Summary Minutes of the
U.S. Environmental Protection Agency (EPA)
Chartered Clean Air Scientific Advisory Committee (CASAC)
Public Meeting on Particulate Matter
October 24- 25, 2019

Date and Time: Thursday, October 24, 2019 - Friday, October 25, 2019

Location: Embassy Suites by Hilton Raleigh Durham Research Triangle, 201 Harrison Oaks Boulevard, Cary, North Carolina, 27513; telephone; and live audio webcast.

Purpose: The purpose of the meeting is to conduct a peer review of EPA's *Policy Assessment (PA) for the Review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM) (External Review Draft – September 2019).*[1]

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

Mr. Aaron Yeow, Designated Federal Officer (DFO)
Mr. Tom Brennan, EPA Science Advisory Board Staff Office

Dr. Erika Sasser, EPA Office of Air Quality Planning and Standards (OAQPS)
Ms. Karen Wesson, EPA OAQPS
Dr. Scott Jenkins, EPA OAQPS

Other Attendees (See Attachment A)

Thursday, October 24, 2019

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), CASAC meetings are held in public, with advanced notice given in the Federal Register.[3] He stated that the CASAC had received written public comments, which were posted on the October 22 meeting webpage and that oral public comments were given during the October 22 teleconference. He noted that there was a clarifying public comment period on the agenda where members of the public could make short clarifying comments, providing additional information to the CASAC. He stated that the meeting minutes would be made publicly available after the meeting. He stated that the SAB Staff Office determined that there were no financial conflicts of interest or an appearance of a loss of impartiality for any of the CASAC members.

He turned the meeting over to Mr. Tom Brennan, Director of the EPA Science Advisory Board Staff Office, who welcomed everyone and thanked the members of the public who provided written and oral comments, the CASAC members for all their hard work and effort; the pool of consultants who contributed to this effort; and the EPA staff that developed the PM PA. He then turned the meeting over to Dr. Tony Cox, Chair of the CASAC.

Dr. Tony Cox welcomed everyone and briefly went through the agenda,[4] indicating that they would begin with EPA's presentation, then the CASAC members would have an opportunity to ask clarifying questions after the presentation.

EPA Presentation

Dr. Erika Sasser, Director of the Health and Environmental Impacts Division of EPA OAQPS, welcomed everyone and thanked the members of CASAC for their time and initial feedback they have provided and stated that EPA looked forward to hearing the rest of CASAC's comments. Ms. Karen Wesson, Group Leader of the Ambient Standards Group of EPA OAQPS, began EPA's presentation,[5] covering the Outline of the Presentation, Background and Statutory Requirements, and the Process and Schedule for This Review of the PM NAAQS. Dr. Scott Jenkins, EPA OAQPS, continued the presentation, covering the Policy Assessment: Purpose and Focus, Current PM Standards Under Review, National Emissions Trends, National Air Quality Trends, Primary $PM_{2.5}$: Summary of Approach, $PM_{2.5}$ Concentrations in Epidemiological Studies, Design Value-Like $PM_{2.5}$ Metrics, $PM_{2.5}$ Annual Psuedo-Design Values in Locations of Key Studies, $PM_{2.5}$ Risk Assessment – Background and Approach, Summary of $PM_{2.5}$ Risk Estimates, Preliminary Conclusions on the Current Primary $PM_{2.5}$ Standards, Preliminary Conclusions on the Level of the Annual $PM_{2.5}$ Standard, Preliminary Conclusions on the Level of the 24-Hour $PM_{2.5}$ Standard, Primary PM_{10} Standard, Secondary PM Standards: Summary of Approach and Scientific Evidence, Secondary PM: Summary of Quantitative Information for Visibility Impairment, and Secondary PM: Preliminary Conclusions.

Dr. Cox had a question on slide 15, the concentration-response (C-R) functions from U.S. cities. He asked whether this was referring to regression-type C-R functions or causal-type C-R functions. Dr. Jenkins responded that for the specific studies included in the risk assessment, they were regression-type C-R functions.

Dr. Lange sought clarification for the relationship between pseudo-design values (PDV) and maximum design values for each of the areas. Dr. Jenkins clarified that to calculate PDVs, they took each three-year period of a study, and for each county of the study identified the maximum design value-like metric for that three-year period, and averaged those maximums over the duration of the study.

Dr. Frampton asked how the PA would address CASAC comments on changes to causality determinations in the Integrated Science Assessment (ISA). Dr. Jenkins indicated that the final PA would reflect any changes made to causality determinations made in the final ISA.

Dr. Cox asked whether the beta coefficients in BENMAP were 100% causal or could they be partially causal and partially due to omitted confounders. Dr. Jenkins indicated that by using a variety of studies and C-R functions from various studies, and looking across the literature, they would have general confidence that they are in the right ballpark. They recognize that the absolute risk estimate of any one study would be more uncertain than from looking across multiple studies and multiple C-R functions. Dr. Cox asked whether EPA thought that the beta coefficients from the regression C-R functions provided a useful approximation of causal C-R functions. Dr. Jenkins indicated that was a fair statement

if they were referring to the right ballpark in looking across multiple studies. Dr. Cox asked when they state that a C-R function is causal, does that imply that reducing concentration will reduce risk, holding all other factors fixed. Dr. Jenkins indicated that the causal determination is not referring to an individual C-R function, but to the broad body of evidence in the ISA. In the PA, key studies are being pulled out of that evidence and using that to try to estimate what might be the implications for risk of changing the levels of $PM_{2.5}$ in the air. In that analysis, there is an implication of causality, but that implication is based on the body of evidence in the ISA. Dr. Cox asked whether this hypothesis has been tested. Dr. Jenkins responded that they do not do the tests of this type of information. They look to the published literature to evaluate and test these ideas. There is this emerging body of evidence that use causal inference modeling, quasi-experimental approaches, some of which are looked at the ISA, but not necessarily pulled into the PA. But when looking at the causal relationship, conclusions are based on those types of studies.

Discussion of PA Charge Questions

Dr. Cox asked if any CASAC members had questions regarding the charge questions.[6] Dr. Masuca sought clarification regarding the last general charge question that asks for the CASAC to advise the Administrator on any adverse economic issues, yet they are not supposed to consider costs when deliberating on the science. Dr. Cox indicated that for the secondary standard, they could identify costs from harm to materials, but for the primary standards, to protect human health with an adequate margin of safety, they do not consider economic issues.

Discussion of Response to PA Charge Questions

Chapter 1- Introduction

Dr. Cox presented slides of his comments on Chapter 1 of the PM PA.[7] His slides focused on asking CASAC what does current sound scientific evidence imply for whether the current PM NAAQS must be revised to protect human health with an adequate margin of safety and stated that CASAC's answer should be based on sound science. He defined what makes a scientific argument "sound," presented principles of sound science, and illustrated an unsound argument. He presented several science and risk analysis questions pertaining to how simulated results in the PA would change if the C-R functions were corrected for confounding, measurement errors, exposure estimation errors, modeling biases, p-hacking, and more recent and relevant literature such as intervention and accountability studies. He pointed out omitted studies and caveats as well as common methodological limitations of the 8 selected key studies in the PA. He concluded that it is not sound science to use associations from the 8 key studies to simulate or predict effects on health risks of changing $PM_{2.5}$. He stated that predictive validity is essential for sound science and provided recommendations for creating a sound science basis for policy.

In response to the Chapter 1 charge question, Dr. Cox found Chapter 1 to provide useful context. He found that the information in Chapter 1 is clearly presented in part, but conflates associations with causation, does not clearly distinguish between regression C-R functions and causation C-R functions, and refers to causal determination categories that could use clarification. He recommended that the PA should state that regression coefficients were treated as causal coefficients. Dr. Packham agreed with Dr. Cox and stated that there were huge problems with confounders, not only with factors like temperature, but also with the human organism itself. Dr. Cox stated that he was open to whether to recommend fuller documentation of NAAQS review process changes (consistent with several public comments), but that the stated intentions of the PA were incompletely fulfilled because of the lack of clarity in distinguishing between association and causation and between regression C-R functions and causal C-R functions.

Dr. Frampton agreed with some of Dr. Cox's points, however he stated that Dr. Cox's comments were revisiting the causality issues in the ISA. He noted that the PA was not attempting to review all the positive and negative studies, but was pulling out studies for the causal and likely-to-be-causal determinations from the ISA to estimate risk. He disagreed with Dr. Cox's key question and stated that accountability studies were very difficult to conduct and were fraught with confounders. He stated that to tie determinations of causality to being able to demonstrate in accountability studies that health risks go away is wrong. He also stated that it was not legitimate to throw out hundreds of epidemiology studies showing associations and the associated toxicological and human clinical studies because a few accountability studies had mixed results. Dr. Cox stated that there were no beta coefficients in the ISA and they are only presented in the PA, so he was not revisiting the causality issues of the ISA. Dr. Frampton acknowledged that observational studies have the potential for confounders that were not looked at. However he agreed with the opinions of the experts, the people that do the research, and understand the epidemiological literature, it is extremely unlikely that a set of confounders that haven't been looked at is responsible for the associations between PM and mortality across the entire body of evidence.

Dr. Frampton indicated that he could not provide an adequate response to Dr. Cox's concerns because he is not an epidemiologist, biostatistician, nor an expert in causality determination and that there was not anyone on CASAC that was. He stated that, judging from the responses by the experts and the Independent PM Review Panel (IPMRP), Dr. Cox's risk analysis views do not reflect the consensus of risk analysis experts. Dr. Frampton stated that what was missing was a panel of experts (who have read both the ISA and PA) who could be at the meeting and respond to Dr. Cox's questions. Dr. Frampton thought that the process was broken because they did not have the expertise needed to do the reviews due to the dismissal of the PM panel, that the pool of consultants could not be present at the meeting, and that the pool of consultants had much more limited expertise in epidemiology than the original PM panel. He stated that the difficulty in reaching consensus on some of the causal determinations in the ISA and the difficulty they were currently facing was in part due not having access to enough expertise to supplement the 7-member CASAC. He stated that so far they have accepted all the process changes by EPA, accepted the fact that EPA did not want to give CASAC a 2nd Draft ISA to review, that they wanted the CASAC to review the PA before the ISA was finalized, that EPA expected them to do this with very limited outside expert help, and so far CASAC has soldiered on and tried to do the best they could. Dr. Frampton stated that the review process was so dysfunctional that they needed to stop and that they should ask EPA for the minimum that they need so that CASAC could provide quality advice to EPA and that they did not currently have access to sufficient expertise in order to do that. He stated that he was proceeding under protest. Dr. Cox asked if there were specific technical questions that Dr. Frampton could not get answers to from the consultants. Dr. Frampton stated that he did not have such questions, but indicated that what he was seeking was having a group of experts sitting at the meeting who have reviewed the agency materials and prepared comments for CASAC's consideration, and could respond to all of Dr. Cox's concerns. Dr. Cox indicated that he was delighted with the consultants because they have shown far more technical depth in risk analysis and causality than he has ever seen in previous deliberations. Dr. Cox asked if other CASAC members had specific technical questions they felt they could not get answered by the consultants. Dr. Boylan indicated that he did not think he had such questions, but did want to echo Dr. Frampton's concerns. He stated he was on a previous CASAC panel on SO_2 and found it significantly more informative to have deliberations with a panel. He stated that the current process with the pool of consultants is significantly limiting and expressed major concerns with it. Dr. Packham agreed with Dr. Frampton's concerns, but did not think that they needed to halt the review, that the committee could still give good advice to the Administrator. He disagreed that what was needed was more epidemiologists. Dr. Cox disagreed with criticisms that the CASAC was

not qualified and stated that they were well qualified to give the advice that they have on controlling confounders, looking at measurement error, quantifying uncertainties, etc. He stated that they could provide useful advice on whether the conclusions of the PA follow from its premises, staying within their respective expertise and competence. Dr. Masuca agreed with Dr. Cox and stated that they have the knowledge and expertise to proceed forward with rationally-based recommendations. Dr. Cox asked Mr. Yeow if there was a way to formally note the reservations that Drs. Frampton and Boylan have expressed. Before answering, Mr. Yeow indicated that Dr. Lange had some comments. Dr. Lange indicated that the current CASAC has risk assessors, which has not been the case on previous CASAC panels, which provides a different perspective. Dr. Cox responded to Dr. Frampton's earlier point that causality has already been determined in the ISA, by stating that causality as used in quantitative simulations is new to the PA and is well worth examination. Dr. Cox summarized another one of Dr. Frampton's points as there is a lot of consistent associations and they should not be thrown out. Dr. Cox stated that he is not recommending throwing them out, but that they should only be used for what they could legitimately be used for, to quantify associations. Dr. Packham asked Dr. Frampton how long his recommendations on process would take to implement. Dr. Frampton stated that he did not have the answer, but was seeking for a panel similar to previous CASAC panels, who reviewed the agency documents and were included in deliberations at the meetings. He also indicated that he would like to review a 2nd Draft ISA as well as another draft of the PA after the ISA was completed. Dr. Cox stated that after lunch, they would go through the responses to the rest of the charge questions, then after that, they could make process recommendations. Mr. Yeow indicated that it seemed that the CASAC was recommending that Chapter 1 should more clearly describe and document the process changes and that the CASAC's concerns or issues on process could be documented there.

Chapter 2 – PM Air Quality

Dr. Boylan found that the information in Chapter 2 was clearly presented and provided useful context for the review, but there were a few areas that should be expanded to provide additional context for the review. These areas include: providing a more detailed discussion of uncertainty on sources of PM exposure; add a discussion of measurement uncertainty associated with ambient PM monitors; compare co-located FEMs/FRMs across the country; add a discussion of how differing $PM_{2.5}$ biases would impact the evidence-based and risk-based assessments in Chapter 3; add a discussion of the Southeastern Aerosol Research and Characterization Study (SEARCH) network; add a discussion of exceptional events, including a discussion of background concentrations for the daily $PM_{2.5}$ standard; and add a discussion of ^{14}C research to distinguish between fossil-derived carbon from "modern" carbon and implications for background organic carbon. Dr. Masuca found that, overall, the chapter was well written, as Dr. Boylan stated. He suggested adding a discussion of personal air monitors along with their shortcomings and stated that he did not see any mention of background transport form interstate transmission. Dr. Lange asked if they should add something about the FEM/FRM discrepancy possibly being due to volatilization. Dr. Boylan agreed that this would be good to add.

Chapter 3- Review of the Primary $PM_{2.5}$ Standard

Dr. Lange went through the major points that she outlined in her preliminary comments.[8] She stated that it was not clear what EPA was going to do with the CASAC recommendations for causal determinations in the ISA. She questioned whether the life expectancy studies included in the PA should be considered as accountability studies and recommended that EPA clarify what constitutes an accountability study. She indicated that EPA should provide a balanced summary of the study results for each health endpoint. She stated that the uncertainties identified in the last PM review should be explicitly addressed to determine whether more certain information is available in this review than there was in the past. She

noted that errors and heterogeneity in epidemiology study variables can alter the proper shape of the C-R function and obscure thresholds, and studies with these known errors should not be used to determine the shape of the association between $PM_{2.5}$ and health effects. She indicated that there are a substantial number of controlled human exposure (CHE) study results available that can be used not just as binary yes/no information for potential biological plausibility of epidemiology studies, but to provide information about dose, timing of effects, and potential sensitive populations. She stated that mean $PM_{2.5}$ concentrations from short-term and long-term studies should not be combined or compared. She indicated that the EPA should carefully consider what they are measuring and comparing when they derive pseudo-design values, as they do not really represent concentrations or conditions for either short- or long-term studies. She stated that she had concerns about the methods used to derive the risk estimates, and that it was not clear why certain studies were chosen to base the risk estimates on. Specific technical concerns included the Draft PA using C-R functions derived from epidemiology studies and applying them to risk estimation, conflating hazard ratios and relative risks, and substituting beta-coefficients derived from Cox proportional hazards models into time-series-type equations for the purposes of estimating population risk. Lastly, she indicated that there was very little quantitative uncertainty analysis provided with the risk assessment.

Dr. Frampton agreed that EPA needs to address CASAC's recommendations for changes in causal determinations, for instance, cancer. He did not think, however, that removing cancer mortality would significantly change the overall risk assessment. Overall he found that EPA did an excellent job on the PA. He addressed Dr. Lange's point regarding the PA not presenting negative studies and asked EPA to provide clarification. Dr. Jenkins indicated that study inclusion/exclusion criteria were applied regardless of whether the studies were positive or negative. Dr. Lange indicated that she had issues with how study results were characterized, which Dr. Frampton did not agree with. With regards to human clinical studies, Dr. Frampton stated that clinical studies should not be used in an attempt to establish a threshold for clinical effects. He indicated that in clinical studies, investigators are not looking at clinical effects, but are looking at surrogate markers of physiologic effects. They are also looking at small numbers of low-risk people, which cannot be used to derive a clinical effect threshold for a large population with sensitive subpopulations.

Dr. Cox stated that the PA should recognize or keep clear that there is a distinction between regression C-R functions and causal C-R functions. He indicated that the hypothesis that a regression C-R function closely approximates a causal C-R function, and that a regression C-R function can be used to simulate the effects of reducing $PM_{2.5}$, has not been tested and validated. He stated that model validity should be addressed for the BENMAP risk model. He indicated that it is absolutely essential to control for significant confounders before treating a coefficient as causal, that one must account for exposure measurement error. He recommended there should be a quantitative uncertainty analysis, including the contribution from model uncertainty, and noted that it is puzzling that there were so many significant negative C-R associations in past studies.

Dr. Boylan found that the study area selection for the risk assessment, the $PM_{2.5}$ air quality scenarios that were evaluated, model-based approach to adjust air quality, and linear extrapolation and interpolations to additional standards all seemed appropriate. He stated that the selection of which health outcomes were selected and why needed further discussion. He indicated that the risk assessment only focused on selected CBSAs and that CMAQ model performance should be evaluated at those selected locations, that model uncertainty should be quantified and incorporated into the risk assessment, that CBSAs with poor model performance should be excluded from the risk assessment, and that given the overlapping confidence bounds, EPA should evaluate if there is a statistically different risk between meeting the current NAAQS and alternative standards.

Dr. Cox asked Dr. Lange about her thoughts about the specific standards proposed in Chapter 3. Dr. Lange responded that thinking about it from the risk assessment perspective, she did not find much to have changed since the last PM NAAQS review. The hazard identification is largely the same, the dose-response is the same (linear, no threshold dose response, steepness of slope and beta coefficients haven't really changed), exposure has decreased, and the risk characterization doesn't show much difference. She stated that it was difficult to trust the risk estimates due to many of the reasons discussed earlier. Because she did not see much that has changed from the risk assessment perspective from the last review, she did not find any justification for changing the primary $PM_{2.5}$ standard.

Dr. Cox proposed proceeding to Chapters 4 and 5 and then coming back to the discussion on Chapter 3. Dr. Frampton was fine with that but stated that he did not agree with not changing the standard. He believed that there was new evidence that reduces uncertainty at lower exposure levels that renders the current standard not sufficiently protective.

Chapter 4 – Review of the Primary PM_{10} Standard

Dr. Frampton agreed with the PA that the evidence does not call into question the adequacy of public health protection afforded by the current PM_{10} standard. He noted that this differed from the IPMRP recommendations, but did agree with some of their recommendations for future assessments to use newer monitoring techniques to directly measure coarse particles, which has the potential to be more accurate in exposure assessment, further reducing uncertainty. Dr. Lange agreed that Chapter 4 provides a good summary from the ISA, but reiterates her concern that the PA needs to be clearer in summarizing the causal determination evidence. She agreed with the PA conclusions on the PM_{10} standard.

Chapter 5 – Review of the Secondary Standards

Dr. Cox presented slides of his comments on Chapter 5.[9] He found the discussions of several topics (e.g., visibility, materials damage, etc.) to be informative, but did not find the discussion of impacts of $PM_{2.5}$ changes on climate change to be adequate to support well-informed policy making. He wanted to focus on climate change because it could become a dominant contributor, with uncertainties about effects on climate change swamping effects coming from other sources. He presented the PA discussion of climate impacts and did not agree that the data are insufficient to conduct quantitative analyses for PM effects on climate. He stated that climate impacts of $PM_{2.5}$ are too important and well-studied to skip, there are $PM_{2.5}$-temperature interactions, that quantitative models and quantitative data are available, that quantitative impact estimates have been available for more than a decade, and that EPA has previously reported on aspects of $PM_{2.5}$ and climate change. He concluded that the PA should inform policy makers about the effects of $PM_{2.5}$ changes on warming, dimming, and brightening; high and low daily temperatures; resulting public health impacts related to daily temperatures; land carbon sink capacity; crop yields, agricultural productivity; and other weather variables. He stated that these could be large effects and could be important in setting secondary standards.

Dr. Boylan found that the 24-hour secondary standard was protective of visibility and therefore did not need to be changed.

Dr. Cox asked Mr. Yeow to inform everyone about the new, seventh CASAC member. Mr. Yeow indicated that CASAC did have a new, seventh member, Dr. Ron Kendall, an ecologist. However, Dr. Kendall was not able to participate in the meeting, but would participate in the December meeting on ozone.

Research Needs (Chapters 3-5)

Dr. Boylan stated that he would like to recommend a FRM for measuring ultrafine particles and that states be required to run these monitors.

Dr. Cox indicated that perhaps the easiest way to address the charge question regarding research needs is for each of the lead authors to roll the research needs into the consensus response for each chapter.

For Chapter 5, Dr. Cox indicated that a research need was to further look at climate change impacts.

For Chapter 3, Dr. Cox identified several needs, such as what would be the effect of controlling for confounding, what would be the effect of controlling for measurement error, etc., but wasn't sure those constituted new research needs. Dr. Lange identified taking the pieces that had methodological uncertainties and ensuring not just generation of more primary health effects data, but also how to do quantitative uncertainty analysis and further adjusting things such as determining the cause of regional heterogeneity, so that some of the uncertainties could be reduced. Dr. Cox also proposed developing validated quantitative causal models as a research need. Dr. Masuca also identified mechanisms of distribution in the body, PBPK modeling, as another research need.

For Chapter 4, Dr. Frampton identified extending the direct coarse particle monitoring to facilitate further health effect studies as a research needs.

Chapter 3- Review of the Primary $PM_{2.5}$ Standard (cont'd.)

Dr. Cox found conclusive evidence of a significant positive association between fine particulate matter and various health effects, including mortality. He stated that the extent to which health risks, including mortality risks, would be reduced by reducing $PM_{2.5}$ has not been convincingly quantified, with well-developed uncertainty bands.

Dr. Lange stated that she had previously indicated that not much has changed from the last review and that she did not find any justification for changing the primary $PM_{2.5}$ standard.

Dr. Frampton stated that there was enough evidence, considering the new studies, that the current standard of 12 $\mu g/m^3$ is not adequate to protect public health. He indicated that there was enough evidence that the PM-mortality relationship was causal. The current standard was set at 12 $\mu g/m^3$ because studies showed mean concentrations of effects slightly above 12 $\mu g/m^3$. Now new studies are showing associations at lower concentrations, as low as 8 $\mu g/m^3$, indicating that the current standard is not adequately protective.

Dr. Cox asked if confounding, particularly confounding by daily maximum and minimum temperature, could be convincingly ruled out. Dr. Frampton indicated that he would need the help of epidemiologists to help him adequately respond to that. He stated that these studies probably did not adjust for daily maximum and minimum temperatures, but they were not just looking at a few studies done in the same climate, the studies were done around the world in different seasons, different temperatures, different climates, different temperature ranges, that have consistently shown these kind of relationships with morbidity and mortality. He thought it was extremely unlikely that a single potential confounder would explain the relationships they were seeing.

Dr. Cox asked if the results were homogeneous. Dr. Frampton indicated that they were not. He pointed out that, as Dr. Packham had previously mentioned, there is heterogeneity in the way individual people respond to an insult. Therefore when a study is done that includes many cities, large populations, to see a couple of places that respond differently or do not show the effect that most of the others do, is not terribly surprising. Dr. Packham indicated that to a common environmental condition (i.e. particulates in the air), he would not expect differences between the way human organisms in Philadelphia to be different from human organisms in London or any place else. He stated that if there were something so pernicious about this environmental phenomenon of particles in the air, he would expect almost absolute consistency in terms of how people would respond to those things. Dr. Frampton disagreed. He stated that these were small relative risks, a small increase in mortality. He indicated there are certainly differences in people in different cities (socioeconomic status, availability of health care, temperature, etc.). He stated that when you are looking at the results of an individual study, you are cutting your population, your *n*, way down and the statistical power to see an association is reduced.

Dr. Frampton stated that what was missing in their discussion was a panel of experts, including epidemiologists, sitting at the table, answering these questions a lot better than what he could do. He indicated that this was not his area of expertise and he was not doing an adequate job at answering these questions. He stated that his inability to defend the database of PM literature should not result in the committee making inadequate recommendations due to lack of expertise. Dr. Packham stated that he felt the same exact way, but on the other side of the argument.

Dr. Cox stated that if there were no relationship between $PM_{2.5}$ and mortality risk, the data might look exactly like the data we are seeing – as long as you don't fully control for confounding, you see positive associations; as soon as you fully control for confounding, those positive associations disappear. He indicated that to date, epidemiological studies have not addressed fully controlling for confounders such as temperature and latent confounders or unobserved, unmeasured confounders. He stated that although they may not have epidemiologists, the committee did not lack sufficient knowledge and expertise to agree that confounding needs to be dealt with and that the PA does not distinguish between effects from confounders and possible effects from $PM_{2.5}$. If they could agree to that much, then they could perhaps agree to what conclusions logically flow from the evidence presented and they would not need to go to the whole wide world of expertise to answer that question.

Dr. Cox summarized Dr. Lange's position as being there was not any new evidence since the last review to justify changing the standard. He summarized Dr. Frampton's position as there is compelling new evidence consistent with previous evidence, but at lower estimated exposures that justify a changing of the standard. He summarized Dr. Packham's position as the new evidence confirms what was shown before, that there is a linear non-threshold C-R association. He asked what Dr. Masuca and Boylan thought. Dr. Masuca indicated that he agreed with Dr. Lange's position. Dr. Cox indicated that his position was that he did not see a compelling reason to change the standard. He stated that the observed associations could be due to confounders and that the intervention studies have not demonstrated that decreases in PM have resulted in decreases in mortality. Dr. Boylan stated that he was leaning toward Dr. Frampton's position. He did acknowledge large uncertainties and therefore the standard should not be lowered as low as 8 or 9 $\mu g/m^3$, but that the current standard is not adequate and should be reduced. Dr. Cox asked what Dr. Boylan's expectations were for public health if the standard were reduced. Dr. Boylan indicated that there were estimates in the risk assessments, but that there were uncertainties. Dr. Cox pointed out that those coefficients were not adjusted for confounding. Dr. Boylan asked if they could be accounted for in this document. Dr. Cox indicated that he was going to suggest methods to use to quickly adjust for confounders, such as estimating the fraction of the coefficient due to confounders. Dr. Boylan stated that normally the risk assessment is done before the PA as a separate document and

the change in process and accelerated timeline has hindered their ability to look at it with the detail it needs to be looked at.

There was discussion about how daily maximum and minimum temperatures in the weeks prior to mortality could act as confounders and how to make recommendations to address that. The committee could not come to consensus and Dr. Frampton stated that their struggle illustrated the need for additional expertise of the committee. He suggested that they recommend that EPA do these additional analyses to address unmeasured confounding, exposure measurement error, etc., but that they revisit the PA review with an expert panel that include epidemiologists. Dr. Cox stated that in order to be relevant, they should provide advice in the timeframe required. He indicated that they should give their best shot at addressing the charge questions before them. He proposed proceeding with the clarifying public comments and then continuing the deliberations the next day.

Clarifying Public Comments

Mr. Yeow indicated that members of the public who registered[10] to provide clarifying comments would be limited to three minutes each.

Gretchen Goldman, Union of Concerned Scientists, stated that the committee should demand the additional expertise needed, and to be given a final ISA before deliberating on the PA. She indicated that if the CASAC was not going to do that, then they needed to listen to the IPMRP as they have the additional expertise, including epidemiological expertise.

John Bachmann, Environmental Protection Network, stated that the CASAC was created to provide EPA and the Administrator the best possible scientific advice on what EPA put together regarding science and policy. He indicated that this CASAC would be the first one to deemed irrelevant due to lack of expertise and lack of consensus. He urged the CASAC to stand up to the Administrator and tell him that it was better to do it right than to do it fast.

Chris Frey, North Carolina State University, stated that the IPMRP had 20 people engaged, with 16 assigned discussants on the charge question for Chapter 3, whereas the CASAC only had 2 plus the chair. He stated that the IPMRP concluded that for long-term exposure to PM, there was neither the rationale nor the empirical support for concern over confounding by temperature. He indicated that it might be a different story for the daily studies, but that annual studies are the bulk of the studies for mortality effects. He stated that the CASAC was completely ignoring at-risk populations in their deliberations. He indicated that CASAC was going to sink themselves into irrelevance if they kept going down this path. He stated that they needed a panel at the table with the requisite expertise to participate in the deliberations.

Dan Greenbaum, Health Effects Institute (HEI), stated that temperature was not a new issue, that it was brought up by the investigators in HEI's NMAPS study where they stated that temperature had a greater effect on mortality than air pollution. Their challenge was to carefully control for temperature so that they could still see anything related to air pollution. He indicated that their work along with 25 other investigators and HEI panel reviewers extensively tested for temperature and did not find temperature to be a likely major confounder. He stated that for accountability studies, he was surprised to see the Burns et al. study cited in comments. He indicated that the study authors included HEI senior scientists and they would point to other more specific and U.S.-relevant studies rather than the formulaic approach used in the Burns study, one of which HEI submitted during the ISA review. That study and a number of other studies do show improvements in public health with reductions in air pollution. Dr. Cox asked if

the 2013 study HEI mentioned had looked at daily maximum and minimum temperatures. Mr. Greenbaum indicated that he could not remember exactly what was done in each one of the studies, but that the NMAPS investigators and Canadian investigators found a problem with the statistical package that was used and all of those analyses were redone and reviewed by an HEI review panel that looked at time trends, temperature, etc. Dr. Cox stated that for spline-based models, he agreed, that the temperature effects get washed out.

Mr. Yeow recessed the meeting at 5:00 pm, indicating that the CASAC would continue deliberations the following day and would postpone the writing session.

Friday, October 25, 2019

The CASAC reconvened at 8:30 am.

Dr. Cox began with describing limitations and shortcomings of judgement-based approaches and how sound scientific methods can help overcome these limitations. He indicated that this involves testing predictions implied by scientific theories or hypothesis against data. This implies that scientific claims must have testable and potentially falsifiable implications. Testing null hypotheses is inherently skeptical, but that is also how scientific progress is made.

Dr. Cox suggested some proposition statements about Chapter 3 and wanted to see whether there was agreement about those, and then wanted to try to apply Dr. Lange's framework. The first statement was that the risk assessment in the PA was based on treating regression C-R functions as if they were causal C-R functions. The second statement was that there was no explicit justification given for treating regression C-R functions as if they were causal C-R functions. The regression C-R functions have not been empirically validated as yielding correct predictions of changes in mortality as a result of changes in PM exposure. The estimated C-R functions do not control for confounding by daily high and low temperatures in the weeks prior to mortality. The estimated C-R functions do not accurately express heterogeneity in C-R associations of the underlying studies. There are no regression diagnostics justifying the use of proportional hazard assumptions. The models have not been subjected to tests of model prediction versus observations. Dr. Cox stated that, if the committee could agree on the above-mentioned facts of what is and is not in the PA, then they could turn to Dr. Lange's framework and ask if the document provides convincing evidence that we now have a new reason to think that lower exposures would be more protective than last time the standards were set. These were the criteria Dr. Cox proposed for how the committee should decide what to recommend. He stated that if there is evidence that reducing $PM_{2.5}$ will be more protective than has been previously believed, then that could provide a valid reason for recommending a reduction of the $PM_{2.5}$ standard. If there is no such evidence, then he thought they should not recommend a change.

Dr. Frampton was in agreement that the more they could apply the scientific method, to use quantitative approaches, to pin down the rationale, he was all for that. However, the so-called scientific method has been used by some to follow an agenda to obscure what the data is showing (he stated that he was not implying that Dr. Cox was doing this). He stated that the approach Dr. Cox proposed, including the ISA review, does not represent the mainstream science in this area. He indicated there is a written document by 20 experts (IPMRP) that disagree with Dr. Cox. He indicated that Dr. Cox was proposing and imposing an approach on the Committee. Dr. Frampton's opinion about the PA is a judgement that is shared by most experts in the field and is based on a body of data that has been scrutinized more extensively than most scientific questions over the past 30 years, by numerous independent scientists and review panels. With all of the different ways of looking at the data, with all of the studies that have

been done with a significant body of human and animal data that support the physiologic effects, he thought the data was overwhelming and until the quantitative studies suggested by Dr. Cox could be performed and demonstrate that the associations they are seeing are false, he was not going to be convinced. Dr. Cox did not agree that the associations seen were consistent and stated that he was not suggesting throwing out any studies, but was suggesting that they not be interpreted more strongly than they warranted.

Dr. Cox asked if there was agreement on the proposition that the risk assessment in the PA was based on treating regression C-R functions as if they were causal C-R functions. Dr. Frampton stated that this was Dr. Cox's first step in his pathway leading to questioning the approach taken by EPA and EPA's recommendation of the standards. He stated that he objected to Dr. Cox's approach. Dr. Cox stated that he just wanted to get agreement on the contents on Chapter 3 before moving on to recommendations. Dr. Frampton stated that this was the first step in leading down a pathway to conclude that EPA's whole analysis is misinformed and that additional analyses were needed. He stated that he did not agree with this path and did not have the expertise to respond to the path that Dr. Cox was taking them down. Dr. Lange stated that acknowledging that things were not perfect was the not the same thing as throwing them away. She stated that it was their job to tell EPA what pieces were good, what pieces were not, that the pieces will inform how to interpret the risk assessment. So stating that association does not equal causation helps interpret the results from the analysis. Dr. Cox requested that Dr. Frampton raise any disagreements with the statements he was to make. Dr. Cox stated that in the Draft PA, there was not explicit justification given for treating the regression C-R functions as if they were causal C-R functions. Dr. Frampton disagreed and stated that the EPA provided a good background and summary from the ISA in support of their approach that was reasonable and sufficient. Dr. Cox pointed out however, that there was not an explicit justification. Dr. Cox stated that within Chapter 3, the regression coefficients have not been empirically validated as yielding correct predictions of changes in mortality caused by changes in exposure. Dr. Frampton stated that was true, but that there would be a lot of debate over how to do such validation and that EPA would not be able to do this in the requested timeframe. He stated that making this statement that this validation was not included in Chapter 3 implies that EPA should have done it and he did not find that to be reasonable. Dr. Lange stated that some accountability studies were included, so it was not fair to say that Chapter 3 did not have any validation. However, she noted that not all the accountability studies were included. Dr. Cox stated that the estimated C-R functions did not control for confounding by daily high and low temperatures. Dr. Frampton stated that there is always the possibility of unmeasured confounders and disagreed with picking high and low temperatures as a particular confounder to mention. Dr. Cox stated that the estimated C-R functions do not accurately express the heterogeneity in the C-R associations in the underlying studies, both within and between studies. Dr. Frampton stated that he did not have enough expertise to comment on that statement and needed additional experts in epidemiology to address that. Dr. Cox stated that they did not need additional experts to state whether this heterogeneity was expressed in Chapter 3 or not. Dr. Cox stated that the estimated C-R functions do not contain quantitative uncertainty bands that reflect model uncertainty and effects of exposure or covariate estimation error and no regression diagnostics are reported justifying the use of proportional hazard associations. Dr. Frampton again objected because he had questions as to how it could be done, whether it was reasonable to do that in this kind of analysis, and whether doing so was more of an attempt to obfuscate the process than it was to make it more definitive. He stated that his expertise did not allow him to evaluate the pathway Dr. Cox was leading them on. Dr. Cox stated that reporting regression diagnostics is not an attempt to obfuscate, that they are part of the standard output of a statistical package and that reporting them is part of good statistical housekeeping. Dr. Frampton agreed that it would be good to report regression diagnostics.
Dr. Lange went over her main points from her preliminary comments[8] which were discussed during the previous day starting with major point 3, providing a balanced and accurate summary of results from the

ISA. There was general agreement on points 3 and 4. For major point 5, Dr. Frampton objected to the statement that epidemiology studies with those known errors should not be used to determine the shape of the association between $PM_{2.5}$ and health effects. The CASAC agreed to remove that statement. The CASAC generally agreed with the main statements of major points 6 and 7 and agreed to leave out major point 8. For major point 9, the CASAC generally agreed that EPA needs to carefully consider what they are measuring and comparing when they derive pseudo-design values. The CASAC agreed that there should be more quantitative uncertainty analyses and Dr. Cox agreed to provide further details on examples and suggestions.

Dr. Cox stated that slide 18 of EPA's presentation[5] laid out the four bases for EPA's preliminary conclusion that the science can be reasonably viewed as calling into question the adequacy of public health protection of the current standard. For point 1 (long-standing body of health evidence), he stated that there was nothing new. He stated that they could further discuss point 2 (epidemiological studies reporting health effect associations at current standards) and point 3 (pseudo design values indicating study areas with air quality likely to be allowed by current standards). He disagreed with point 4 (risk assessment estimates showing thousands of $PM_{2.5}$-associated deaths per year) and stated that the risk assessment amounted to one big unverified assumption and was not sound. Dr. Frampton indicated that for point 1, the new evidence strengthens and justifies the causality determinations in the Draft PM ISA. For point 2, Dr. Frampton stated that the data are overwhelming. He indicated that points 1 and 2 show that there are problems occurring at levels below the current standard and that the current standard is not adequate to protect public health. The CASAC generally agreed with point 1 but disagreed with the causal and policy significance of the associations. For point 2, some CASAC members stated that the studies needed to be interpreted appropriately due to methodological limitations.

Dr. Cox asked the members whether they thought the PA provided an adequate basis for concluding the current standard is not sufficient to protect public health. Dr. Boylan stated that he was of similar opinion with Dr. Frampton, that the body of evidence indicates that a lower standard would result in fewer health impacts and that the current annual standard is adequate. He stated that it was hard to state what the level should be, that the risk assessment would inform that, but as discussed during the meeting, there were many issues with the risk assessment in the Draft PA. Dr. Frampton indicated that the Draft PA presents a solid case that the current standard is not adequate. Dr. Lange stated that she did not think there was enough evidence to demonstrate that the current standard is not adequate. Dr. Masuca stated that he thought the current standard was protective of public health and should not be lowered. Dr. Packham did not think the current evidence was compelling to justify changing the standard. Dr. Cox stated that he was not convinced by the evidence before them that the current $PM_{2.5}$ annual standard was not adequate. He indicated that further reducing/clarifying uncertainty, including in the near term, may lead to a more constructive answer. The CASAC agreed that 24-hour $PM_{2.5}$ standard did not need to be changed.

Dr. Frampton indicated that the concerns regarding the changes to the review process should be brought forward to the Letter to the Administrator. Dr. Cox did not agree that this should be put in the letter and asked the other CASAC members what they thought. Drs. Packham and Masuca were not in favor of putting it in the letter. Drs. Lange and Boylan were supportive of including it in the letter. It was agreed that Dr. Frampton would draft something and it could be further discussed at the December meeting.

The meeting was adjourned by Mr. Yeow at 2:30 pm.

Respectfully Submitted:	Certified as Accurate:	
/s/	/s/	November 15, 2019
Mr. Aaron Yeow Designated Federal Officer EPA SAB Staff Office	Dr. Louis Anthony Cox, Jr. Chair CASAC	Date

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 October 24-25, 2019 meeting webpage: https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/49FAF8892AD2D38285258473006D1F4A?OpenDocument

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[1] *Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019)*
[2] Chartered CASAC Roster
[3] Federal Register Notice Announcing the Meeting
[4] Agenda
[5] EPA Presentation - Review of the National Ambient Air Quality Standards for Particulate Matter - Overview of the Draft Policy Assessment.
[6] Charge for Particulate Matter Policy Assessment for the National Ambient Air Quality Standards (NAAQS)
[7] Slides of Dr. Cox's Comments on Chapter 1 of the PM PA
[8] 10-21-19 Preliminary Comments from CASAC Members on the PM PA
[9] Slides of Dr. Cox's Comments on Chapter 5 of the PM PA
[10] List of Registered Public Speakers - Clarifying Comments

ATTACHMENT A – Other Attendees

Name	Affiliation	10/24/19	10/25/19
Akers, Brad*	EPA		
Akers, David*	EPA		
Allen, George*	NESCAUM		
Alman, Breanna*			
Babu, Sainath*			
Bachmann, John	EPN	x	
Bahadori, Tina*	EPA		
Benromdhane, Souad*	EPA		
Black, Julia*	EPA		
Blase, Kurt*			
Brown, Marie*			
Buckley, Barbara	EPA	x	
Chan, Elizabeth	EPA	x	
Coffman, Evan*	EPA		
Copley, Bruce*	ExxonMobil Biomedical Sciences, Inc.		
Curran, Trisha	EPA	x	
Daniels, Rebecca	EPA	x	
DiBiase, Scott*	Pinal County Air Quality		
Dolwick, Pat*			
Dutton, Steven	EPA	x	
Edwards, Lariah*	Gradient		
Enstrom, James*	UCLA and Scientific Integrity Institute		
Fann, Neal*	EPA		
Fitzsimmons, Catharine*			
French, Timothy*	Truck and Engine Manufacturers Association		
Frey, Chris	NCSU	x	
Gantt, Brett*			
Goldman, Gretchen	Union of Concerned Scientists	x	
Goodman, Julie*			
Gorman, Teresa*			
Graham, Stephen*	EPA		
Greenbaum, Dan	HEI	x	
Guillen, Alex*			
Hagan, Nicole	EPA	x	x
Hanley, Tim	EPA	x	
Hashimoto, Hayden*	Clean Air Task Force		
Hassan, Iman*	EPA		
Hodson, Elke*	OMB		
Hogue, Cheryl*			
Hutson, Mary	EPA	x	
Igoe, Sheila	EPA	x	x
Jansen, John*			
Jenkins, A*			

Name	Affiliation	10/24/19	10/25/19
Johnson, Cortina	EPA	x	
Kamal, Ali	EPA	x	
Kelly, Jim	EPA	x	
Koplitz, Shannon	EPA	x	
Lacey, Anthony*			
Lamichhane, Archana	EPA	x	
Lamson, Amy*	EPA		
Langdon, Robin*	EPA		
Langstaff, John*	EPA		
Langworthy, Cindy	Hunton Andrews Keith	x	x
Lefohn, Allen S.*	A.S.L. & Associates		
Li, Alice*	Gradient		
Luben, Tom*	EPA		
McDow, Steve	EPA	x	
McGuire, Maygan*	Environment and Climate Change Canada		
Miles, Kenyatta*	Shell		
Mocka, Corey	EPA	x	
Mudasiru, Omobola	API	x	
Nichols, Jennifer	EPA	x	
Oldham, Carla	EPA	x	
Owen, Russell	EPA	x	
Parker, Stuart*	IWP News		
Peffers, Mel*	House E&C		
Pekar, Zachary	EPA	x	x
Penn, Stefani*	Industrial Economics, Inc.		
Perlmutt, Lars	EPA	x	x
Petesch, Tess*	EPA		
Popovech, Marusia*	ExxonMobil Biomedical Sciences, Inc.		
Reilly, Sean	E&E News	x	
Reyes, Jeanette*	EPA		
Rice, Byron	EPA	x	
Rice, Richard*	EPA		
Rizzuto, Pat*			
Sauerhage, Maggie*	EPA		
Sax, Sonja*	Ramboll		
Schultz, David*			
Sheppard, Lianne*	University of Washington		
Silverman, Steven*	Environmental Protection Network		
Simmons, Jane Ellen	EPA	x	x
Simon, Nathalie*	EPA		
Srivastava, Ravi*	EPA		
Steichen, Ted*	American Petroleum Institute		
Stewart, Michael	EPA	x	
Textor, Marise*	Marathon Petroleum		
Thompson, Lisa	EPA	x	
Turpin, Barbara*			

Name	Affiliation	10/24/19	10/25/19
Valberg, Peter*			
Vandenberg, John	EPA	x	x
Vanderpool, Robert	EPA	x	
Walters, Chris*	Industry - CNH Industrial		
Warner, Mandy*			
Wayland, Robert J.	EPA	x	
Weitekamp, Chelsea	EPA	x	
Winner, Darrell*	EPA		
Wulf, Brian*	ExxonMobil		
Yazhe, Melissa*			
Yukhananov, Anna*	Bloomberg Environment		
Zarba, Chris*			

*participated via teleconference or webcast