jacobs, Wendy	
Jarabek, Annie	USEPA
Jenkins, Allison	TCEQ
Jenkins, Scott	USEPA
Johnson, Giffe	
Johnson, Seth	Earthjustice
Johnston, Greg	
Jones, Ryan	USEPA
Jones, Samantha	USEPA
Kalisz, Cathe	API

Name	Affiliation
Katz, Stacey	USEPA
Kaufmann, Rob	
Kaylor, Doug	USEPA
Kennedy, Diamond	NPR
Kerr, Lukas	USEPA
Kim, A.	
Kirrane, Ellen	USEPA
Kruger, Nancy	NACAA
Lamson, Amy	USEPA
Langworthy, Cindy	Hunton Andrew Kurth LLP
Lavelle, Marianne	InsideClimate News
Lavoie, Emma	USEPA
Lebens, Bob	WESTAR
Lefohn, Allen	A.S.L. & Associates
Lein, Mckayla	USEPA
Limaye, Vijay	Natural Resources Defense Council
Liu, Coco	Electric Power Research Institute
Long, Chris	
Long, Tom	USEPA
Lopez, Daniella	
Luben, Tom	USEPA
Marshall, Kristin	
Mazza, Karl	USEPA
McCaslin, Steve	
McDow, Steve	USEPA
Miller, Andy	USEPA
Mingle, Jonathan	
Miyasato, Lori	CARB
Mongoven, Karen	National Association of Clean Air Agencies
Mongoven, Karen	
Moutinho, Jennifer	ExxonMobil Biomedical Sciences, Inc.
Nichols, Jen	USEPA
Niebling, William	
Nolan, Sean	State Government
Nolen, Janice	American Lung Association
Novak, Kris	PA DEP
Ondras, Martha	Tufts University
Orlin, David	USEPA
Owens, Beth	USEPA
Papadogeorgou, Georgia	Duke University
Parent, Stephanie	

Name	Affiliation
Parker, Stuart	IWP News
Paunio, Mikko	
Peffers, Mel	House E&C Committee
Plautz, Jason	
Popovech, Marusia	ExxonMobil Biomedical Sciences, Inc.
Prettyman, Mark	
Raso, Lindy	Health Effects Institute
Rech, Amee	
Rees, Sarah	South Coast Air Quality Management District
Reilly, Sean	E&E News
Reyes, Jeanette	USEPA
Rice, Richard	USEPA
Richmond-Bryant, Jen	USEPA
Rizzo, Albert	American Lung Association
Rohr, Annette	Electric Power Research Institute
Ross, Mary	USEPA
Russo, Andrew	Illinois EPA
Sacks, Jason	USEPA
Saiyid, Amena	Bloomberg Environment
Salas, Paola	
Samet, Jonathan	Colorado School of Public Health
Sasser, Erika	USEPA
Schreiber, Danielle	Verdant Law PLLC
Schwartz, Joel	Harvard University
Shaikh, Rashid	
Shallal, Sue	USEPA
Sheppard, Lianne	University of Washington
Shprentz, Deborah	Atmospherix
Silverman, Steve	NGO
Skipper, Nash	
Smith, Linda	California Air Resources Board
Song, Jamie	
Steichen, Ted	American Petroleum Institute
Thayer, Kris	USEPA
Thurston, George	NYU School of Medicine
Tollefson, Jeff	Nature
Uhl, Mary	
Valberg, Peter	
Vinig, Rose	
Wajda-Griffin, Scott	New York State Department of Environmental Conservation

Name	Affiliation
Wakelyn, Phillip	
Weitekamp, Chelsea	USEPA
Wesson, Karen	USEPA
Winner, Darrell	USEPA
Woock, Steve	Weyerhaeuser Company
Wu, D Pei	Oregon DEQ
Wulf, Brian	Exxon Mobil Corporation
Zarba, Chris	
Zigler, Corwin	The University of Texas at Austin