DATE

EPA-CASAC-22-XXX

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: CASAC Review of the EPA's *Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – October 2021)*

Dear Administrator Regan:

The 2021 Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel, hereafter referred to as the Panel, met on October 14, 2021, November 17-19, 2021, December 1-2, 2021 and <<Insert follow-up meeting dates>> to peer review the EPA's *Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – October 2021)*, hereafter referred to as the Draft PA. The Chartered CASAC approved the Panel's report on <<Insert follow-up meeting date>>. The CASAC's consensus responses to the agency's charge questions and the individual review comments from the Panel are enclosed.

Overall the CASAC finds the Draft PA to be well-written and appropriate for helping to "bridge the gap" between the agency's scientific assessments and quantitative technical analyses, and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the National Ambient Air Quality Standards (NAAQS). The CASAC has several recommendations for strengthening and improving the document highlighted below and detailed in the consensus responses.

The Draft PA clearly presents the legislative requirements, the history of the NAAQS for PM, and the scope of the current review. However, additional detail should be provided about the rationale for reconsidering the December 2020 decision to retain the PM NAAQS, including further detail about the previous PM NAAQS review.

In general, the CASAC agrees that the approach taken to describe major PM emission sources, chemistry, monitoring, trends, hybrid modeling, relationships with design values, and background PM is thorough, appropriate, and informative. The material is clearly presented and provides useful context for consideration. However, the CASAC has several recommendations regarding the presentation of coarse, ultrafine, near roadway, and sub-daily PM measurements, as well as wildfire PM, biogenic secondary organic aerosol, ammonium, emissions estimates, and background PM. The CASAC recommends that the EPA revisit its definition of exceptional events as applied to wildfires.

The Draft PA adequately captures and appropriately characterizes the key aspects of the evidence assessed and integrated in the 2019 ISA and Draft ISA Supplement of $PM_{2.5}$-related health effects. The toxicology (controlled human exposures and animal toxicological studies) information is used, for the most part, as supporting evidence and to provide biological plausibility for the long-term and short-term cardiovascular health effects observed in the epidemiologic studies. The discussion of epidemiologic studies is clearly organized, well written, and accurately describes the body of available epidemiologic literature. The technical approach evaluating the relationship between the mean $PM_{2.5}$ concentrations reported in the epidemiologic studies and annual design values is clearly presented. However, the CASAC has concerns about the singular utility of this approach for the purpose of informing the adequacy of the primary $PM_{2.5}$ standards and recommends a discussion of its limitations as well as and the likely effect of using other approaches.

Overall, the draft PA accurately describes the results of the risk assessment conducted. The interpretation of the risk assessment for the annual standard is appropriate given the scientific findings presented. The results support the conclusion that the current primary annual $PM_{2.5}$ standard does not adequately protect public health. However, the CASAC questions whether the results of the current risk assessment can be used to conclude that the annual standard is protective of short-term exposures (due to exclusion of areas where the 24-hour $PM_{2.5}$ standard is controlling due to wintertime stagnation and/or home woodstove heating). It is important to note that risk disparities remain substantial with the focus on an annual standard. The CASAC recommends more attention be given to the disparities and consideration of the 24-hour standard. Although the lower alternative standards narrow the gap between risk for White and Black populations, a substantial disparity remains. The PA should include additional text to convey this information.

Regarding the annual $PM_{2.5}$ standard, the CASAC reached consensus that the indicator, form, and averaging time should be retained, without revision. Furthermore, all CASAC members agree that the current level of the annual standard is not sufficiently protective of public health and should be lowered. In concurring with the EPA's recommendation to lower the annual standard, the CASAC agrees with the EPA's assessment that there are large populations at risk of $PM_{2.5}$ health effects, and that the Draft ISA Supplement provides new evidence of disparities in risk across various population subgroups. The evidence base for adverse health effects below the current annual standard has been strengthened and that, while uncertainties remain in the epidemiologic evidence, recent studies that employ alternative analysis approaches have helped to reduce those uncertainties (e.g., by addressing the potential for residual confounding). The CASAC concurs with the EPA's assessment that meaningful risk reductions will result from lowering the annual $PM_{2.5}$ standard.

Regarding the level of the annual $PM_{2.5}$ standard, the majority of the CASAC finds that an annual average in the range of 8-10 µg/m^3 would be appropriate. The range of 8-10 µg/m^3 is supported by placing more weight on epidemiologic studies with mean concentrations below 10 µg/m^3, including some newer studies not cited in the ISA and by considering Canadian studies, some of which had means even lower than 8 µg/m^3. A recommendation of 8-10 µg/m^3 is also supported by placing emphasis on the protection of vulnerable demographic groups. Arguments supporting 8-10 µg/m^3 also include: evidence consistent with no threshold and a possible supra-linear concentration-response function at lower levels, recognition that the use of the mean to define where the data provide the most evidence is conservative since robust data clearly indicate effects below the mean in concentration-response functions, and consideration that people are not randomly distributed over space such that populations in neighborhoods near design value monitors are exposed to the levels indicated at those monitors and likely to be more at risk.

A minority of CASAC members find that a range of 10-11 µg/m^3 is more appropriate. This range places more weight on the remaining uncertainties as well as the fact that design values are generally higher than area average exposure levels. Key U.S. epidemiologic studies indicate consistently positive and statistically significant health effect associations based on air quality distributions with overall mean $PM_{2.5}$ concentrations that range between 8.1 and 12.2 µg/m^3. The form of the standard and the way attainment with the standard is determined (i.e., highest design value in the core-based statistical area) are important factors when determining the appropriate level for the standard. According to the PA, the area annual design values are generally higher than the study means by 10-20%, and possibly up to 50%, depending on the approach to exposure assessment and averaging. Also, the recommendation of 10-11 µg/m^3 emphasizes increasing uncertainties in the epidemiological findings at concentrations below 10 µg/m^3, and the large uncertainties in the risk assessment.

Regarding the 24-hour $PM_{2.5}$ standard, the majority of CASAC members find that the available evidence calls into question the adequacy of the current 24-hour standard. The CASAC notes that the level is conditional on the form, and all of the CASAC members conclude that the PA does not provide sufficient information to adequately consider alternative form and level combinations. Thus, the discussion that follows first addresses the level conditional on the current form, and then considers revisions of the form.

Regarding the level of the 24-hour standard, conditional on retaining the current form, the majority of CASAC members favored lowering the 24-hour standard. There is substantial epidemiologic evidence from both morbidity and mortality studies that the current standard is not adequately protective. This includes three U.S. air pollution studies with analyses restricted to 24-hour concentrations below 25 µg/m^3. It is also noted that the controlled human exposure studies are not the best evidence to use for justifying retaining the 24-hour standard. These studies preferentially recruit less susceptible individuals and have a typical exposure duration much shorter than 24 hours. Thus the evidence of effects from controlled human exposure studies with exposures close to the current standard support epidemiological evidence for lowering the standard. Overall, this places greater weight on the scientific evidence than on the values estimated by the risk assessment. The risk assessment may not adequately capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective. There is also less confidence that the annual standard could adequately protect against health effects of short-term exposures. A range of 25-30 µg/m^3 would be adequately protective.

In contrast, a minority of CASAC members concur with the EPA's preliminary conclusion to retain the current 24-hour standard. This view places greater weight on the risk assessment. The risk assessment not only accounts for the level of the standard, but also accounts for the form of the standard and the way attainment with the standard is determined (i.e., highest design value in the CBSA). The risk assessment indicates that the annual standard is the controlling standard across most of the urban study areas evaluated and revising the level of the 24-hour standard is estimated to have minimal impact on the $PM_{2.5}$-associated risks. Therefore, the annual standard can be used to limit both long- and short-term $PM_{2.5}$ concentrations. There is limited epidemiologic evidence to determine the adequacy of the current level of the 24-hour standard. This view places more emphasis on the human exposure studies, showing effects at $PM_{2.5}$ concentrations well above those typically measured in areas meeting the current standards suggesting to them that the current standards are providing adequate protection against these exposures.

The CASAC recommends that in future reviews, the EPA provide a more comprehensive assessment of the 24-hour standard that includes the form as well as the level. The CASAC recognizes that they have insufficient information with which to evaluate alternative forms of the 24-hour standard and the CASAC recommends that the form be revisited.

Regarding the primary PM_{10} standard, the Draft PA focuses on scientific evidence of health effects from $PM_{10-2.5}$ exposure. Given this focus, the Draft PA should discuss in more detail whether PM_{10} is still the appropriate indicator for the standard. There is a clear progression of the strength of evidence in $PM_{10-2.5}$ causality determinations from the 2009 PM ISA for long-term mortality, cardiovascular effects, and cancer. The Draft PA should discuss how the agency considered the strengthening of these causal determinations in their preliminary conclusions on the adequacy of the current primary PM_{10} standard.

The CASAC agrees with the EPA's determination of a causal relationship between $PM_{2.5}$ and visibility effects. Greater justification needs to be provided for a secondary standard for PM based on a visibility index of 30 deciviews (12 miles). Additional region- and view-specific visibility preference studies and data analyses are needed to support a quantitative index. According to the Draft ISA Supplement, contrast rather than total light extinction appears to make the level of acceptable visual air quality more uniform across different locations. However, the Draft PA does not use contrast to evaluate an appropriate target level of visibility protection. The final PA should use an "acceptable" contrast value to help develop the secondary PM standards.

The CASAC appreciates the opportunity to provide advice on the Draft PA and looks forward to the agency's response.

Sincerely,

Dr. Elizabeth A. (Lianne) Sheppard, Chair
Clean Air Scientific Advisory Committee

Enclosures

NOTICE

U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee

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Consensus Responses to Charge Questions on the EPA's *Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – October 2021)*

Chapter 1 - Introduction

To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for this reconsideration?

The information in Chapter 1 is very clearly presented. This chapter does a good job covering the legislative requirements and National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) history for health and welfare effects. The scope of the current review is clearly described, noting that this Policy Assessment (PA) considers the evidence covered in both the original 2019 Integrated Science Assessment (ISA) for PM and the Draft Supplement to the 2019 ISA for PM (Draft ISA Supplement), and that the Draft ISA Supplement is limited to recent evidence on outcomes that were previously judged to have a causal relationship to PM. However, it does not provide sufficient background to and context for this reconsideration. In particular, it does not describe the unusually contentious aspects of the previous review, including the CASAC's failure to reach consensus on whether the annual $PM_{2.5}$ NAAQS was adequate and the CASAC's questioning of the weight-of-evidence (WOE) causal determination framework that resulted in the National Academies of Sciences, Engineering, and Medicine (NASEM) committee on "Assessing Causality from a Multidisciplinary Evidence Base for National Ambient Air Quality Standards" (https://www.nationalacademies.org/our-work/assessing-causality-from-a-multidisciplinary-evidence-base-for-national-ambient-air-quality-standards). The EPA should expand its discussion of the previous NAAQS review. Furthermore, the EPA should provide additional detail on the rationale for this reconsideration. Section 1.4.1 simply says: "The EPA is reconsidering the December 2020 decision because the available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act." There is additional information in the cited EPA News Release that could be incorporated. The CASAC notes that the conclusions in the current Draft PA are essentially the same as the conclusions in the 2019 PA, although the evidence base has expanded, as documented in the Draft ISA Supplement.

The CASAC suggests a few additional changes:

- The statement on page 1-18 is confusing "…the EPA filed a motion with the Court to hold the consolidated cases in abeyance until March 1, 2023. The court has not yet acted on the EPA's motion, which the court granted on October 1, 2021." Please clarify whether the EPA's motion has been granted or not.

- The Draft PA could reiterate the intended role of the weight-of-evidence causality determinations in its Section 1.3.5 discussion of the review completed in 2020.

Chapter 2 – PM Air Quality

What are the Panel's views on the technical approach taken and analyses completed to inform our understanding of how $PM_{2.5}$ *concentrations calculated using composite monitors and area averages from hybrid modeling approaches compare to area design values?*

To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for this reconsideration?

In general, the CASAC agrees that the approach taken to describe major PM emission sources, chemistry, monitoring, trends, hybrid modeling, relationships with design values, and background PM is thorough, appropriate, and informative. The material in Chapter 2 is generally clearly presented and provides useful context for consideration. However, the CASAC has the following comments on improving this section:

- Emissions estimates: The limitations posed by emissions estimate uncertainties are overstated. On page 2-13, the text states that: *"It is not clear how uncertainties in emission estimates affect air quality modeling, as there are no numerical empirical uncertainty estimates available for the NEI. However, by comparing modeled concentrations to ambient measurements, overall uncertainty in model outputs can be characterized."* These two sentences are misleading and should be removed or rewritten, making use of the body of available literature in this area. Comparison of top-down and bottom-up approaches can and do provide bounds on emissions uncertainty, and varying emissions within those bounds in sensitivity analyses in chemical transport models inform us as to how uncertainties in emissions estimates result in variability in air quality modeling results. There is a substantial body of literature that has used these techniques to characterize the effects of emissions estimate uncertainties on model results (e.g., Hanna et al., 2005; Napelenok et al., 2011; Tian et al., 2010; Tang et al., 2010; Huang et al. 2019; Moore et al., 2001).

- Monitoring networks: A table summarizing monitoring network information would be helpful. The table could include the: (1) name of the networks (AQS, IMPROVE, CSN, etc.), types of measurements ($PM_{2.5}$, speciated $PM_{2.5}$, PM_{10}, $PM_{10-2.5}$, UFP, etc.), number of monitors, collection frequency (daily, continuous, 1-in-3 days, 1-in-6 days), and siting (urban, rural).

- Federal Reference Methods (FRM) and Federal Equivalency Methods (FEM) monitors: There is an increasing trend to replace FRMs with FEMs across the country. FEMs can result in annual and 24-hour $PM_{2.5}$ concentrations that are meaningfully different (higher or lower) compared to FRMs, which can potentially lead to erroneous attainment designations. The EPA should include a detailed summary of the number of FEMs and FRMs (see example in Table 1 below). The FEM bias needs to be addressed to make the FRMs and FEMs more comparable. One option would be to allow states to develop correction factors for co-located FRMs and FEMs. These correction factors could be used to adjust FEM concentrations downward (or upward) to be comparable to FRMs. Another option would be for the EPA to revise the "equivalency box"

(EB) criteria used to judge whether the bias of a new continuous $PM_{2.5}$ monitor relative to an FRM is acceptable during field testing.

Table 1. Current National Count of $PM_{2.5}$ Measurement Methods (AQI and Compliance).

$PM_{2.5}$ Measurement Method	Count
FRM-Gravimetric	562
FEM-Beta Attenuation Monitor	397
FEM-Broadband spectroscopy (T640 and T640X)	285
FEM-FDMS TEOM	26
FEM-Laser Light Scattering	8
Total	**1,278**

- Ammonium: Ammonium should be identified as a significant PM component and ammonia as an important precursor (pp. 2-7, 2-8, 2-10).

- Coarse PM: There are 10 years of measurements and over 280 sites monitoring $PM_{10-2.5}$. These data should be presented and discussed more thoroughly, including spatial and temporal trends. The EPA should provide a more thorough examination of the data, which may provide insight into the significant increases in the annual average $PM_{10-2.5}$ in the mountain west (Figure 2-25). $PM_{10-2.5}$ emissions density maps and pie charts would be informative. Page 2-6 states "Although the NEI does not estimate emissions of $PM_{10-2.5}$ (coarse PM) specifically, estimates of PM_{10} emissions can provide insight into sources of coarse particles." It would be better to directly calculate the emissions of $PM_{10-2.5}$ by subtracting the $PM_{2.5}$ emissions from the PM_{10} emissions to create a $PM_{10-2.5}$ county-level emission density plot and $PM_{10-2.5}$ pie chart. This would allow the reader to better understand the sources of $PM_{10-2.5}$ emissions. Regarding Figures 2-23 and 2-24, it should be clarified why there are fewer sites in one figure than the other.

- Ultrafine Particulates (UFP): More care should be taken to reference the measurement method when discussing UFP data.

- Near Roadway Measurements: These measurements should be presented and discussed more thoroughly, including spatial and temporal variability in concentrations, the size of enhancements above ambient PM, and potential implications for exposure disparities.

- Sub-daily: Descriptive statistics and correlation analyses for various measurements including sub-daily would be helpful. Analyses examining sub-daily peaks and between-pollutant correlation patterns are especially important for multi-pollutant epidemiologic analyses, which assess potential co-pollutant confounding through an examination of covariance patterns among the pollutants. Biologically-relevant exposure windows for specific acute health outcomes, including myocardial infarctions and out-of-hospital-cardiac arrest (OHCA), may occur over minutes to hours, necessitating greater analyses of sub-daily exposures and correlations.

- Wildfires: Wildland and wildland-urban interface (WUI) fires are no longer exceptional, and it is not always accurate to call them natural events (page 2-3). The CASAC recommends that the EPA revisit its definition of exceptional events as applied to wildfires. According to Nagy et al. (2018), humans have ignited four times as many large fires as lightning, and humans were the dominant source of large fires in both eastern and western US. Their emissions have enormous impacts on nearfield exposures, regional (and continental) air quality and health over a considerable portion of the year. They are an increasing contributor to high $PM_{2.5}$ concentrations over an increasing fraction of the year. These events risk eroding the progress that has been made in air quality and health in the U.S. and it is possible that increasing wildfires and increasing exceptional events designations could substantially reduce the effectiveness of air pollution policy (David et al., 2021; Williams, 2021). More discussion is needed about wildland and WUI fire contributions to emissions, long term trends, health impacts, the changing nature of these fires, and their treatment with respect to PM standard setting and enforcement. There are places in the document where high concentrations at certain times of year and regions of the country seem to be dismissed as not being relevant to standard setting because the concentrations might be driven by wildfires. For example, page 2-34, line 2 implies that the high 2-yr concentrations during April – September are due to wildfires. That may be true, but it is also the photochemical smog season, so other causes are possible.

- Biogenic Secondary Organic Aerosol (SOA): The influence of anthropogenic emissions on secondary organic aerosol formation from biogenic VOCs is not adequately recognized. Several places in the ISA and PA discuss SOA from biogenic hydrocarbons as if it is natural. However, "biogenic SOA" is not necessarily natural. Its formation is substantially influenced by anthropogenic emissions. This should be recognized in the text. For example, page 2-3, lines 26-27, calls "oxidation of biogenic hydrocarbons such as isoprene and terpenes to produce secondary organic aerosol" a natural source of SOA. However, anthropogenic emissions can control the formation of biogenic SOA. For example, SOA formation from isoprene oxidation products (i.e., isoprene epoxydiol) is dependent on the acidity and liquid water associated with sulfate, and sulfate is largely anthropogenic. Thus, isoprene-epoxydiol-derived secondary organic aerosol (IEPOX SOA) is formed as a result of reactions with anthropogenic emissions and is not natural. Field studies and modeling suggest that it is a major source of aerosol in the southeastern US in both rural and urban locations and that it is controllable by reducing sulfate (Budisulistiorini et al., 2013, 2015; Marais et al., 2016). The term "biogenic SOA" is shorthand for "SOA from biogenic hydrocarbons," and thus the term "biogenic SOA" should be defined at first use because it is often confused with natural SOA.

- Background PM: The CASAC agrees that, since the 2012 review, "*our scientific understanding of organic aerosol formation has evolved*" (page 2-69). Modeling to better assess background aerosol with this new scientific understanding is possible and should be undertaken for future reviews. The assessment of background organic PM provided in the current PA is undoubtedly an upper-bound. On page 2-68 in the analysis of background PM, the PA says that the highest organic matter (OM) concentration for any sites in Figure 2-40 is 2 $\mu g/m^3$. However, there are OM concentrations in Figure 2-40 that are greater than 2 $\mu g/m^3$. Also, the PA states that OM did not decrease over the time period presented in Figure 2-40, however that is not consistent with the data. Figure 2-40 shows decreases in OM in all but two sites. This may be because of a decrease in primary or precursor emissions. The influence of anthropogenic precursors on SOA from biogenic hydrocarbons is recognized (page 2-64), as appropriate. The work by Marais et al. (2016) regarding the importance of anthropogenic sulfate to the formation of SOA would strengthen this statement.

- Design Values (DVs): Table 2-6 is quite helpful. The EPA should clarify in the text how design value *ratios* (Ratio of Average Maximum Annual DVs to Average Annual $PM_{2.5}$ Concentrations and Ratio of Average Maximum Annual DVs to Population Weighted Average Annual $PM_{2.5}$ Concentrations) in this table were calculated. Some *ratio* values in this table were unable to be reproduced.

- Hybrid modeling: The CASAC agrees with the statement (page 2-61) that *"Hybrid $PM_{2.5}$ modeling methods have improved the ability to estimate $PM_{2.5}$ exposure for populations throughout the conterminous U.S. compared with the earlier approaches based on monitoring data alone. Excellent performance in cross-validation tests suggests that hybrid methods are reliable for estimating* $PM_{2.5}$ *exposure in many applications."* Additionally, hybrid models do a better job of characterizing the exposures of rural residents, which are not as well represented by monitors. Thus, they better represent the diversity of exposures experienced. The CASAC suggests adding this point. The CASAC also expects future policy assessments to incorporate an increasing body of research incorporating advanced satellite products in hybrid modeling. Only a few references incorporating the use of satellite aerosol optical depth in hybrid modeling are provided in the current PA.

Chapter 3 – Reconsideration of the Primary Standards for $PM_{2.5}$

1. To what extent does Chapter 3 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on $PM_{2.5}$ *-related health effects?*

Chapter 3 provides a well-written summary and, for the most part, appropriately characterizes the key aspects of the evidence assessed in the 2019 ISA and the Draft ISA Supplement.

The chapter places "particular emphasis" on health effects with a causal or likely causal relationship with $PM_{2.5}$ from the 2019 ISA, as listed in Table 3-1. Thus, respiratory effects, long-term nervous system effects, and cancer, all of which were determined to be likely causal, are included in this summary. Outcomes with "suggestive" causality determinations are only briefly summarized (Section 3.3.1.6). Given the focus on $PM_{2.5}$ and cardiovascular effects and mortality in this reconsideration, this is appropriate.

The CASAC notes that a key area where evidence has been strengthened in the Draft ISA Supplement is evidence of long-term mortality effects at lower $PM_{2.5}$ concentrations. In particular, the evidence from evaluations restricting concentrations below a specific threshold, as well as accountability studies that start with concentrations below 12 μg/m^3, convincingly indicate mortality effects at concentrations below the NAAQS.

Specific Comments:

- Section 3.4.2.5, Variability and Uncertainty in Risk Estimates, appropriately and clearly discusses sources and magnitude of uncertainty in relevant scenarios. It would be helpful where possible to describe the direction of the effect on estimated risk of the bias, confounder, or alternative approach being considered; i.e., whether it will increase or decrease the estimated risk.

- The CASAC recommends the PA replace the term "non-White" with "People of Color (POC)" or "Communities of Color (COC)," as appropriate. There are multiple terms utilized to describe the span of races and ethnicities in the United States, which is reflected by the studies included in the Draft ISA Supplement. Race/ethnicity is a fluid concept that is relevant by time, country, region, population and government. Therefore, the most useful terminology for the purpose of protecting public health has changed over time. Changes should be made throughout the document to reflect this.

- The CASAC suggests ordering categories such as race and ethnicity alphabetically, when there is no other basis for ordering within a particular section. As examples, Figure 3-20 gives excellent data broken down by race and ethnicity. Here, in Figure 3-21, and throughout the document, ordering the categories alphabetically allows a comparison of all race/ethnicities more equally, because there is not a focus on White as the referent category.

- Given the large and virtually complete samples included in the recent U.S. and Canada studies, the focus on statistical significance of the measures of association, even in those restricting to below a specific concentration, could be emphasized less, with the focus on the continued positive association observed at those concentrations.

- Although the evidence presented for consideration of alternative annual standards of 10 μg/m^3 and 8 μg/m^3 is strong and compelling, the evaluations rely on evidence that includes more uncertainty than the evidence at higher concentrations. Thus, these sections may benefit from a more thorough discussion of the different approaches of the various studies to estimate the shape of the concentration-response (C-R) function.

- The PA cites findings from human controlled exposure studies to support retaining the current $PM_{2.5}$ 24-hour standard. For example, the following is found on page 3-202. "Human clinical studies support the occurrence of effects following single short-term exposures to $PM_{2.5}$ concentrations that correspond to the peak of the air quality distribution, though these concentrations are well above those typically measured in areas meeting the current standards, *suggesting that the current standards are providing protection against these exposures*"

[Emphasis added]. This use of the human study data to establish a lower no-effect threshold is misplaced, for the following reasons. In general, human studies require levels higher than ambient to elicit effects, in order to provide a contrast with continuous pollutant exposures experienced in daily life. In addition, numbers of research participants are usually relatively small, less than 30 or 40 participants, and exposure durations relatively short, less than 6 hours, in part because of the difficulty and expense involved. Participants are generally healthy, or have mild and stable cardiac or respiratory disease. Children and frail elderly, as well as other at-risk groups, are generally not studied. Regardless of the pollutant being studied, in order to detect meaningful differences in effects across treatment groups, human studies generally require concentrations considerably higher than ambient, and higher than those found to have effects in epidemiology studies. For all of these reasons, absence of an effect at a given concentration in human studies should not be interpreted to represent a no-effect threshold in the "real world."

- Given the multiple differences between $PM_{2.5}$ and UFP, we suggest separating UFP into its own subsection when summarizing the results from the PM ISA in Chapter 3 of the PA. This would make it easier to identify the conclusions and research gaps relevant to UFP when compared to $PM_{2.5}$. It is also important to distinguish and clarify particle number concentration used to characterize UFP from $PM_{2.5}$ mass.

2. What are the Panel's views on the interpretation of the human exposure and animal toxicologic studies for short- and long-term $PM_{2.5}$ exposures for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ standards? To what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

In general, the CASAC agrees that the interpretation of the collective evidence is sound and appropriate. Furthermore, the CASAC believes that mechanistic data from animal studies are highly supportive of the evidence from human studies. The toxicology (controlled human exposures and animal toxicological studies) information in Chapter 3 is used, for the most part, as supporting evidence and to provide biological plausibility for epidemiologically determined long-term and short-term cardiovascular health effects. The consistency across studies, particularly the epidemiological studies is very persuasive.

Additionally, controlled human exposure studies from the 2019 PM ISA are cited to support the plausibility of the serious cardiovascular effects that have been linked with ambient $PM_{2.5}$ exposures. The document also states that $PM_{2.5}$ exposure concentrations evaluated in most of these controlled studies are well above the ambient concentrations typically measured in locations meeting the current primary standards. However, there is an underlying assumption that the 24-hour standard adequately controls for short-term effects of peak exposures embedded in the 24-hour period but there is no adjustment made regarding the increased incidences of short-term peak exposures in recent years. If the prior 20 hours of ambient exposure and the 2-4 hours of the controlled exposure were taken as a time-averaged 24-hour concentration, the exposure would likely be in the realm of normal ambient 24-hour exposures. Similarly, as discussed in the previous charge question response with respect to a threshold for effects in clinical studies, the absence of detectable effects at low concentrations does not necessarily represent threshold effects. Moreover, it must be noted that the majority of these controlled human exposure studies utilized healthy participants and therefore the threshold for susceptible subgroups is uncertain.

The cardiovascular effects and other effects of UFP are left as 'suggestive', likely because of uncertainties in exposure assessment, but the growing animal toxicology data provide some biological plausibility for an important influence of UFP. It might be pointed out that because of increasing numbers and intensities of wildfires, population exposures to UFP are most likely increasing and strategies for considering UFPs could be discussed.

3. What are the Panel's views on conclusions related to the full body of currently available epidemiologic literature, and in particular, the technical approach taken to conduct new analyses to inform our understanding of the relationship between mean $PM_{2.5}$ concentrations reported in epidemiologic studies and annual $PM_{2.5}$ design values? What are the Panel's views on the interpretation of that information and evidence for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ standards?

Chapter 3 is clearly organized, well written, and accurately describes the body of available epidemiologic literature (with some exceptions of omitted relevant publications discussing experimental evidence at near-ambient concentrations noted in Dr. Peel's individual comments). The sections describing the technical approach evaluating the relationship between the mean $PM_{2.5}$ concentrations reported in the epidemiologic studies and annual design values was clearly presented. However, in response to this specific charge question, the CASAC has concerns about the approach comparing the study means and design values, and questions the singular utility of this approach for informing the adequacy of the primary $PM_{2.5}$ standards.

The CASAC has the following comments and suggestions, and in particular for strengthening the approach evaluating the adequacy of the current primary $PM_{2.5}$ standards:

- The focus on the mean concentration in this approach has some limitations for informing the adequacy of the annual and 24-hour standards. The CASAC suggests that using mean $PM_{2.5}$ concentrations from epidemiologic studies is not the only way to estimate where any or the bulk of health effects are observed in these studies. Other approaches can also be used for the purpose of informing the adequacy of the standards, including evaluation of the distribution of concentrations reported in epidemiology studies, including the median concentration and 25th percentile concentration, if available. Another approach could be the evaluation of results from analyses excluding concentrations above the current standard or an alternative value (e.g., 12 $\mu g/m^3$).

- Further, many epidemiologic studies demonstrate associations with exposure to concentrations (based on the mean concentration) below both the current daily and annual standards. Therefore, the question posed on page 3-102, "What are the overall mean $PM_{2.5}$ concentrations reported by key epidemiologic studies?" may not be the only relevant question for evaluating the adequacy of the current standards. Another relevant aspect to consider in this context would be the reported distribution of $PM_{2.5}$ concentrations in studies that reported an association between $PM_{2.5}$ and a health outcome.

- The use of area mean values, and how they relate to the design value, is likely not providing adequate protection to people who live in areas with higher concentrations, such as those living near the monitoring location where the design value was recorded, and people who live in areas that do not have ground monitors but have concentrations higher than the design or mean value. Even though the design value is higher than the area mean value, people exposed to concentrations near the design value monitoring location may more often experience health effects as a function of the higher exposure at the design value monitor, not the area mean value. Thus, while the area mean value may be a useful metric for determining average health effects of the area population as a whole, health effects of that population may be unequally distributed and more pronounced among people living near the design value monitor and those exposed to higher ambient PM concentrations than the area mean value. Importantly, people exposed to these higher concentrations are often disproportionately persons of color and lower-income populations. Therefore, tying standards to the area mean value is not providing adequate protection to the entire population. Note that the CASAC is not suggesting that the EPA redo the analysis for the current policy assessment document. Instead, the CASAC is suggesting adding a discussion that includes the limitations of the current approach (using the mean value) and the likely effect that using other distributional concentrations would have on the results and conclusions of the current document. For future policy assessment documents, the CASAC recommends that the EPA consider approaches other than using just the mean value.

- Chapter 3 could better emphasize the need to have standards that provide an "adequate margin of safety," including safety for potentially sensitive subpopulations, not just an adequate margin of safety for the average person.

- Although the CASAC is not suggesting for the EPA to add studies done outside of the U.S. and Canada to this policy assessment, further justification for restricting to only U.S. and Canadian studies in the document should be provided within the document, particularly given that some areas (e.g., Seoul, South Korea) may have $PM_{2.5.}$ concentrations and composition that is very similar to the U.S.

- Regarding the sentence on page 3-128: "epidemiologic studies do not identify a population-level threshold below which it can be concluded with confidence that $PM_{2.5}$-related health effects do not occur" – It would be more informative to note in the text here that epidemiologic studies provide evidence that such a threshold does not exist, or if it does it is likely at low levels below ambient concentrations in real-world settings.

- For future documents, epidemiologic studies should report more details on the distribution of concentrations (including 25th, 50th, and 75th percentile concentrations) observed in the study location during the study period, and not just the mean concentration.

4. What are the Panel's views on the technical approach taken to update the risk assessment, including the approach to evaluating impacts in at-risk populations?

The technical approach for risk assessment in the PA is appropriate and the CASAC appreciates the efforts taken to broaden the scope of the assessment to at-risk populations. Section 3.4.1 would benefit from added clarification in several areas identified in the recommendations below:

- The risk assessment approach should be clarified further by describing the need for both primary and secondary PM modeling approaches.

- Race/ethnicity and socioeconomic status should be described as both factors that may increase risk of exposure, and as possible effect modifiers of the relationship between $PM_{2.5}$ exposure and mortality.

- The term "at-risk" has not been used as consistently in this chapter as in the Draft ISA Supplement. The CASAC recommends that Section 3.4.1.6 provide explicit detail and/or a citation to the use of this term as described in the ISA Preamble.

For future PAs, the CASAC suggests:

- Integrating at-risk analyses into the broader risk assessment discussion instead of containing it within its own subsection. This would better align the presentation with the EPA's stated mission to determine requisite standards that are protective of the most sensitive in the U.S. population.

- Consider morbidity-based risk assessments. The focus solely on mortality does not incorporate the massive burden of chronic disease that is distributed disproportionately in the country. Including morbidities may also increase the number of studies for possible inclusion, some of which are more diverse regarding race, ethnicity, income and at-risk populations than those currently included.

- Given the analytical capacity currently available, a clearer description of the barriers to conducting a risk assessment of the entire U.S. population, or an expansion of the geographic scope of risk assessments. Completing a national risk assessment would utilize data across the country and could improve estimation by being inclusive of multiple areas (e.g., urban and rural), and sub-populations based on race/ethnicity, income, and other factors. The current capabilities of hybrid exposure models enable this advancement.

- Consider updating and refining the current strategy of a single "Primary PM" and a single "Secondary PM" adjustment approach for simulating just meeting current and alternative standards within the risk assessment. A new strategy would need to be responsive to the following conditions: (1) the incidence of wildfires (and accompanying PM levels) will likely increase further due to climate change impacting specific regions, while average mean $PM_{2.5}$

levels in the U.S. continue to decline; and (2) evolving evidence that toxicity varies according to specific sources or source categories.

- Consider the estimation of cumulative risk and impacts on health morbidity and mortality. There is increasing evidence that risk is cumulative and methods to estimate this risk are improving. In addition, the relationships between multiple exposures or co-pollutants, modifiers and outcomes (e.g., demographic, socioeconomic, built environment factors) should also be incorporated or acknowledged as sources of uncertainty.

To what extent does the draft PA accurately and clearly communicate the results of these analyses?

Overall, the draft PA accurately and clearly describes the results of the risk assessment conducted. The results support the conclusion that the current annual standard does not adequately protect public health. However, the CASAC is concerned that the current risk assessment may not adequately characterize mortality risks associated with short-term $PM_{2.5}$ exposures. This is because, in an effort to exclude areas influenced by wildfire PM, areas where the 24-hour $PM_{2.5}$ standard is controlling due to wintertime stagnation and/or home heating by woodstoves were also excluded. Therefore, the CASAC questions whether the results of the current risk assessment can be used to conclude that the annual standard is protective of short-term exposures. The CASAC recommends that the EPA clarify this limitation in the text and exercise caution when using the risk assessment in this way. In the future, the risk assessment should address this limitation in order to more fully support future assessments of the 24-hour $PM_{2.5}$ standard. Explanation of the categorization of the selected urban study areas (CBSAs) could be expanded and clarified.

In addition, the CASAC suggests revising the figures (e.g., Figure 3-16) to better distinguish between those just meeting the standard and those exceeding the standard. That information is a good accompaniment to the text.

What are the Panel's views on staff's interpretation of these results for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ standards?

The interpretation of the risk assessment for the annual standard is appropriate given the scientific findings presented. As discussed above, the CASAC questions whether the results of the current risk assessment can be used to conclude that the annual standard is protective of short-term exposures. Risk disparities remain substantial for the annual standard. The CASAC recommends more attention to both disparities and consideration of the 24-hour standard. Although the lower alternative standards narrow the gap between risk for White and Black populations, a substantial disparity remains. The PA should include additional text to convey this information.

5. What are the Panel's views on preliminary conclusions regarding adequacy of the current primary $PM_{2.5}$ standards and on the public health policy judgments that support those preliminary conclusions?

This section is well written and accurately summarizes both the health evidence for $PM_{2.5}$ as well as the associated uncertainties. The CASAC recommends the following improvements.

- The language on vulnerable populations could be expanded to better highlight that the current scientific evidence indicates that some subpopulations face higher health burdens from $PM_{2.5}$, including for higher levels of exposure and for increased risk of adverse health responses to a given level of exposure. This includes subpopulations based on race/ethnicity, socio-economic position, age (e.g., children), and others. Improved text on how changes in or retention of the standard would impact different subpopulations that are at higher risk is warranted.

- The discussion on "adequate margin of safety" should be clarified to note that this corresponds to an adequate margin of safety for vulnerable subpopulations, not the average person. This relates to multiple concepts of a margin of safety such as allowing for uncertainty in health effect estimates and protection of vulnerable populations.

- The discussion of threshold, a level below which exposure does not adversely impact human health, includes language noting that the currently available scientific studies "have not identified a threshold," which is technically correct but should be expanded to give the richer context that epidemiological studies have demonstrated associations at low levels, including below the current NAAQS, such that the science indicates that if such a threshold does exist it is at extremely low levels well below the current NAAQS.

- With respect to the discussion of the 24-hour $PM_{2.5}$ standard, the CASAC has concerns about relying on the findings from human exposure studies in identifying the minimum concentration for which health responses are elicited. As discussed in the responses to charge questions 1 and 2 in this chapter, human exposure studies generally do not include subpopulations with substantially increased risk, such as children, elderly frail adults, or those with severe underlying illness.

a. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary 24-hour $PM_{2.5}$ standard, without revision, in this reconsideration?

The majority of the CASAC does not find the rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary 24-hour $PM_{2.5}$ standard without revision to be appropriate and sufficient. They find the state of scientific evidence warrants consideration of lowering of the 24-hour standard given the epidemiologic evidence of health effects at levels below the current standard. This includes epidemiologic studies of short-term exposure to $PM_{2.5}$ that are restricted to days below a specified level (i.e., a subset method) and those that estimate a non-linear concentration-response curve and also provide evidence of risk at levels below the current standard. A minority of the CASAC, however, finds that the rationale provided in the draft PA justifies retaining the current primary 24-hour $PM_{2.5}$ standard, without revision, in this reconsideration, based on the risk assessment provided.

Additional discussion on the CASAC's perspectives is included in in the section "CASAC Advice on the Primary $PM_{2.5}$ Standards" below.

b. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider revising the current primary annual $PM_{2.5}$ standard in this reconsideration?

With respect to the discussion of the primary annual $PM_{2.5}$ standard, the CASAC finds the discussion to provide appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider revising the current standard to a lower level in this reconsideration. The CASAC concurs with the preliminary conclusion that it is appropriate to consider revising the current primary annual $PM_{2.5}$ standard. Additional discussion on the CASAC's perspectives is included in in the section "CASAC Advice on the Primary $PM_{2.5}$ Standards" below.

Importantly, the CASAC find that both primary standards, 24-hour and annual, are critical to protect public health given the evidence on detrimental health outcomes at both short-term and longer-term exposures including peak events (e.g., wildfires).

6. In the Panel's view, has the evidence and risk information, including limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative annual $PM_{2.5}$ standards? Does the discussion provide an appropriate and sufficient rationale to support preliminary conclusions regarding alternative primary annual $PM_{2.5}$ standard levels that are appropriate to consider?

This section is generally well written and the CASAC agrees that the evidence provided in the 2019 ISA and Draft ISA Supplement is appropriate for the purposes of considering potential alternative annual $PM_{2.5}$ standards. This includes evidence related to addressing questions of possible co-pollutant confounding, the application of newer causal inference methods to reduce the chance of confounding bias, and the assessment of effects at $PM_{2.5}$ levels below current standards including significant effects found in accountability studies with starting concentrations below current standards. The PA does a good job describing how the evidence in the 2019 ISA is further confirmed and strengthened by newer evidence in the Draft ISA Supplement. This entire body of evidence provides the rationale for reconsidering the current annual standard.

While the PA does cover studies addressing the issue of co-pollutant confounding and this discussion is an improvement over past ISAs, some concerns remain about confounding by co-pollutants. Since the literature on methods for adjusting for co-pollutant confounding and environmental mixtures continues to evolve, future improvements are likely. The CASAC recommends more explicit acknowledgment of the limitations of studies addressing co-pollutant confounding, including the role of varying spatiotemporal scales of co-pollutant variability relative to the resolution of $PM_{2.5}$, and the possible role of sampling variability in the interpretation of small changes in coefficient estimates when comparing estimates with and without co-pollutant adjustment.

The CASAC has some concerns related to the characterization and interpretation of some key elements of studies in relation to preliminary conclusions regarding alternative primary annual $PM_{2.5}$ standard levels that are appropriate to consider. Notably, first, an over reliance on the mean $PM_{2.5}$ concentration of a study as defining where findings are most robust. Epidemiologic studies require consideration of distribution around the mean of exposure to identify effects and thus lower levels than the mean must be considered as part of the range where the data provide higher confidence. Further, several newer studies (see Draft ISA Supplement, Table 3-6) show significant effects when restricted to levels well below 12 $\mu g/m^3$ when overall means are below 12 $\mu g/m^3$ and even below 8 $\mu g/m^3$, which would therefore have had even lower means in the restricted set. Second, there is concern with exclusion of Canadian studies because of not having design values in Canada to relate to area averages. The Canadian epidemiologic studies identify associations with area averages, and while there may be no design value in Canada, there are data that indicate what a U.S. design value would be if an area average like that found in the Canadian studies were to occur in the U.S. Third, even if a design value is somewhat higher than the area average, it reflects actual exposure levels and thus any portion of the population living near the design value monitor does experience exposures at that level and consequent health effects of exposure to that higher concentration. Lastly, there is some inconsistency in the assessment of effects at lower concentrations. While the PA refers to increasing uncertainties below 8 $\mu g/m^3$ (p. 3-196), several places in the Draft Supplement ISA describe more certainty in effects below 8 $\mu g/m^3$ and even down to 4 $\mu g/m^3$ (e.g. Draft ISA Supplement, pp. 3-19, 3-99, 3-105, and several studies in Table 3-6). Many of these same issues of interpretation of the studies related to the annual standard are also relevant for interpretation of the studies related to the 24-hour standard. The CASAC recommends that the EPA revise their characterization of key elements of studies to take into account these perspectives.

An additional uncertainty is the possibility of over- or under- representation of monitors in high exposure areas where at-risk populations reside. For example, Chapter 2 provides data on the $PM_{2.5}$ concentrations comparing near-road monitors to those away from roads, finding that those near roads were higher. The limited number of near-road sites could impact both epidemiological findings and risk estimates insofar as at-risk populations are differentially represented near and far from roads. Risk estimates could be improved with additional monitoring in key locations, and the draft PA should include language detailing this complex relationship and its possible impact on risk estimates for both the general and at-risk populations.

7. What are the Panel's views on the areas for additional research that are identified in Chapter 3? Are there additional areas that should be highlighted?

Chapter 3 provides a fairly comprehensive list of areas of research of particular importance to future $PM_{2.5}$ assessments. The CASAC recommends several additional areas for research that should be included.

- $PM_{2.5}$ background: As an upper-bound, background is estimated by assuming all biogenic secondary organic aerosol (SOA) is natural, which is not the case. There have been substantial improvements in the CMAQ model's ability to predict the anthropogenic influences (e.g., NOx and acidic sulfate) on biogenic SOA. Future model predictions of background $PM_{2.5}$ should reflect this new knowledge, and additional research is needed to further understand the atmospheric chemistry linkages between anthropogenic emissions and SOA concentrations.

- Hybrid modeling: Advances in and uses of hybrid modeling, including the use of state-of-the-art satellite products are needed. Studies should report the hybrid model concentration distribution statistics (i.e., 10th, 25th, 50th, 75th, 90th percentiles), validation, and statistics comparing hybrid model concentrations with monitoring concentrations and design values where available.

- Consideration of Low-cost Sensor Data: Research to support the continued development of models that incorporate low-cost sensor data would be of benefit because they may improve spatiotemporal resolution in $PM_{2.5}$ exposure estimates. Low-cost sensor networks have the potential to reduce some sources of $PM_{2.5}$ exposure misclassification, but it also should be recognized they may introduce other, new sources of error.

- Sources and components: Future controlled human exposure studies with primary and secondary PM sources and components are warranted, as they could eventually aid the design of more effective air pollution control strategies.

- Epidemiologic study reporting: Epidemiology studies should report concentration distribution statistics (i.e., 10th, 25th, 50th, 75th, 90th percentiles) as well covariance between pollutants.

- Life course epidemiologic and mechanistic studies: There is need for more research that examines exposures during the life course (beginning *in utero*) and intergenerational vulnerabilities that stem from parental exposure to elevated levels of $PM_{2.5}$. Further, studies are needed to examine potential biologic mechanisms of such associations.

- PM composition and sources in accountability studies: Epidemiology studies examining health effects associated with PM and changes in associations over time (e.g., in accountability studies) should consider changes in PM composition and PM sources over time, and not just changes in PM concentration. It is important to understand whether a difference in health effects associated with high $PM_{2.5}$ versus low $PM_{2.5}$ concentrations represents a true difference in the human biologic response to high versus low concentrations, or whether it may just reflect differences in PM composition between high and low concentrations and different biologic response to different PM components. Future epidemiology studies should provide information on the PM composition and PM source(s) observed during the study period, whenever possible.

- Health effects of ultrafine particles: Similarly, more studies are needed that assess health effects associated with ultrafine particle (<100nm) count concentrations, as well as investigate the health effects associated with different particle sizes within the ultrafine fraction.

CASAC Advice on the Primary Standards for $PM_{2.5}$

Regarding the annual $PM_{2.5}$ standard, the CASAC reached consensus that the indicator, form, and averaging time should be retained. Furthermore, all CASAC members agree that the current level of the annual standard is not sufficiently protective of public health and should be lowered. In concurring with the EPA's recommendation to lower the annual standard, the CASAC agrees with the EPA's assessment that there are large populations at risk of $PM_{2.5}$ health effects, and that the Draft ISA Supplement provides new evidence of disparities in risk across various population subgroups. The evidence base for adverse health effects below the current annual standard has been strengthened and that, while uncertainties remain in the epidemiologic evidence, recent studies that employ alternative analysis approaches have helped to reduce those uncertainties (e.g., by addressing the potential for residual confounding). The CASAC concurs with the EPA's assessment that meaningful risk reductions will result from lowering the annual $PM_{2.5}$ standard.

CASAC members had differing opinions about the best recommended range for the alternative level. The majority of the CASAC judged that an annual average in the range of 8-10 $\mu g/m^3$ should be the recommended alternative annual standard. A minority of the CASAC thought that the range of the alternative standard of 10-11 $\mu g/m^3$ was more appropriate. The CASAC highlights that the alternative standard level of 10 $\mu g/m^3$ is within the range of acceptable alternative standards recommended by all CASAC members, and that an annual standard below 12 $\mu g/m^3$ is supported by a large and coherent body of evidence. The following two paragraphs discuss the justifications for these ranges.

The majority of CASAC members believe that a recommendation of 8-10 $\mu g/m^3$ is best supported. This argument places more weight on epidemiologic studies with mean concentrations below 10 $\mu g/m^3$, including some newer studies not cited in the Draft ISA Supplement (e.g., Yazdi et al., 2021; Vodonos et al., 2018) and by considering Canadian studies, some of which had means even lower than 8 $\mu g/m^3$. A recommendation of 8-10 $\mu g/m^3$ is also supported by placing emphasis on the protection of vulnerable demographic groups. For example, while estimated health risks for Black communities are still higher than for majority White communities, the risk assessment predicts a substantial risk reduction for Black residents with a decrease in the annual standard to 9 $\mu g/m^3$ or lower (Figure 3-21). Arguments supporting 8-10 $\mu g/m^3$ also include: evidence consistent with no threshold and a possible supra-linear concentration-response function at lower levels, recognition that the use of the mean to define where the data provide the most evidence is conservative since robust data clearly indicate effects below the mean in concentration-response functions, and consideration that people are not randomly distributed over space such that populations in neighborhoods near design value monitors are exposed to the levels indicated at those monitors and likely to be more at risk.

A minority of CASAC members believe that a recommendation of 10-11 $\mu g/m^3$ is best supported. This argument places more weight on the remaining uncertainties as well as the fact that design values are generally higher than area average exposure levels. Key U.S. epidemiologic studies indicate consistently positive and statistically significant health effect associations based on air quality distributions with area average mean $PM_{2.5}$ concentrations at or above 9.9 $\mu g/m^3$ for monitor-based studies, at 9.3 $\mu g/m^3$ for hybrid modeling with population-weighted averages of grid cells, and ranging between 9.8-12.2 $\mu g/m^3$

or 8.1-11.9 µg/m^3 for hybrid modeling with unweighted averages of grid cells averaged to the same resolution as the study data (ZIP code, census tract, or postal code) or to the entire study area, respectively (p. 3-112). The form of the standard and the way attainment with the standard is determined (i.e., highest design value in the CBSA) are important factors when determining the appropriate level for the standard. According to the PA, the area annual design values are generally higher than the study means by 10-20% for monitor-based studies, 14-18% for hybrid modeling with grid cells averaged to the resolution of the study data, and 40-50% for hybrid modeling with grid cells averaged to the entire study area (p. 3-112). Also, the recommendation of 10-11 µg/m^3 emphasizes increasing uncertainties in the epidemiological findings at concentrations below 10 µg/m^3, and the large uncertainties in the risk assessment.

Regarding the 24-hour $PM_{2.5}$ standard, most of the CASAC members find that the available evidence calls into question the adequacy of the current 24-hour standard. The CASAC notes that the level is conditional on the form, and all CASAC members conclude that the PA does not provide sufficient information to adequately consider alternative form and level combinations. Thus, the discussion that follows first addresses the level conditional on the current form, and then considers revisions of the form.

Regarding the level of the 24-hour standard conditional on retaining the current form, the majority of CASAC members favored lowering the 24-hour standard. These members are convinced that there is substantial epidemiologic evidence from both morbidity and mortality studies that the current standard is not adequately protective. This includes three U.S. air pollution studies with analyses restricted to 24-hour concentrations below 25 µg/m^3 (Table 3-10). The members also note that the controlled human exposure studies are not the best evidence to use for justifying retaining the 24-hour standard. As discussed earlier, these studies preferentially recruit less susceptible individuals and have a typical exposure duration much shorter than 24 hours, so the evidence of effects from controlled human exposure studies with exposures close to the current standard support epidemiological evidence for lowering the standard. Overall, these members place greater weight on the scientific evidence than on the values estimated by the risk assessment. They were concerned that the risk assessment may not adequately capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective. They also were less confident that the annual standard could adequately protect against health effects of short-term exposures. These members suggest that the EPA revise the level as part of the current review, and that a range of 25-30 µg/m^3 would be adequately protective.

In contrast, the minority of CASAC members who agree with the EPA's preliminary conclusion to retain the current 24-hour standard place greater weight on the risk assessment. The risk assessment not only accounts for the level of the standard, but also accounts for the form of the standard and the way attainment with the standard is determined (i.e., highest design value in the CBSA). The risk assessment indicates that the annual standard is the controlling standard across most of the urban study areas evaluated and revising the level of the 24-hour standard is estimated to have minimal impact on the $PM_{2.5}$-associated risks. Therefore, the annual standard can be used to limit both long- and short-term $PM_{2.5}$ concentrations. These members judge that there is limited epidemiologic evidence to determine the adequacy of the current level of the 24-hour standard. Finally, these members place more emphasis on the human exposure studies, showing effects at $PM_{2.5}$ concentrations well above those typically measured in areas meeting the current standards suggesting to them that the current standards are providing adequate protection against these exposures.

The CASAC recommends that in future reviews, the EPA provide a more comprehensive assessment of the 24-hour standard that includes the form as well as the level. The CASAC recognizes that they have insufficient information with which to evaluate alternative forms of the 24-hour standard and recommends that the form be revisited. In particular, the midnight-to-midnight averaging time splits high wood smoke episodes into two days, thus potentially underestimating the effect of high 24-hour exposures, especially in areas with wood-burning stoves and wintertime stagnation. The CASAC suggests considering a rolling 24-hour average and examining alternatives to the 98th percentile of the 3-year average (e.g., average of concentrations $\geq 98^{th}$ percentile or alternative percentiles).

Chapter 4 – Reconsideration of the Primary Standard for PM_{10}

1. To what extent does Chapter 4 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on $PM_{10-2.5}$-related health effects?

Chapter 4 does an excellent job of characterizing the key points of evidence regarding coarse PM's association with adverse health effects. In particular, it:

- Describes the general approach used to examine the premise of reconsidering the 2020 final decision, and

- Examines the four basic elements of the NAAQS (i.e., indicator, averaging time, form, and level) in evaluating the health protection afforded by the current standard.

There is a clear progression of the strength of evidence in $PM_{10-2.5}$ causality determinations from the 2009 PM ISA for long-term mortality, cardiovascular effects, and cancer, elevating their significance from "Inadequate" to "Suggestive of, but not sufficient to infer" in the 2019 ISA. Nervous system effects and metabolic effects were not discussed previously but are also determined in the 2019 ISA to be "suggestive of, but not sufficient to infer."

The PA concludes that "the available evidence in this reconsideration of the 2020 final decision supports retaining the current standard." The PA did not consider alternative standards. However, Chapter 4 in essence discusses $PM_{10-2.5}$ whereas the NAAQS addresses PM_{10}. Additional clarification would be helpful.

2. What are the Panel's views on the interpretation of the health evidence for short- and long-term $PM_{10-2.5}$ exposures for the purpose of evaluating the adequacy of the current primary PM_{10} standard?

Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

The draft PA draws from the evaluation of the health effects evidence for $PM_{10-2.5}$-related effects in the 2019 ISA and considerations of such effects in the 2020 PA because the Draft ISA Supplement does not include an evaluation of new studies for $PM_{10-2.5}$ reported after the deadline for the 2019 ISA. The overarching question for these analyses is "**Does the available scientific evidence support or call into question the adequacy of the protection afforded by the current primary PM_{10} standard against health effects associated with exposures to $PM_{10-2.5}$?"** The 24-hour PM_{10} standard has not been changed since its 2006 promulgation, despite the recent findings of health effects. Chapter 4 needs to discuss in more detail whether PM_{10} is still the appropriate indicator since $PM_{10-2.5}$ was the focus of the chapter, and whether the increasing level of causality might warrant a re-evaluation of the NAAQS.

The descriptions of the uncertainties in evaluating the health effects of coarse PM are well written. These uncertainties include, compared to $PM_{2.5}$ studies, the more limited number of epidemiology studies with positive statistically significant findings, and the difficulty in extracting the sole contribution of coarse PM to observed adverse health effects in light of the causal evidence for $PM_{2.5}$ which can be a confounder in studies of PM_{10} health effects.

3. What are the Panel's views on conclusions regarding support for new or updated quantitative analyses?

No new quantitative analyses are described, however it might have been instructive to formally analyze the uncertainties to determine the direction of bias inferred from the data. It would seem for example, that the potential uncertainty around the exposure would increase the 'noise' and reduce the possibility of detecting a signal if it were there.

4. What are the Panel's views on preliminary conclusions regarding adequacy of the current primary PM_{10} standard and on the public health policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary PM_{10} standard, without revision, in this reconsideration?

Retention of the PM_{10} indicator may be warranted, to account for the varying concentrations of $PM_{10-2.5}$ permitted in urban versus non-urban areas, however the justification for this should be discussed in more detail.

The PA concludes that the available evidence does not call into question the scientific judgments that informed the decision in the 2020 review to retain the current primary PM_{10} standard in order to protect against $PM_{10-2.5}$ exposures, but recognizes that the PA did not consider any new evidence beyond that included in the last ISA. The CASAC would appreciate additional discussion of the significance, or lack thereof, of the stronger relationship of $PM_{10-2.5}$ exposure and health effects than in previous assessments, with respect to reconsidering the primary PM_{10} standard.

5. What are the Panel's views on the areas for additional research that are identified in Chapter 4? Are there additional areas that should be highlighted?

The PA repeatedly indicates that prior reviews noted the potential for exposure measurement error and co-pollutant confounding in $PM_{10-2.5}$ epidemiologic studies. The literature is still evolving on how best to account for co-pollutant confounding; the document could be improved if the uncertainties of current approaches considered in the PA were more explicitly discussed.

The PA mentions several areas of future research; they are all appropriate. Efforts to increase particle speciation studies, especially in high impact areas, and areas that are disproportionally affected by $PM_{10-2.5}$, both urban and rural, could eventually lead to mitigation efforts that can improve health and well-being.

There is a need for additional research to reduce uncertainties in the $PM_{10-2.5}$ exposure estimates used in epidemiologic studies, to assess the independence of $PM_{10-2.5}$ health effect associations, and evaluate the biological plausibility of $PM_{10-2.5}$-related effects.

Expanded development of low-cost sensors that provide direct measurements could fill in the sparse $PM_{10-2.5}$ monitoring network.

The CASAC recognizes a need for, and supports investment in research and deployment of measurement systems to better characterize $PM_{10-2.5}$ and better quantify its spatial variability. Efforts to develop and deploy appropriate FRM systems will provide information that can improve public health, especially when considering implications for respiratory diseases such as asthma and bronchitis.

More studies of $PM_{10-2.5}$ effects in high-risk populations, including children are needed. Studies are needed that focus on health equity; considerations include ensuring adequate sample size across sub-populations, examining for exposure burden (both short-term and long-term), and obtaining health effect estimates in sub-populations. Further, research is needed to identify the areas where health effects for exposure to $PM_{10-2.5}$ are most likely to occur, such as dry and windy, rural and agriculturally intensive regions of the Mountain West.

Chapter 5 – Reconsideration of the Secondary Standards

1. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on PM-related visibility effects?

2. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related climate effects?

3.To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related materials effects?

4. What are the Panel's views on the interpretation of the evidence for PM-related welfare effects for the purpose of evaluating the adequacy of the current secondary PM standards? Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

5. What are the Panel's views on conclusions regarding support for new or updated quantitative analyses? What are the Panel's views of the technical approach taken to conduct updated analyses to inform our understanding of the relationship between PM in ambient air and visibility impairment?

6. What are the Panel's views on preliminary conclusions regarding adequacy of the current secondary PM standards and on the public welfare policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current secondary PM standards, without revision, in this reconsideration?

7. What are the Panel's views on the areas for additional research that are identified in Chapter 5? Are there additional areas that should be highlighted?

The CASAC agrees with the EPA's determination of a causal relationship between $PM_{2.5}$ and visibility effects. However, limited new data (2015 onward) on PM-light extinction relationships are available that would highlight sulfate reductions in the eastern U.S., ammonium and nitrate increases in the central U.S., and primary organic carbon increases in the intermountain west and southwest. Large changes in aerosol composition and light extinction indicate that PM-visibility relationships are region specific. Figures for different versions of the IMPROVE algorithms (e.g., original, revised, modified, and Lowenthal and Kumar (2016)) should be presented to reflect visibility effects under current air quality conditions and the accuracy of chemical extinction estimates.

Recent technologies to measure single particle and multiwavelength light absorption, scattering, and extinction should be acknowledged. Changes in organosulfate to inorganic sulfate ratios and increases in light absorbing brown carbon due to increased wildfires, along with associated differences in hygroscopicity and light extinction, need to be evaluated to reduce the differences between optical and chemical light extinction.

A visibility index of 30 deciviews (12 miles) as an appropriate target level of protection for visibility needs to be justified given that existing visibility preference studies show <50% acceptability where the $PM_{2.5}$ visibility index ranged from 20-30 deciviews (12-33 miles). From Table 2 below, extracted from Table D-8 of the PA for visibility preference studies, it appears that an appropriate target level of visibility protection should be in the range of 20-25 deciviews. Additional region- and view-specific visibility preference studies and data analyses are needed to support a quantitative index. If a value of 25 deciviews (or lower) is deemed an appropriate visibility target level of protection, then the current secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ may be called into question.

Table 2. Location and mean deciview (dv) found "acceptable" extracted from Table D-8.

Location	Mean dv found "acceptable"
Denver, CO (1991)	20.3
Phoenix, AZ (2003)	23-25
Vancouver, British Columbia (1996) Chilliwack: Abbotsford:	 ~23 ~19
Washington, DC (2001)	~20 (range 20-25)
Washington, DC (2009)	~30

Since the visibility analysis was based on the 3-year average of the 90th percentile of daily light extinction, evidence to support a 15 µg/m^3 annual secondary standard needs to be provided. One alternative is to set the annual secondary $PM_{2.5}$ standard equal to the primary $PM_{2.5}$ standard, following the precedent for the O_3, NO_2, and lead NAAQS.

According to the Draft ISA Supplement, contrast rather than total light extinction appears to make the level of acceptable visual air quality more uniform across different locations. However, the PA does not use contrast to evaluate an appropriate target level of visibility protection. The final PM PA should use an "acceptable" contrast value to help develop the secondary PM standards.

The CASAC recognizes that there is a causal relationship between PM and climate change, but large uncertainties remain. The physical science basis in the most recent IPCC report may be consulted to provide an up-to-date understanding of interactions and feedbacks in the climate system. A trend analysis (Requia et al., 2019) over the last three decades (1988-2017) identified weather-associated penalties in $PM_{2.5}$ composition and the effects of biomass burning generated brown carbon on climate and visibility. The CASAC recommends updating the information in the document to provide an up-to-date understanding of the climate system and climate change. Furthermore, the CASAC recommends more climate-related research.

Quantitative information on the relationship between PM and material damage is lacking, and more documentation in the PA should be included. Individual comments from committee members provide references to recent reviews that discuss forms of material damage, deterioration, mechanisms, and approaches to quantify pollution effects on materials. In addition to ground-based measurements, satellite observations (Christodoulakis et al., 2018) can be used to examine material damage and establish dose-response relationships to provide additional understanding of corrosion/soiling effects.

The growing amounts of microplastic emissions and presence in airborne particles, with potential effects on the Earth's radiation balance a well as deposition onto materials, soils and waterways merits further research into their concentrations, chemical compositions, optical properties, and size ranges.

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Appendix A

Individual Comments by the 2021 CASAC Particulate Matter Review Panel Members on the EPA's *Policy Assessment for the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – October 2021)*

Mr. George A. Allen

Chapter 1 – Introduction

Chapter 1 provides introductory information including a summary of the legislative requirements for the NAAQS, an overview of the history of the PM NAAQS and the decisions made in prior reviews, and a summary of the scope and approach for the reconsideration of the 2020 final decision.

1. To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for this reconsideration?

This chapter does a good job covering the legislative requirements and PM NAAQS history for health and welfare effects. The scope of the current review is clearly described, noting that this PA considers the evidence covered in both the original 2019 ISA and the 2021 supplement, and that the supplement is limited to recent evidence on outcomes that have a causal relationship to PM.

However, it does not describe the unusually contentious aspects of the review (failure to reach consensus on the annual PM2.5 NAAQS, and CASAC dismissing the PA conclusion of 10 annual based on the WOE framework long used by the agency) that concluded in 2020 that is the basis for this reconsideration and that resulted in the NAS committee on Assessing Causality for NAAQS (status update?). Additional detail on this would inform the reader on the rationale for this reconsideration. (Drs. Sheppard, Frampton, and Boylan to provide?) Section 1.4.2 simply says: "The EPA is reconsidering the December 2020 decision because the available scientific evidence and technical information indicate that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act." This is not a useful explanation of why we're doing this, because the conclusions in the 2020 PA were essentially the same.

Chapter 3 – Reconsideration of the Primary Standards for PM2.5:

1. To what extent does Chapter 3 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on PM2.5-related health effects?

It seems that this charge question is on Section 3.3.1, which summarizes the evidence from the 2019 ISA and 2021 draft ISA supplement with a "particular emphasis" on those with a causal or likely causal relationship with PM2.5 from the 2019 ISA, as listed in table 3-1. Thus respiratory, and long-term cancer and long-term nervous system likely causal effects are included in this summary. Outcomes with "suggestive" causality determinations are only briefly summarized (section 3.3.1.6). Given the focus on PM2.5 and cardiovascular mortality in this reconsideration, this is appropriate.

The summary of this section (3.3.1.7) is a well written and a concise recap of long and short-term PM2.5 health effects. I agree with its overall conclusion that "the evidence available in the draft ISA Supplement reaffirms, and in some cases strengthens, the conclusions from the 2019 ISA regarding long- and short-term PM2.5 exposures and mortality and cardiovascular effects."

<u>Chapter 5 – Reconsideration of the Secondary Standards for PM:</u>

General comment: EPA staff conclude in this review that the current Secondary Standard for PM is adequate and no change was considered. In light of the importance of the reconsideration of the Primary PM Standard and the limited time for its discussion in this review, it is difficult to justify putting significant time or effort into a discussion about possible revisions to the Secondary Standard at this time. Visibility is the indicator of concern, with climate and materials effects playing minor roles (the ISA Supplement did not consider new climate and materials studies). Currently the Secondary PM NAAQS is set to 15 $\mu g/m^3$ annual average (a remnant of the 2006 Primary Standard), higher than the Primary Standard, rendering it useless (the 24-h Standard is set equal to the Primary Standard). Secondary Standards, without any limit on implementation time, have always taken a back seat to the Primary Standards for NAAQS, and for NO2, lead, PM, and ozone are just set to the value of the Primary. The good news: for visibility, the NAAQS is not the only driving force for improvement. The 1999 Regional Haze Rule with its use of reconstructed visibility metrics and a glidepath to natural background by 2064, although specific to Class 1 airsheds, has and will continue to be an effective regulation for improving visibility. Regional PM2.5 drives visibility at these airsheds, and reducing it there will tend to reduce it elsewhere as well. Reducing the level of the Primary Standards can also contribute to improved visibility. For the limited scope of this reconsideration review, I see no reason to not simply set the Secondary equal to the Primary PM Standards, whatever they may be. A serious discussion of revisions to the visibility standard can take place during the next PM NAAQS review. Thus my comments on this chapter are brief.

The 2010 CASAC review of the PM PA is here: EPA-CASAC-10-015 https://casac.epa.gov/ords/sab/f?p=105:18:6853824302596:::RP,18:P18_ID:2064. I concur with what CASAC said 11 years ago on this topic. Not much has changed since, and the recommended research on a FRM for visibility has not been done. See also the IPMRP comments on the 2019 draft PA visibility chapter here: https://www.ucsusa.org/meeting-independent-particulate-matter-review-panel

Other comments

Chapter 2, PM2.5 monitoring. There continue to be substantial issues with data quality from the FEM continuous PM2.5 monitors. At least 1/3 of the FEM monitors in use do not meet the required data quality for comparison to the NAAQS. Of those that do, they tend to report higher concentrations than the FRM by as much as 10%, presenting challenges to state and local air agencies that are or would be close to the annual PM2.5 NAAQS. FEM data can be retrospectively adjusted to be "FRM-like". One approach that has been shown to work well uses regressions of FEM daily data on collocated 6th day FRM data with a rolling 3-month basis; EPA should consider making this an optional approach in this or the next review, and could implement this approach to assess its performance at the national scale.

Exceptional events. EPA allows exclusion of wildfire PM events under the exceptional event rule when calculating PM2.5 design values. In some parts of the country wildfires are no longer "exceptional". The dramatic increase in wildfires over the last decade is not natural; it is a combination of anthropogenic climate change, forest management practices, and power line ignition incidents. These are (in theory) at least partially controllable. Given the potential for significant adverse health events, it may be time to reconsider the current approach to excluding the high PM exposures from wildfire events in design values.

Typos: Aethalometer should always be capitalized, like Teflon.

Chapter 3, PM2.5 primary standards.

Consideration of an alternate daily standard should also consider the form, specifically how the 24-hour average is measured. For towns and small cities with substantial PM emissions from residential wood heating appliances, a midnight start time is not an appropriate measure of daily exposure since it can break a single night with high woodsmoke PM into two separate days. A rolling 24-h metric (if sufficient FEMs are reporting – see above) or a noon to noon sample day would be more appropriate. If the midnight start time is retained, then this issue should be taken into consideration when a lower daily NAAQS value is considered in this review.

The historical ratios of daily to annual PM2.5 NAAQS can inform the choice of an alternate daily standard. That has varied from 2.3 (2006) to 2.9 (2012) to 4.3 (1997). Although EPA makes arguments that the annual is the controlling standard, the daily "backstop" value must also be reduced in step with the primary to control short-term exposures in seasonal scenarios like PM from residential wood heating.

When considering an alternate annual PM NAAQS, the increased mortality risk of Blacks compared to other racial and ethnic groups (see Di et al. 2017b, NEJM, figure 2a) suggests that a standard at the low end of the 10 to 8 $\mu g/m^3$ range be considered to provide protection to this subgroup that makes up 15% of the US population.

Dr. John R. Balmes

Chapter 1 – Introduction

Chapter 1 provides introductory information including a summary of the legislative requirements for the NAAQS, an overview of the history of the PM NAAQS and the decisions made in prior reviews, and a summary of the scope and approach for the reconsideration of the 2020 final decision.

1. To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for this reconsideration?

I find the information presented in Chapter 1 to be clearly presented and very useful to the current PM NAAQS review.

Chapter 2 – Air Quality

Chapter 2 describes the major PM emissions sources; the atmospheric chemistry related to PM in ambient air; the PM monitoring network; PM ambient air quality trends and relationships; an overview of hybrid modeling methods used to estimate PM2.5 concentrations; analyses to inform our understanding of mean PM2.5 concentrations from monitors and hybrid models and their relationships with design values; and background PM.

1. What are the Panel's views on the technical approach taken and analyses completed to inform our understanding of how PM2.5 concentrations calculated using composite monitors and area averages from hybrid modeling approaches compare to area design values?

I find the technical approach and analyses informative to an understanding of how PM2.5 concentrations are calculated for the purposes of the current NAAQS review.

2. To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for this reconsideration?

I find the information in Chapter 2 to be clearly presented and to provide a useful context for the current NAAQS review. That said, I find the discussion of wildfire smoke PM2.5 to be woefully insufficient to the magnitude of the problem in the Mountain West. No longer is this area seeing occasional high PM2.5 concentrations during a few days per year. Over the last two wildfire seasons (2020-2021), poor air quality due to wildfire smoke has lasted for at least one month in certain areas. Some of the fires have occurred in the wildland-urban interface and thus have exposed communities to toxic emissions from combustion of man-made materials in addition to biomass smoke. Moreover, not all wildfires can be considered a natural source of PM2.5 since many of the fires are caused by power line failures. In my opinion, the days when EPA can allow air districts to ignore exceedances due to wildfire events should be over. The public health impact of exposure to wildfire smoke PM2.5 is great and air districts that have poor air quality due to wildfires should be mandated to address this problem, not be given a "free pass."

Chapter 3 – Reconsideration of the Primary Standards for PM2.5

Chapter 3 summarizes key aspects of the health effects evidence and evaluates mean PM2.5 concentrations reported in key epidemiologic studies that are particularly relevant to considering the adequacy of the current primary PM2.5 standards. Chapter 3 also summarizes the risk assessment and at-risk analyses to inform preliminary conclusions on the primary PM2.5 standards. Finally, Chapter 3 presents the preliminary conclusion that, collectively, the scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as supporting retention of the 24-hour PM2.5 standard, while calling into question the adequacy of the public health protection afforded by the current primary annual PM2.5 standard, and presents alternative annual PM2.5 standards that could be supported by the available scientific and technical information. Chapter 3 also identifies key areas for additional research and data collection, in order to inform future reviews.

1. To what extent does Chapter 3 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on PM2.5-related health effects?

In my view, Chapter 3 does capture and appropriately characterize the key aspects of the evidence assessed and integrated in both the 2019 ISA and the draft Supplement. That said, taking the Chapter as a whole, I find it somewhat difficult to read because of repetition of information, primarily on the epidemiological evidence. I find that Section 3.5 on Conclusions on the Primary PM2.5 Standards is clearly presented and most useful for the purpose of the current NAAQS review.

2. What are the Panel's views on the interpretation of the human exposure and animal toxicologic studies for short- and long-term PM2.5 exposures for the purpose of evaluating the adequacy of the current primary PM2.5 standards? To what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

Overall, I find the interpretation of the experimental evidence appropriate for the purpose of the current NAAQS review. That said, I disagree with the 2019 ISA assessment of the evidence for respiratory effects as only "likely causal." Because causal determinations are based on the weight of evidence, integrating human and animal experimental evidence with the epidemiological evidence, my interpretation of the weight of evidence regarding both long-term and short-term exposures to PM2.5 as "causal." My assessment of the epidemiological evidence is that it supports a causal relationship, even if experimental evidence is weaker than for cardiovascular effects. In addition, I find it somewhat logically inconsistent with the likely causal determination for respiratory effects that respiratory tract inflammation is used as part of the biological mechanism rationale for cardiovascular effects. I also find this inconsistency with regard to the discussions of respiratory-specific mortality (used to support the mortality causal relationship determination) and growth of lung function in children (used to support the vulnerability of children). In addition, the likely causal relationship determination for lung cancer (and lack of evidence for other cancers) also supports the respiratory toxicity of exposures to PM2.5 exposures.

3. What are the Panel's views on conclusions related to the full body of currently available epidemiologic literature, and in particular, the technical approach taken to conduct new analyses to inform our understanding of the relationship between mean PM2.5 concentrations reported in epidemiologic studies and annual PM2.5 design values? What are the Panel's views on the interpretation of that information and evidence for the purpose of evaluating the adequacy of the current primary PM2.5 standards?

In my opinion, the conclusions presented by staff based on the available epidemiological literature reasonable with the caveat that I disagree with the likely causal determinations for long-term and short-term exposures to PM2.5 and respiratory effects as noted in my response to Charge Question 2. The interpretation of the epidemiological evidence for the purpose of evaluating the adequacy of the current primary PM2.5 standards is also reasonable.

4. What are the Panel's views on the technical approach taken to update the risk assessment, including the approach to evaluating impacts in at-risk populations? To what extent does the draft PA accurately and clearly communicate the results of these analyses? What are the Panel's views on staff's interpretation of these results for the purpose of evaluating the adequacy of the current primary PM2.5 standards?

Overall, it is my opinion that the staff's approach to the risk assessment for the annual PM2.5 current and alternate standards is consistent with that used for previous NAAQS review risk assessments. That said, I suggest the choice of health outcomes to use in the risk assessment needs a rationale. All three outcomes are for mortality (total non-accidental, ischemic heart disease, and lung cancer). In my view, having at least one morbidity outcome, such as cardiovascular disease hospitalizations, would have strengthened the risk assessment, especially given that a greater proportion of individuals would be expected to have adverse cardiovascular effects than those who die of ischemic heart disease. I also have concerns about the use of the Turner at al. 2016 ozone paper as the sole source for the concentration-response (C-R) function for PM2.5-lung cancer mortality, especially if staff used only the hazard ratio and 95% confidence intervals for regional PM2.5 presented in that paper as opposed to the full range of the data. The Turner et al. paper reports the results of a thorough analysis, but given that it is really an ozone paper, I am curious why this study was selected for the C-R for lung cancer mortality as opposed to the other studies listed in Figure 3-3.

It is also my opinion that the use of only 47 CBSAs for the risk assessment is problematic because it excludes some CBSAs that experience exceedances due to wildfire smoke (e.g., exceptional events) and which also experience wintertime peak exposures due to residential wood-burning when there is a lower boundary layer.

Given the presentation in the Supplement to the 2019 PM ISA about the increased vulnerability of low-income communities of color as a consequence of disproportionate burden of exposure and increased risk of adverse health outcomes, the risk assessment would be stronger if it addressed this issue more directly. For example, the use of mean PM2.5 concentrations for a CBSA necessarily down weights the impacts on communities that experience exposures higher than the mean, which are often low-income communities of color.

5. What are the Panel's views on preliminary conclusions regarding adequacy of the current primary PM2.5 standards and on the public health policy judgments that support those preliminary conclusions?

a. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary 24-hour PM2.5 standard, without revision, in this reconsideration?

The discussion that supports the retention of a 24-hour PM2.5 standard uses experimental human and animal evidence to make the case. I think the epidemiological studies that show associations between daily exposures to PM2.5 and mortality at concentrations less than 25 or 35 μg/m3 provide sufficient rationale to revise the 24-hour standard to 25-30 μg/m3.

b. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider revising the current primary annual PM2.5 standard in this reconsideration?

Yes, the rationale provided is both appropriate and sufficient to support revising the annual PM2.5 standard downward. In particular, the epidemiological studies that provide evidence of mortality effects at annual concentrations below 12 μg/m3 strongly support that annual PM2.5 standard be revised downward.

6. In the Panel's view, has the evidence and risk information, including limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative annual PM2.5 standards? Does the discussion provide an appropriate and sufficient rationale to *support preliminary conclusions regarding alternative primary annual PM2.5 standard levels that are appropriate to consider?*

In general, the discussion of limitations and uncertainties of the information used in the risk assessment are appropriately characterized. That said, I find the "Potential confounding of the PM2.5-mortality effect" bullet in section 3.3.2.4 somewhat incomplete. While I agree with the text in this bullet that states "For studies of long-term exposures, confounders may include socioeconomic status, race, age, medication use, smoking status, stress, noise, and occupational exposures," these potential confounders can also act as effect modifiers to increase risk of adverse health outcomes from long-term PM2.5 exposures.

The discussion provides an appropriate and sufficient rationale to support preliminary conclusions about appropriate alternative annual PM2.5 standards.

7. What are the Panel's views on the areas for additional research that are identified in Chapter 3? Are there additional areas that should be highlighted?

In my opinion, all of the bullets listed are important areas for future research. My primary concern is the lack of specific mention of race/ethnicity and SES in the bullet on "Research to improve our understanding of variability in PM2.5 exposures within and across various populations (e.g., defined by life stage, pre-existing condition, etc.)…" and the bullet on "Improving our understanding of the PM2.5 concentration-response relationships near the lower end of the PM2.5 air quality distribution, including the shapes of concentration-response functions and the uncertainties around estimated functions for various health outcomes and populations (e.g., older adults, people with pre-existing diseases, children)."

Chapter 4 – Reconsideration of the Primary Standard for PM10

Chapter 4 summarizes key aspects of the health effects evidence that are particularly relevant to considering the adequacy of the current primary PM10 standard. Chapter 4 presents the preliminary conclusion that the available evidence does not call into question the adequacy of the public health protection provided by the current primary PM10 standard and that it is appropriate to consider retaining this standard in this reconsideration. Chapter 4 also identifies key areas for additional research and data collection, in order to inform future reviews.
1. To what extent does Chapter 4 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM10-2.5-related health effects?

Chapter 4 captures the key aspects of the evidence presented in the 2019 PM ISA on PM10-2.5-related health effects. A problem is the relative lack of informative evidence in the 2019 ISA.

2. What are the Panel's views on the interpretation of the health evidence for short- and long-term PM10-2.5 exposures for the purpose of evaluating the adequacy of the current primary PM10 standard? Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

Chapter 4 appropriately characterizes and interprets the available evidence from the 2019 PM ISA on the associations between PM10-2.5 exposures and health effects. Unfortunately, no new studies published after the cut-off for the ISA have been reviewed and there are a number of such studies to be considered in future reviews of this standard.

3. What are the Panel's views on conclusions regarding support for new or updated quantitative analyses?

I would not recommend a quantitative analysis of the data available from the 2019 PM ISA.

4. What are the Panel's views on preliminary conclusions regarding adequacy of the current primary PM10 standard and on the public health policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary PM10 standard, without revision, in this reconsideration?

Retention of the PM10 indicator is important to protect public health from high exposures of PM10-2.5 due to windblown dust primarily in rural and/or agriculturally intensive areas (e.g., the San Joaquin Valley in California). The discussion of the uncertainties in the PM10-2.5 exposure estimates used in epidemiologic studies for the assessment of PM10-2.5 health effect associations is appropriate and sufficient to support the retention of the current PM10 standard. The conclusion of the PA that the available evidence does not call into question the decision in the 2020 review to retain the current primary PM10 standard without revision is reasonable.

I strongly urge the EPA to plan a careful review of the available evidence for a coarse PM (PM10-2.5) standard, which would make more biological sense than the current PM10 standard. In addition to health studies, more exposure studies for coarse PM should be supported.

5. What are the Panel's views on the areas for additional research that are identified in Chapter 4? Are there additional areas that should be highlighted?

In my opinion, all of the bullets listed are important areas for future research. In addition, I would like to see research to identify the areas where health effects for exposure to PM10-PM2.5 are most likely to occur, such as dry and windy, rural and agriculturally intensive regions of the Mountain West.

Chapter 5 – Reconsideration of the Secondary Standards for PM

Chapter 5 summarizes key aspects of the welfare effects evidence that are particularly relevant to considering the adequacy of the current secondary PM standards. Chapter 5 also summarizes the quantitative assessment of visibility impairment to inform preliminary conclusions on the secondary PM standards. Chapter 3 presents the preliminary conclusion that the available evidence does not call into question the adequacy of the public welfare protection provided by the current secondary PM standards and that it is appropriate to consider retaining these standards in this reconsideration. Chapter 5 also identifies key areas for additional research and data collection, in order to inform future reviews.

1. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on PM-related visibility effects?

2. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related climate effects?

3. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related materials effects?

4. What are the Panel's views on the interpretation of the evidence for PM-related welfare effects for the purpose of evaluating the adequacy of the current secondary PM standards? Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

5. What are the Panel's views on conclusions regarding support for new or updated quantitative analyses? What are the Panel's views of the technical approach taken to conduct updated analyses to inform our understanding of the relationship between PM in ambient air and visibility impairment?

6. What are the Panel's views on preliminary conclusions regarding adequacy of the current secondary PM standards and on the public welfare policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current secondary PM standards, without revision, in this reconsideration?7. What are the Panel's views on the areas for additional research that are identified in Chapter 5? Are there additional areas that should be highlighted?

No comments on Chapter 5 at this time.

Dr. Michelle Bell

Overall, the Policy Assessment is extremely well-written and thorough. Below are my preliminary comments.

Page 1-2: The definition of "welfare effects" to exclude ecological effects associated with particulate matter, even if used consistently in this document, differs from how this phrase is commonly applied. This is described as a footnote on page 1-1. To make sure readers are aware of this definition of welfare effects, it may be worth moving this footnote to the main text. If possible, it may be useful to have different wording other than "welfare effects" to note that this is a subset of welfare effects, if appropriate alternative phrasing can be developed.

Page 1-4: Section 1.2. Legislative Requirements: The second paragraph in this section notes that the NAAQS must be set "allowing an adequate margin of safety". This has been interpreted to mean an adequate margin of safety for potentially sensitive and vulnerable subpopulations, not an average margin for the average person. This could be clarified here. This important point is current included within footnote 4 but could be highlighted as part of the main text.

Page 1-4: Replace "manmade" with "anthropogenic".

Page 1-7. Minor note: Each row of Table 1-1 replaces the previous row (e.g., the TSP regulation did not remain in effect when the 1987 PM10 regulation was implemented). This might not be clear to all readers and could be clarified in the description of Table 1-1 (page 1-5) and/or a footnote to the Table. I realize this is specified in the subsequent text, but it would be easy to make a note in the table.

Page 1-8: Is there a need to define, even if generally, what is meant by short- and long-term exposure?

Page 2-1: The sentence noting that "distinct health and welfare effects have been linked with exposures to particles of different sizes" is correct, however the scientific literature also clearly shows that factors other than size are relevant, such as chemical composition. This context could be added.

Page 2-1: Ultrafine particles (UFP) are defined here based on a "diameter of less than 0.1 micrometers" whereas this is sometimes $\leq$ 0.1 micrometers. Please check.

Page 2-2: The sentence "Atmospheric distributions of particle size generally exhibit distinct modes that roughly align with the PM size fractions defined above." is misleading. For example, the typical natural break for size distribution is not at 2.5 micrometers.

Page 2-7: The statement that "Major components of PM2.5 include . . ." is correct, but text could be added to note that there are dozens more. Also sulfate is in the form ammonium sulfate, nitrate as ammonium nitrate, etc.

Section 2.1: Missing from this section is clear text that the chemical structure of particulate matter varies dramatically, including by season, region, source, urbanicity, and size. Maps or other figures may be useful in this regard, although text could suffice, too. Aspects of this are mentioned a few times, but all of these aspects should be clearly stated, perhaps towards the beginning of this section. There is a large emphasis on emissions, but not on composition of the resulting PM. This is addressed in Section 2.3, but should be mentioned in relation to size.

Page 2-14: Section 2.2, Ambient PM Monitoring Methods and Networks, needs to note that the existing monitoring network is largely in urban areas and that rural areas are underrepresented.

Page 2-26: For the section on Trends in Monitored Ambient Concentrations, there may be value in noting whether these temporal trends differ by region of the country. This is a paragraph related to this on page 2-30, but a simple figure would be clearer.

Page 2-30: I did not find the Figure 2-17 particularly informative. A Figure like 2-16, but with designation by region, would be easier for readers.

Page 2-36: This section and figure nicely note that the chemical structure of PM2.5 differs by region. It should also note that there are strong patterns by season, urbanicity, etc. The sections that describe comparison of the estimation methods to surface measurements should highlight that such evaluations are limited by the existing air pollution monitoring network, which is skewed towards urban areas, which will have different sources and thus chemical structure, than more rural areas.

Page 2-62: It may be worth noting that there exists no standard definition of "background PM" when the EPA definition is provided.

Page 2-62: Replace "manmade" with "anthropogenic".

Page 3-64: The phrase "such studies evaluate associations between distributions of ambient PM2.5 and health outcomes, and do not identify the specific exposures that can lead to reported effects" is confusing. I disagree that "the use of information from epidemiologic studies to inform conclusions . . . is complicated" when ambient data is used. First, some epidemiologic studies use personal monitoring and other mechanisms beyond ambient data. Second, the links between ambient data and personal exposure are well studied. Third, EPA is regulating at the ambient level, so the link between ambient level and health is in fact particularly relevant.

Page 3-128: The statement that "epidemiological studies do not identify a population-level threshold below which it can be concluded with confidence that PM-related health effects do not occur" would be more informative to note that epidemiological studies provide evidence that such a threshold does not exist, or if it does it is likely at extremely low levels well below that that occur in real-world settings.

Page 3-135: The need to have standards that provide an "adequate margin of safety" includes safety for potentially sensitive subpopulations, not the average person. This concept is missing here.

Page 3-2: The sentence "Epidemiologic studies reported PM2.5 health effect associations with mortality and/or morbidity across multiple U.S. cities and in diverse populations . . ." would be strengthened to note that such associations were observed in many cities around the world, including U.S. cities, rather than referring to U.S. cities only. This would link to the earlier text noting studies in the U.S. as well as Europe and Asia.

Page 3-2: The example of "populations and lifestages that may be at comparatively higher risk of experiencing a PM2.5-related health effect" only lists examples for lifestages: "e.g., older adults, children". Other vulnerable subpopulations should be mentioned, such as racial/ethnic minority populations and persons with low socio-economic position.

Page 3-162: In reference to the text "Time-series control for potential confounders that vary of short time intervals . . . while cohort studies control for community and/or individual-level confounders that vary spatially . . ." is a bit misleading. For example, time-series studies can control for individual-level variables and in some study designs can control for community-level values as well (e.g., Bayesian pooling of city-specific results from time-series models with a community-level variable included).

Page 3-162: The text that "Sensitivity analyses indicate that adding covariates to control for potential confounders can either increase or decrease the magnitude of PM2.5 effect estimates" is potentially misleading. The key question is whether the magnitude changes in a meaningful way.

Page 3-162: In reference to "none of the covariates examined can fully explain the association with mortality", this text seems a bit odd as the purpose of epidemiological studies is not to predict mortality and fully explain associations but to identify the association between a given exposure (or condition, etc.) and health outcome, in this case mortality." More generally, the last two sentences of this paragraph (see comment above) may give the impression that the scientific literature is not as strong as it actually is.

Page 3-173: The statement "The risk assessment estimates that the current primary PM2.5 standards could allow a substantial number of PM2.5-associated deaths in the U.S." would be more accurately worded as "would allow".

Page 3-173 on: In addition to noting that a substantial number of deaths would occur under the current PM2.5 standards, other severe health outcomes would also occur. These could be listed, perhaps with a few as examples.

Page 3-176: Is there value in noting numerical estimates of the number of deaths that are estimated to occur under the current standard?

Page 3-189: The statement "Since the 1997 review, studies that evaluate fine particle-related health effects continue to provide strong support for such effects using PM2.5 mass as the metric for fine particle exposures" is a bit overstated. The studies indicate that PM2.5 is clearly tied to human health, but not that it uniformly represents particles. The question is not so much whether PM2.5 is the best indicator, which this sentence suggests, but whether it is the best available.

Page 3-189 on: The text noting that the scientific literature does not identify any single component or source as the main driver of health effects, could be worded more broadly to note any component, source, or particle characteristic.

Page 3-188: For the second key bullet point on this page, this could be "support for" rather than "limited support for" in relation to health effects at low levels.

Page D-18: In the Table D-8 footnote C, replace "manmade" with "anthropogenic".

General comment: The attention paid to potentially vulnerable populations is insufficient. Issues of environmental justice are mentioned in a few places (e.g., noting that a study examined race), but studies provide evidence, in some cases strong evidence, for higher health burden by some subpopulations including racial/ethnic minorities, individuals and communities with lower socio-economic position, etc.

Overall: The scientific evidence warrants consideration of a lower 24-hour standard. This is based on the epidemiological evidence that indicates adverse health outcomes at levels below the current standard.

Dr. James Boylan

Chapter 1 – Introduction

Chapter 1 provides introductory information including a summary of the legislative requirements for the NAAQS, an overview of the history of the PM NAAQS and the decisions made in prior reviews, and a summary of the scope and approach for the reconsideration of the 2020 final decision.

1. To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for this reconsideration?

The information in Chapter 1 is very clearly presented. The level of detail is appropriate to provide useful context for this reconsideration. The CASAC advice on the PM review completed in 2020 was adequately described "With regard to the primary standards, the CASAC recommended retaining the current 24-hour $PM_{2.5}$ and PM_{10} standards but did not reach consensus on the adequacy of the current annual $PM_{2.5}$ standard. With regard to the secondary standards, the CASAC recommended retaining the current standards."

The last sentence on page 1-18 is confusing "…the EPA filed a motion with the Court to hold the consolidated cases in abeyance until March 1, 2023. The court has not yet acted on the EPA's motion, which the court granted on October 1, 2021." Please clarify if EPA's motion has been granted or not.

Chapter 2 – Air Quality

Chapter 2 describes the major PM emissions sources; the atmospheric chemistry related to PM in ambient air; the PM monitoring network; PM ambient air quality trends and relationships; an overview of hybrid modeling methods used to estimate PM2.5 concentrations; analyses to inform our understanding of mean PM2.5 concentrations from monitors and hybrid models and their relationships with design values; and background PM.

1. What are the Panel's views on the technical approach taken and analyses completed to inform our understanding of how PM2.5 concentrations calculated using composite monitors and area averages from hybrid modeling approaches compare to area design values?

The document provides a good overview of four hybrid modeling methods used to estimate $PM_{2.5}$ concentrations. The comparison of $PM_{2.5}$ concentration surfaces computed using DI2019 and HA2020 to regulatory design values (Table 2-6) was very useful for understanding the relationship between area averages and design values. However, I am unable to replicate the values listed in Table 2-6 in the column labeled "Ratio of Average Maximum Annual DVs to Average Annual $PM_{2.5}$ Concentrations". My calculations are in **red bold**.

Years of Monitoring Data	No. of CBSAs [a]	Average Annual $PM_{2.5}$ Concentration ($\mu g/m^3$) [b]	Population Weighted Average Annual $PM_{2.5}$ Concentration ($\mu g/m^3$) [b]	Average Maximum Annual DVs ($\mu g/m^3$) [b]	Ratio of Average Maximum Annual DVs to Average Annual $PM_{2.5}$ Concentrations	
DI2019 Surface from Di et al. (2019)						
2008-2010	67	8.61	10.17	11.67	1.48	**11.67/8.61=1.36** (not 1.48)
2011-2013	64	8.10	9.37	10.91	1.47	**10.91/8.10=1.34** (not 1.47)
2014-2016	61	7.22	8.26	9.57	1.41	**9.57/7.22=1.33** (not 1.41)
HA2020 Surface from Hammer et al. (2020) and van Donkelaar et al. (2019)						
2008-2010	67	8.25	9.93	11.67	1.50	**11.67/8.25=1.41** (not 1.50)
2011-2013	64	7.92	9.34	10.91	1.43	**10.91/7.92=1.38** (not 1.43)
2014-2016	61	6.98	8.19	9.57	1.43	**9.57/6.98=1.37** (not 1.43)

[a] The number of CBSAs with 3 or more valid design values for the 3-year period
[b] Averaged across CBSAs

If my calculation above are correct, then the sentence on page 2-61 (lines 4-7) should be changed from "As shown in Table 2-6, these analyses show that the results are similar for both the DI2019 and HA2020 surfaces and the maximum annual $PM_{2.5}$ design values are often **40% to 50%** higher than average annual $PM_{2.5}$ concentrations when population weighting is not applied" to "As shown in Table 2-6, these analyses show that the results are similar for both the DI2019 and HA2020 surfaces and the maximum annual $PM_{2.5}$ design values are often **33% to 41%** higher than average annual $PM_{2.5}$ concentrations when population weighting is not applied". Also, the sentence on page 2-62 (lines 4-8) should be changed from "Additionally, when average annual $PM_{2.5}$ concentrations from the hybrid modeled surfaces are compared to the average maximum annual design value measured at ground-based monitors in a subset of CBSAs, the average of the maximum annual design values tends to be a **40-50%** higher than the average annual $PM_{2.5}$ concentration estimated from the hybrid modeling surfaces" to "Additionally, when average annual $PM_{2.5}$ concentrations from the hybrid modeled surfaces are compared to the average maximum annual design value measured at ground-based monitors in a subset of CBSAs, the average of the maximum annual design values tends to be a **33-41%** higher than the average annual $PM_{2.5}$ concentration estimated from the hybrid modeling surfaces".

2. To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for this reconsideration?

In general, the information in Chapter 2 is clearly presented. However, there are some areas that need additional discussion.

The emission density maps and emission pie charts were very informative. Page 2-6 states "Although the NEI does not estimate emissions of $PM_{10-2.5}$ (coarse PM) specifically, estimates of PM_{10} emissions can provide insight into sources of coarse particles". While this approach is ok, it would be easy to calculate the emissions of $PM_{10-2.5}$ (coarse PM) by simply subtracting the $PM_{2.5}$ emissions from the PM_{10} emissions to create a $PM_{10-2.5}$ (coarse PM) county-level emission density plot and $PM_{10-2.5}$ (coarse PM) pie chart. This would allow the reader to better understand the sources of $PM_{10-2.5}$ (coarse PM) emissions.

In some parts of this chapter (page 2-7, 2-8, 2-10), the document fails to mention ammonium (NH_4^+) as a major component of $PM_{2.5}$ mass and ammonia (NH_3) as an important gaseous precursor. They are mentioned later in the chapter, but should be included throughout the chapter anytime major component of $PM_{2.5}$ mass and important gaseous precursors are mentioned. On page 2-10 (lines 14-17), "sulfate" needs to be added to the sentence "Anthropogenic SO_2 and NO_X are the predominant precursor gases in the formation of secondary $PM_{2.5}$, and ammonia also plays an important role in the formation of sulfate and nitrate PM by neutralizing sulfuric acid and nitric acid." On page 2-11 (lines 13-14), the author states "In addition, biogenic sources (not shown in Figure 2-8) are significant contributors to both VOC and NOx emissions." However, it is unclear what is meant by "significant". The author should include a comparison of biogenic VOC and NOx emission to anthropogenic VOC and NOx emission. Figure 2-9 (A) shows that 8% of the SO_2 emissions are from "Dust". It appears that this is a mistake and the author likely meant to label this "Fires".

Section 2.2.3.1 discusses "Federal Reference Method and Continuous Monitors". In this section it states that in 2020 there were 527 FRM filter-based samplers and 660 continuous FEMs used for comparison with the PM NAAQS. Table 1 contains a summary of the current national count of $PM_{2.5}$ measurement methods used for AQI and compliance (https://www.epa.gov/outdoor-air-quality-data). Previously, the PM monitoring network was dominated by FRM samplers (1,150 in 2001) since the emergence of FEMs is relatively recent. In 2016, Georgia EPD ran 24 FRM and 2 FEMs. Currently (2021), Georgia EPD is running 15 FRMs and 14 FEMs (Teledyne T640) and has plans to aggressively replace FRMs with FEMs (as does many other states). In fact, EPA is using millions of dollars of American Rescue Plan funds to provide grant money to states to help with the transition from FRMs to FEMs. Page 2-19 states "Continuous FEMs compared to collocated monitoring agency FRMs were biased high by 11.5% bias with a large sample size of 85,539 collocated pairs for 2018-2020 (all cases where both the FRM and continuous FEM are at or above 3.0 $\mu g/m^3$)." This is higher than EPA's goal of ±10 percent for total bias. Since this high bias is based on averages across many different locations, this implies that some FRM/FEM pairs may have biases much higher than 11.5% while others may be lower.

Table 1. Current National Count of $PM_{2.5}$ Measurement Methods (AQI and Compliance).

$PM_{2.5}$ Measurement Method	**Count**
Reference Methods-Gravimetric	562
EQ-Method Beta Attenuation	397
EQ-Broadband spectroscopy (T640 and T640X)	285
EQ-FDMS Gravimetric	26
EQ-Laser Light Scattering	8
Total	**1,278**

Georgia EPD has a number of co-located FRM/FEM pairs. Table 1 contains a comparison of the average FRM and FEM values and the maximum 24-hour differences in Georgia. As shown in Table 1, the difference between FEM and FRM long-term averages (similar to annual average) range from approximately 0.9 mg/m^3 (12.4%) to 2.5 mg/m^3 (36.7%). If the annual standard is lowered, these significant differences can result in an area violating the annual $PM_{2.5}$ NAAQS with an FEM while being well below the NAAQS with an FRM. Also, the maximum difference between FEM and FRM short-term averages (24-hour averages) range from approximately 3.4 mg/m^3 to 15.6 mg/m^3. Most of the high FEM readings are related to smoke from wildland fires. If the 24-hour standard is lowered, these significant differences can result in an area violating the 24-hour $PM_{2.5}$ NAAQS with an FEM while being well below the NAAQS with an FRM. The range of differences in the long-term and short-term averages are similar to the range of alternative standards being considered in this reconsideration. It should be noted that most historical health studies are based on FRM measurements since FEMs are relatively new. However, newer studies are using both FRM and FEM data which can result in significantly different results.

Table 1. Georgia EPD comparison of FRM and FEM values (green is <1 mg/m^3 and <15%, yellow is 1-2 mg/m^3 and 15-25%, and red is >2 mg/m^3 and >25%.

	24-Hour FRM COUNT	Average FRM (mg/m^3)	Average FEM (mg/m^3)	Avg. FEM - Avg. FRM (mg/m^3)	Average Percent Difference	Max. 24-Hour FEM - FRM (mg/m^3)
Athens	116	6.68	9.13	2.45	36.7%	7.31
Augusta - Bungalow	125	8.14	9.92	1.79	22.0%	9.42
Macon - Forestry	320	7.05	8.15	1.10	15.6%	15.61
Rossville	341	7.94	9.13	1.19	15.0%	7.28
Albany	557	8.91	10.83	1.92	21.6%	12.29
Gainesville	113	7.14	8.02	0.89	12.4%	3.43
Gwinnett Tech	112	8.22	10.28	2.06	25.1%	7.08
Savannah - Mercer	485	7.36	8.85	1.49	20.2%	8.34
Warner Robins	378	7.58	9.83	2.25	29.6%	11.78
S. Dekalb	977	7.95	9.14	1.19	15.0%	8.25

This phenomenon is not isolated to the state of Georgia as multiple other states in the Southeast, Midwest, Northeast, and California have all documented similar bias issues with the Teledyne T640s. The FEM high bias needs to be addressed to make the FRMs and FEMs more comparable. One option would be to allow states to develop correction factors for co-located FRMs and FEMs. These correction factors could be used to adjust FEM concentrations downward to be comparable to FRMs. Another option would be for EPA to revise the "equivalency box" (EB) criteria used to judge whether the bias of a new continuous $PM_{2.5}$ monitor relative to an FRM is acceptable during field testing. If the candidate $PM_{2.5}$ continuous monitor passes the equivalency test, it becomes an FEM. Ideally, as the annual NAAQS is lowered, the equivalency criteria should become more stringent to make it less likely that inter-method differences between FEMs and the FRM will result in erroneous attainment designations. However, when the annual NAAQS was reduced from 15 µg/m^3 to 12 µg/m^3 in 2012, no modifications were made to the EB. If the annual NAAQS is lowered again, the EB criteria should be revised to be commensurate with the new level of the annual NAAQS.

Page 2-25 states "Declining SO_2 emissions during this time period are primarily a result of reductions at stationary sources such as EGUs, with substantial reductions also from mobile sources". This does not seem to be a true statement since Figure 2-8 (A) shows that mobile sources account for 1% of the SO_2 and Table 2-1 does not list "mobile sources" in the "Major Sources that contribute to changes over time" column for SO_2. There are fewer monitoring stations included in Figure 2-24 (e.g., 3 Georgia sites) compared to Figure 2-23 (no Georgia sites). EPA should provide a reason for the differences in the number of monitors.

The values in the last column in Table 2-2 "Ratio of Maximum 24-hour DV to CBSA Average" do not seem reasonable. I assume this column is associated with Figure 2-29 which compares CBSA Maximum 2017-2019 Daily Design Values to CBSA Average 2017-2018 Annual Design Values. Based on Figure 2-29, the "Ratio of Maximum 24-hour DV to CBSA Average" should range from approximately 2-6 (not 1.22-1.26). EPA should update the values in the Table 2-2 or clarify the actual meaning of "Ratio of Maximum 24-hour DV to CBSA Average" if it has a different meaning.

Page 2-68 (lines 29-31) states "The highest organic matter contribution for any of the sites shown in Figure 2-40, including the three Southeast monitors, is approximately 2 $\mu g/m^3$". This is not correct. According to Figure 2-40, GLAC1, OKEF1, and SIPS1 had 4 $\mu g/m^3$ in 2004 and OKEF1 and SIPS1 had 3 $\mu g/m^3$ in 2016.

Page 2-68 (lines 31-33) states "While contributions from ammonium sulfate have decreased substantially at some of the monitors, particularly the eastern sites, contributions from organic aerosol are roughly consistent between 2004 and 2016…" This is not correct. According to Figure 2-40, it appears that there were only 2 sites where to OM was not reduced between 2004 and 2016 (BRID1 and SHRO1) while the other 10 sites had significant reductions in OM ranging from 20% to 50%.

Chapter 3 – Reconsideration of the Primary Standards for $PM_{2.5}$

Chapter 3 summarizes key aspects of the health effects evidence and evaluates mean PM2.5 concentrations reported in key epidemiologic studies that are particularly relevant to considering the adequacy of the current primary PM2.5 standards. Chapter 3 also summarizes the risk assessment and at-risk analyses to inform preliminary conclusions on the primary PM2.5 standards. Finally, Chapter 3 presents the preliminary conclusion that, collectively, the scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as supporting retention of the 24-hour PM2.5 standard, while calling into question the adequacy of the public health protection afforded by the current primary annual PM2.5 standard, and presents alternative annual PM2.5 standards that could be supported by the available scientific and technical information. Chapter 3 also identifies key areas for additional research and data collection, in order to inform future reviews.

4. What are the Panel's views on the technical approach taken to update the risk assessment, including the approach to evaluating impacts in at-risk populations? To what extent does the draft PA accurately and clearly communicate the results of these analyses? What are the Panel's views on staff's interpretation of these results for the purpose of evaluating the adequacy of the current primary PM2.5 standards?

Page 3-130 states "Consistent with the overall approach for this reconsideration, this risk assessment has a targeted scope that focuses on all-cause or nonaccidental mortality associated with long-term and short-term $PM_{2.5}$ exposures." However, the overall approach in the draft ISA Supplement and draft PA is targeted on short- and long-term $PM_{2.5}$ exposure and mortality and cardiovascular effects, not just mortality. Therefore, the risk assessment should also include an evaluation of cardiovascular mortality and cardiovascular morbidity. Including these two additional endpoints would provide useful information to help inform the decision on the level of the $PM_{2.5}$ NAAQS.

EPA's approach to estimate risk involves four main steps: (1) primary data, (2) data fusion, (3) projecting $PM_{2.5}$ to target standards, and (4) risk assessment. In Step 1, the use of AQS measured total and speciated $PM_{2.5}$ and CMAQ photochemical modeling to simulate $PM_{2.5}$ for baseline and emission sensitivity cases is appropriate. The CMAQ model configuration and input files used in the air quality modeling appear to be appropriate for this application. In Step 2, the use of downscaler to grid $PM_{2.5}$ spatial fields based on CMAQ and AQS data is appropriate. The use of SMAT-CE to model relative response factors (RRFs) and speciated $PM_{2.5}$ at monitors and grid cells is appropriate. In Step 3, projecting monitors to just meet target NAAQS and the corresponding spatial fields is appropriate (see comments in next paragraph). In Step 4, the use of BenMAP-CE to generate risk metrics is appropriate.

In Chapter 3, the main question I would like answered is "How many premature deaths will be prevented if the annual standard is lowered from 12.0 mg/m^3 to a lower level?" The risk assessment is the best way to estimate $PM_{2.5}$-accociated health risks for various alternative standards. EPA's approach evaluates the change in risk associated with moving from $PM_{2.5}$ air quality "just meeting" the current standards (12/35) to "just meeting" alternative annual and/or 24-hour standards (10/30). While this approach is appropriate for CBSAs that are currently above the current standards, this approach is not appropriate for CBSAs that are currently below the current standards and results in estimated reductions in $PM_{2.5}$-accociated mortality that are significantly overestimated compared to the actual number of prevented deaths. For example, the 2014-2016 annual maximum $PM_{2.5}$ design values (Table C-3) for the Atlanta CBSA and New York CBSA were 10.38 mg/m^3 and 10.20 mg/m^3, respectively. The EPA approach increases these design values to 12.0, then reduces them to 11, 10, 9, and 8 to calculate the reductions in $PM_{2.5}$-accociated mortality at each alternative standard. In these two cities alone, the EPA approach calculates thousands of deaths prevented as you go from 12 to 11, 11 to 10, 10 to 9, and 9 to 8. However, the 2018-2020 $PM_{2.5}$ design values for the Atlanta CBSA and New York CBSA are 9.5 mg/m^3 and 8.7 mg/m^3, respectively. This means that a new standard of 11 mg/m^3 or 10 mg/m^3 would result in no actual deaths being prevented in those CBSAs. This example was given for Atlanta and New York (which accounts for 25% of the total study area population) but is applicable to many of the other CBSAs in the study area that currently have 2018-2020 annual design values that are below 10 mg/m^3 or 9 mg/m^3. As a result, the number of deaths that would be prevented at lower standards could be overestimated by a factor of two, or more. **In order to accurately estimate the number of actual deaths that will be prevented if the standard was lowered, the starting point for the risk analysis**

for each CBSA that is already below the current $PM_{2.5}$ NAAQS needs to be the 2018-2020 $PM_{2.5}$ design values, not the current NAAQS.

Tables 3-14, 3-15, 3-16, and 3-17 contain total $PM_{2.5}$-associated mortality across the entire study area. A breakdown of $PM_{2.5}$-associated mortality and risk change by individual CBSA for each study and simulation method should be added to Appendix C. This would allow for a much better understanding of spatial distribution of risk and how individual CBSAs are impacted by alternative standards.

Tables 3-15 and 3-17 present risk change and % risk reduction when moving from the current to an alternative standard. The % risk reduction is presented as a percent of the total $PM_{2.5}$-associated mortality under the various standards. However, it would be useful to see the % risk reduction presented as a percent of the total all-cause mortality under the various standards. For example, Turner (30-99) Pri PM risk change (6,120) as a percent of the total $PM_{2.5}$-associated mortality under the current standard (44,400) is 6,120/44,400 = **13.8%** change, while the Turner (30-99) Pri PM risk change (6,120) as a percent of the total all-cause mortality under the current standard (44,400/.061=727,869) is 6,120/727,869 = **0.84%** change.

Appendix C (Section C.5) provides a quantitative assessment of uncertainty (3 components) and a qualitative assessment of uncertainty (11 sources). It is difficult to determine the actual magnitude of the overall uncertainty associated with the estimated $PM_{2.5}$-associated mortality and risk changes presented in the risk assessment; however, it does appear that the overall uncertainty is significantly larger when accounting for all the possible sources.

Without the additional information and analyses requested above, less weight should be placed on the absolute changes in estimated $PM_{2.5}$-associated mortality presented in the risk assessment since they are overly conservative (overestimated) and highly uncertain.

5. What are the Panel's views on preliminary conclusions regarding adequacy of the current primary $PM_{2.5}$ standards and on the public health policy judgments that support those preliminary conclusions?
a. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary 24-hour $PM_{2.5}$ standard, without revision, in this reconsideration?

Yes, EPA provides sufficient rationale to retain the current primary 24-hour $PM_{2.5}$ standard, without revision. The risk assessment not only accounts for the level of the standard, but also accounts for the form of the standard and the way attainment with the standard is determined (i.e., highest design value in the CBSA). The risk assessment indicates that the annual standard is the controlling standard across most of the urban study areas evaluated and revising the level of the 24-hour standard is estimated to have minimal impact on the $PM_{2.5}$-associated risks. Therefore, the annual standard can be used to limit both long- and short-term $PM_{2.5}$ concentrations.

Epidemiologic studies provide the strongest support for reported health effect associations for the overall mean concentrations rather than near the upper end of the concentration distribution; therefore, there is limited epidemiologic evidence to determine the adequacy of the level of the 24-hour standard. The epidemiologic studies included in this document do not indicate that the reported health effect associations are strongly influenced by exposures to the peak concentrations in the air quality distribution.

Finally, the $PM_{2.5}$ concentrations used in human clinical studies to show short-term exposure effects are well above those typically measured in areas meeting the current standards, suggesting that the current standards are providing adequate protection against these exposures.

b. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider revising the current primary annual $PM_{2.5}$ standard in this reconsideration?

Yes, EPA provides sufficient rationale to revise the current primary annual $PM_{2.5}$ standard to a level in the range of 10.0 to 11.0 mg/m^3. To simply set the standard at the same level as the mean $PM_{2.5}$ concentration used in epidemiological studies that indicate significant health effect associations would be overly conservative because it does not account for the full distribution of $PM_{2.5}$ concentrations across the CBSA. Rather, the form of the standard and the way attainment with the standard is determined (i.e., highest design value in the CBSA) must be considered when determining the appropriate level for the standard.

Most key U.S. epidemiologic studies indicate consistently positive and statistically significant health effect associations based on air quality distributions with overall mean $PM_{2.5}$ concentrations at or above 9.9 µg/m^3 (monitor-based studies), 9.3 µg/m^3 (hybrid modeling with population-weighting), and 8.1 µg/m^3 (hybrid modeling without population-weighting). According to the PA, the area annual design values are generally higher than the study means by 10-20% for monitor-based studies, 14-18% for hybrid modeling with population-weighting studies, and 40-50% for hybrid modeling without population-weighting studies. Therefore, the range of design values associated with 9.9 µg/m^3 (monitor-based studies) would be 10.9-11.9 µg/m^3; 9.3 µg/m^3 (hybrid modeling with population-weighting) would be 10.6-11.0 µg/m^3; and 8.1 µg/m^3 (hybrid modeling without population-weighting) would be 11.3-12.2 µg/m^3. Based on this information, an annual standard in the range of 10.6-12.2 µg/m^3 is appropriate. In order to protect public health with an adequate margin of safety, an annual standard in the range of 10.0-11.0 µg/m^3 is recommended. In addition, many accountability studies that report public health improvements have starting concentrations within that range. An annual standard of 10.0 µg/m^3 would result in long-term mean $PM_{2.5}$ concentrations in the range of 8.3 to 9.1 µg/m^3 (well below 9.9 µg/m^3), while an annual standard of 11.0 µg/m^3 would result in long-term mean $PM_{2.5}$ concentrations in the range of 9.2 to 10.0 µg/m^3 (mostly below 9.9 µg/m^3).

EPA's risk assessment estimates reductions in $PM_{2.5}$-accociated mortality; however, there are many significant issues with their approach and large uncertainties in the risk results. The risk assessment approach is appropriate for CBSAs that are currently above the current standards. However, this approach is not appropriate for CBSAs that are currently below the current standards and results in estimated reductions in $PM_{2.5}$-accociated mortality that are significantly overestimated compared to the actual number of prevented deaths. In addition, there are a number of uncertainties associated with the risk assessment presented in this document. They include:

- Shape and corresponding statistical uncertainty around the C-R function for long-term and short-term exposure-related mortality (especially at lower ambient PM levels)
- Representing population-level exposure with 12-km grid cells in the model
- Bias in the model predictions used for simulating just meeting current and alternative standards (Downscaler methods and linear extrapolation/interpolation)
- Potential confounding of the $PM_{2.5}$-mortalty effect
- Lag structure in short-term exposure-related mortality epidemiology studies
- Compositional and source differences in PM
- Temporal mismatch between ambient air quality data characterizing exposure and mortality in long-term exposure-related epidemiology studies
- Exposure measurement error in epidemiologic studies assessing the relationship between mortality and exposure to ambient $PM_{2.5}$
- Use of associations reported in epidemiologic studies to estimate how mortality incidence may change with changing $PM_{2.5}$ air quality.

It is difficult to determine the actual magnitude of the overall uncertainty associated with the estimated $PM_{2.5}$-associated mortality and risk changes presented in the risk assessment; however, it does appear that the overall uncertainty is significantly larger when accounting for all the possible sources.

Finally, publication bias (statistically significant results are more likely to be published than studies that report a nonsignificant conclusion) impacts the studies published in peer-reviewed journals. Since the PM ISA and PA only use peer-reviewed publications, the scientific evidence used for this PM review is also biased towards statistically significant results.

7. What are the Panel's views on the areas for additional research that are identified in Chapter 3? Are there additional areas that should be highlighted?

EPA should evaluate alternative forms of the 24-hour $PM_{2.5}$ standard. The current form of the standard is the 98^{th} percentile of 24-hour daily averages (midnight-to-midnight averages), averaged over three years. I support the midnight-to-midnight daily averaging period since many high $PM_{2.5}$ events occur between those times (e.g., prescribed fires in the Southeastern U.S.) and do not support alternative daily averaging periods (noon-to-noon averages or rolling 24-hour averages). Currently, rolling 24-hour averages are not possible with filter based FRM monitors.

Conceptually, an "integrated" form of the standard should provide a better representation of the continuum of health effects associated with the upper end of the $PM_{2.5}$ concentration distribution. Typically, the higher end of the daily 24-hour average concentration distribution drives short-term health effects. The current form of the standard for a $PM_{2.5}$ monitor measuring 365 samples/year, throws away the seven highest 24-hour $PM_{2.5}$ concentrations, uses the 8^{th} highest value (98^{th} percentile), and ignores other potentially high concentrations beyond the 8^{th} highest 24-hour average $PM_{2.5}$ concentration. This means that the entire year is characterized by a single 24-hour average $PM_{2.5}$ measurement. As a result, a monitor that measures seven high $PM_{2.5}$ values (e.g., 120, 115, 107, 101, 98, 62, 45 mg/m^3) and the 8^{th}-high value is 35 mg/m^3, would have the same 98^{th} percentile value as another monitor which measures 35 mg/m^3 for each of its eight highest concentrations. In addition, the remainder of the higher end of the 24-hour average daily concentration distribution is ignored. An integrated form of the standard (e.g., 8-day average, 12-day average, 20-day average) compared to the 98^{th} percentile value would be able to better account for these higher concentrations as part of a multi-day average of 24-hour average $PM_{2.5}$ concentrations. In addition, an integrated form of the standard would provide greater stability than the current form of the standard with regard to implementation of the standard.

EPA should compare the current form of the standard against various integrated forms of the standard to determine if the relationship is linear (r^2 near 1.00) and if the current form of the standard is appropriate for representing the continuum of health effects associated with the upper end of the $PM_{2.5}$ concentration distribution. If the form of the standard is changed (e.g., 8-day average, 12-day average, 20-day average), then an appropriate level of the standard would need to be re-evaluated. If 8 days or fewer are averaged, then the level of the standard would likely need to be increased since this would be a much more restrictive standard if the level was left unchanged.

Chapter 5 – Reconsideration of the Secondary Standards for PM

Chapter 5 summarizes key aspects of the welfare effects evidence that are particularly relevant to considering the adequacy of the current secondary PM standards. Chapter 5 also summarizes the quantitative assessment of visibility impairment to inform preliminary conclusions on the secondary PM standards. Chapter 3 presents the preliminary conclusion that the available evidence does not call into question the adequacy of the public welfare protection provided by the current secondary PM standards and that it is appropriate to consider retaining these standards in this reconsideration. Chapter 5 also identifies key areas for additional research and data collection, in order to inform future reviews.

1. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on PM-related visibility effects?

Chapter 5 does an adequate job of describing the key aspects of PM-related visibility effects.

2. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related climate effects?

Chapter 5 does an adequate job of describing the key aspects of PM-related climate effects.

3. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related materials effects?

Chapter 5 does an adequate job of describing the key aspects of PM-related materials effects.

4. What are the Panel's views on the interpretation of the evidence for PM-related welfare effects for the purpose of evaluating the adequacy of the current secondary PM standards? Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

The entire visibility analysis is based on the assumption that 30 dv is an appropriate target level of protection based on the 3-year average of the 90th percentile of daily light extinction. However, the only justification that is given for this in a footnote on page 5-28 "For comparison purposes in these air quality analyses, we use a 3-year visibility metric with a level of 30 dv, which is the highest level of visibility impairment judged to be acceptable by at least 50 percent of the participants in the preference studies that were available at the time of the 2012 review (78 FR 3191, January 15, 2013)." It is not clear why the "highest" level is picked rather than the lowest level or the average level. By using 30 dv, Figure 5-2 indicates that the percent participants rating "Acceptable" for Washington DC is ~43%, Phoenix is ~8%, British Columbia is ~7%, and Denver is ~3%. Overall, this is far less than 50% acceptance. It appears that a value of 25 dv might have an overall average "Acceptable" level of ~50% across all four study areas.

Table D-8 of the PA provides a summary of visibility preference studies. Table 2 contains the location and mean dv found "acceptable" extracted from Table D-8. Based on this table, it appears that an appropriate target level of visibility protection should be in the range of 20-25 dv. If EPA sticks with a value of 30 dv as the appropriate target level of visibility protection, additional justification needs to be added to the document.

Table 2. Location and mean dv found "acceptable" extracted from Table D-8.

Location	Mean dv found "acceptable"
Denver, CO (1991)	20.3
Phoenix, AZ (2003)	23-25
Vancouver, British Columbia (1996)	Chilliwack: ~23 Abbotsford: ~19
Washington, DC (2001)	~20 (range 20-25)
Washington, DC (2009)	~30

According to the ISA Supplement, the use of contrast rather than total light extinction appears to make the level of acceptable visual air quality across different locations more consistent. However, the PA does not use contrast to evaluate an appropriate target level of visibility protection. The final PM PA should use an "acceptable" contrast value to help develop the secondary PM standards.

5. What are the Panel's views on conclusions regarding support for new or updated quantitative analyses? What are the Panel's views of the technical approach taken to conduct updated analyses to inform our understanding of the relationship between PM in ambient air and visibility impairment?

The use of the original IMPROVE equation, revised IMPROVE equation, and the Lowenthal and Kumar IMPROVE equation is appropriate. However, only figures for the original IMPROVE equation (Figure 5-3) and the Lowenthal and Kumar IMPROVE equation (Figure 5-4) are included in Chapter 5 while the figure for the revised IMPROVE equation was placed in Appendix D (Figure D-2). I would recommend presentation of all three figures in Chapter 5.

6. What are the Panel's views on preliminary conclusions regarding adequacy of the current secondary PM standards and on the public welfare policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current secondary PM standards, without revision, in this reconsideration?

This depends on the EPA's response to my comment in Question 4. If the assumption that 30 dv is an appropriate target level of visibility protection based on the 3-year average of the 90th percentile of daily light extinction, then the current secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ is appropriate. However, if a value of 25 dv (or lower) is deemed an appropriate visibility target level of protection, then the current secondary 24-hour $PM_{2.5}$ standard of 35 $\mu g/m^3$ may not be appropriate.

Also, no evidence has been presented to support the need for keeping the secondary annual $PM_{2.5}$ standard of 15.0 mg/m^3 since the entire visibility analysis was based on the upper end of the visibility distribution (3-year average of the 90th percentile of daily light extinction). If the secondary annual $PM_{2.5}$ standard is not needed to meet the target level of visibility protection, it should be removed.

7. What are the Panel's views on the areas for additional research that are identified in Chapter 5? Are there additional areas that should be highlighted?

There is a need for additional visibility impairment preference studies to help reduce uncertainties.

Dr. Judith C. Chow

Chapter 1: Introduction

Chapter 1 provides introductory information including a summary of the legislative requirements for the NAAQS, an overview of the history of the PM NAAQS and the decisions made in prior reviews, and a summary of the scope and approach for the reconsideration of the 2020 final decision.

1. To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for this reconsideration?

Chapter 1 is well written and documents a history of PM NAAQS reviews completed in 1971, 1987, 1997, 2006, 2012, and 2020. Attention is given to the causality relationships between PM2.5 and adverse health effects, with limited information given on the 24-hour PM10 standard of 150 µg/m3, which follows the same level and form in the 1987 NAAQS. Although a new reference method for PM10-2.5 was specified in 2006, little effort has been made to provide a basis for using the data from these measurements to support future PM NAAQS reviews.

The PM10-2.5 indicator for thoracic coarse particles intends to characterize suspended dust from traffic, construction, and industrial sources, but the 2006 proposal excludes ambient mix that was dominated by rural windblown dust and soils and by PM generated from agriculture and mining sources, thereby created lots of controversy. Some historical aspects of the process to establish PM10-2.5 indicator should be discussed to demonstrate efforts being made in preparation for future PM10-2.5 review. Although it is a challenge to determine emission rates and source contributions from a mixture of fugitive dust sources, analysis of spatial and temporal distributions of PM10-2.5 would be helpful to address the 2020 PM NAAQS evaluation. It should also be recognized that the PM10-2.5 fraction includes carbonaceous aerosols, particularly bioaerosols (Hyde and Mahalov, 2020) and potentially microplastics (Revell et al., 2021).

The 2019 PM ISA includes a "causal relationship" for each of the evaluated welfare effect categories (i.e., visibility, climate effects, and material effects), but the PM ISA Supplement only considers one public preference study for visibility impairment (Malm et al., 2019) without indicating that several evaluations were made of more recent work on climate and material damage effects between June 2018 and March 2021.

<u>References</u>

Hyde, P., Mahalov, A., (2020). Contribution of bioaerosols to airborne particulate matter. Journal of the Air & Waste Management Association, 70, 71-77. 10.1080/10962247.2019.1629360.

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Revell, L.E., Kuma, P., Le Ru, E.C., Somerville, W.R.C., Gaw, S., (2021). Direct radiative effects of airborne microplastics. Nature, 598, 462-467. 10.1038/s41586-021-03864-x.

<u>Chapter 2 – Air Quality</u>

Chapter 2 describes the major PM emissions sources; the atmospheric chemistry related to PM in ambient air; the PM monitoring network; PM ambient air quality trends and relationships; an overview of hybrid modeling methods used to estimate PM2.5 concentrations; analyses to inform our understanding of mean $PM_{2.5}$ concentrations from monitors and hybrid models and their relationships with design values; and background PM.

1. What are the Panel's views on the technical approach taken and analyses completed to inform our understanding of how $PM_{2.5}$ concentrations calculated using composite monitors and area averages from hybrid modeling approaches compare to area design values?

Characterizing Ambient $PM_{2.5}$ Concentrations for Exposure (Section 2.3.3)

The use of hybrid modeling to estimate ambient $PM_{2.5}$ concentrations improves the weight-of-evidence for exposure assessment as a complement to area design value. Evaluation of the performance of hybrid modeling (Section 2.3.3.2.2) based on the R^2 for cross-validation of daily $PM_{2.5}$ prediction in 2015 from three different methods (Bayesian statistical down scales and interpolation-based methods) shows reliable estimates for $PM_{2.5}$ exposure.

However, only a few references used to support the satellite-derived aerosol optical depth (AOD) methodology. The MAIAC (Multi-Angle Implementation of Atmospheric Correction (MAIAC) - LAADS DAAC (nasa.gov)) product may provide more useful results (e.g., Chudnovsky et al., 2013; Emili et al., 2011a; Emili et al., 2011b; Lee et al., 2020; Lyapustin et al., 2011a; Lyapustin et al., 2011b). The upcoming TEMPO (Tropospheric Emissions: Monitoring of Pollution, https://weather.msfc.nasa.gov/tempo/) mission intends to take hourly daytime measurements at higher spatial resolution and may provide new insights on the utilization of satellite measurements in assessing regional air quality and visibility impairment and for epidemiological studies. Integration of satellite observations with high resolution low-cost air quality monitors might also be considered to improve current understanding of temporal and spatial variations of $PM_{2.5}$ mass and chemical composition.

2. To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for this reconsideration?

Chapter 2 adequately documents PM emission sources, monitoring network, as well as ambient and background concentrations. Additional information on emission source of $PM_{10-2.5}$ monitoring and near-road measurements are needed for clarification.

- Sources of PM Emissions (Section 2.1.1)

Figures 2-2 and 2-3 illustrate percent distribution of the major source sectors for $PM_{2.5}$ and PM_{10} national emissions based on 2017 National Emission Inventory (NEI). As $PM_{10-2.5}$ accounts for 11.3 million tons of annual emissions, it will be helpful to present $PM_{10-2.5}$ emissions by national source sectors. Similarly, $PM_{10-2.5}$ emission density map with the same scale (in tons per square mile) as $PM_{2.5}$ will allow cross comparison on the spatial distribution of $PM_{2.5}$ and $PM_{10-2.5}$. Fires (e.g., wildfires, prescribed fires, and agriculture fires) account for 43% of the 5.7 million tons of $PM_{2.5}$ emissions and 63% of the 1.8 million tons of organic carbon (OC) emissions; the frequency and intensity of the fire events over the past decade should be elaborated to illustrate the long term trend in fire acreage and duration and their potential impacts on public health and welfare. As recent wildfire smoke in the west prolonged over a month period of time that pose community health threats (Jaffe et al., 2020; Kleinman et al., 2020), EPA is encouraged to reevaluate the definition of "Exceptional Events" that is not adequate to protect human exposure

- $PM_{10-2.5}$ Monitoring (Section 2.2.4)

As of 2020, there are 287 stations that acquire $PM_{10-2.5}$ measurements with 78 NCore sites dated January 1, 2011, more descriptive data analyses are warranted. Figure 2-22 (page 2-37) shows ~46% reduction in the second highest 24-hour PM_{10} concentrations from 2000-2019, mostly due to the reduction of $PM_{2.5}$ in the eastern U.S. Low $PM_{2.5}/PM_{10}$ ratios for annual average (Figure 2-23) and for the second highest PM_{10} concentrations from 2017-2019 (Figure 2-24) are found mostly in the mountain west states. For annual averages (2017-2019), Section 2.3.2.5 on "National Characterization of $PM_{10-2.5}$ Mass" (page 2-39) acknowledges "… less distinct difference between the eastern and western U.S. than for either $PM_{2.5}$ or PM_{10}" (Lines 4-5, Page 2-39). However, the bottom two panels of Figure 2-5 (page 2-40) show significant increases in both annual average and 98^{th} percentile trend shows significant increases in $PM_{10-2.5}$ in the Eastern Sierra Mountain ranges of California. Sources of coarse particles are intermittent in nature with spatial inhomogeneity. Meteorological data need to be considered to characterize temporal and spatial variations of $PM_{10-2.5}$.

Section 2.2.3.3 on "Recent Changes to $PM_{2.5}$ Monitoring Requirements" (page 2-22) highlights the key changes since 2012 including the establishment of 52 near-road sites (phased in 2015 to 2017, at core-base statistical areas [CBSA] >1 million in population). Many of these sites located ~20-30 meters of target roads to examine potential adverse health effects for those living, working, and attending schools near major roads. However, not much discussion was given on the near-road PM, NO_2, CO, and black carbon measurements. Particle number concentrations from the near-road sites need to be documented in addition to the measurements at the Rochester, NY and Bondville, IL sites.

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Chapter 5 – Reconsideration of the Secondary Standards for PM

Chapter 5 summarizes key aspects of the welfare effects evidence that are particularly relevant to considering the adequacy of the current secondary PM standards. Chapter 5 also summarizes the quantitative assessment of visibility impairment to inform preliminary conclusions on the secondary PM standards. Chapter 3 presents the preliminary conclusion that the available evidence does not call into question the adequacy of the public welfare protection provided by the current secondary PM standards and that it is appropriate to consider retaining these standards in this reconsideration. Chapter 5 also identifies key areas for additional research and data collection, in order to inform future reviews.

1. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on PM related visibility effects?

Section 5.3.1 on "Visibility Effects" states that "… this reconsideration focuses on calculated light extinction when quantifying visibility impairment resulting from recent concentrations of PM in ambient air" (Lines 13-15, page 5-19). The analyses are based on outdated data (i.e., 2005-2008 and 2011-2014) used in the 2019 ISA (U.S.EPA, 2019) with the citation of Hand et al. (2020) who reviewed long term (1990-2018) IMPROVE network measurements with respect to impacts on haze in remote regions.

Large changes in aerosol composition and light extinction (b_{ext}) were found for the period of 2014-2018 with significant extinction reductions in the eastern U.S. (attributed to sulfate reduction), and higher light extinctions in the central U.S., in an area with agricultural activity and elevated ammonium and nitrate concentrations. Light extinction from combined ammonium sulfate and ammonium nitrate decreased from 40% to 31% and contributions from organic mass and elemental carbon increased from 39% to 45% for the period of 2000-2004 and 2016-2018, respectively (Hand et al, 2020). Primary organic mass contributed to a large fraction of light extinction in the U.S. intermountain west and southwest regions during 2016-2018, largely attributed to wildfire smoke emissions. This further emphasizes the need to provide visibility analyses that represent the most recent time periods (e.g., 2015 onward).

2. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related climate effects?

Section 5.3.2.1.1 on "Climate Effects" draws on the fifth IPCC Assessment Report (IPCC, 2014). Although the final Sixth Assessment Report (AR6) is slated for 2022, the physical science basis report (IPCC, 2021a) provides an up-to-date understanding of the climate system and climate change. Historical global temperature changed in Figure SPM.1 (1850-2020) below demonstrating a rapid temperature increase in recent decades. Figure SPM.2 shows observed warming for 2010-2019 relative to 1850-1900 further signifying human-induced climate impact and the important role of gaseous and particulate carbon on climate change.

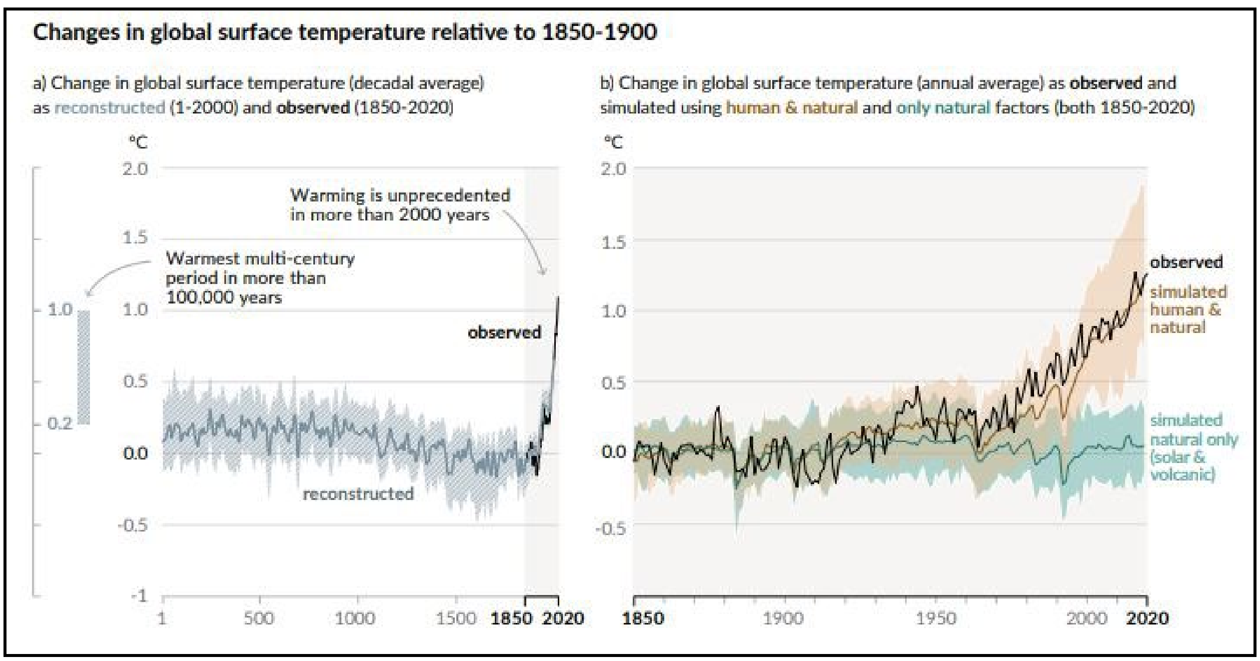

Figure SPM.1. a) Changes in global surface temperature reconstructed from paleoclimate archives (solid grey line, 1–2000) and from direct observations (solid black line, 1850–2020), both relative to 1850–1900 and decade-averaged. The vertical bar on the left shows the estimated temperature (very likely range) during the warmest multi-century period in at least the last 100,000 years, which occurred around 6500 years ago during the current interglacial period (Holocene). The Last Interglacial, around 125,000 years ago, is the next most recent candidate for a period of higher temperature. These past warm periods were caused by slow (multi-millennial) orbital variations. The grey shading with white diagonal lines shows the very likely ranges for the temperature reconstructions. b) Changes in global surface temperature over the past 170 years (black line) relative to 1850–1900 and annually averaged, compared to CMIP6 climate model simulations (see Box SPM.1) of the temperature response to both human and natural drivers (brown), and to only natural drivers (solar and volcanic activity, green). Solid colored lines show the multi-model average, and colored shades show the very likely range of simulations. (see Figure SPM.2 for the assessed contributions to warming). From IPCC (2021a).

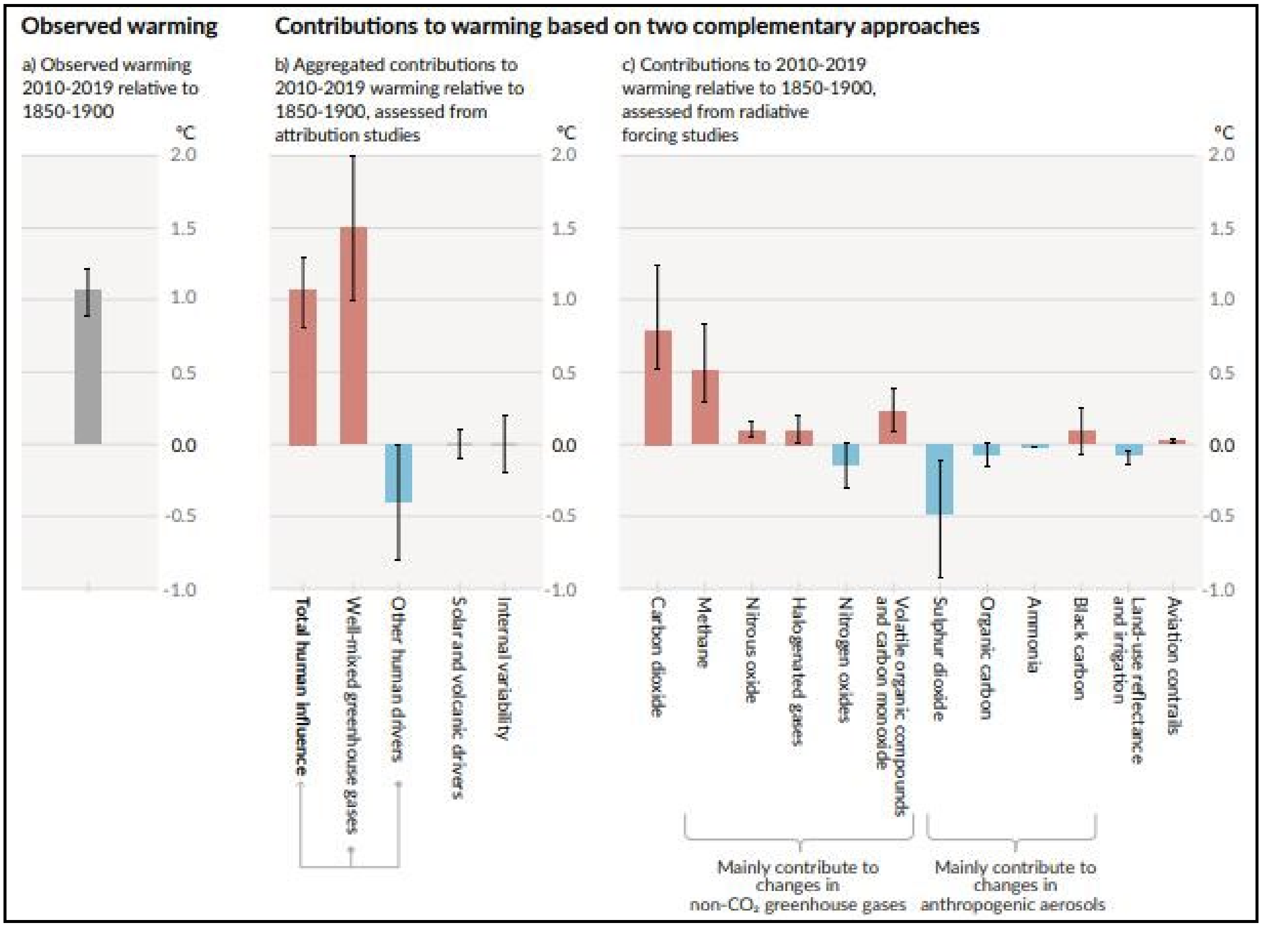

Figure SPM.2. a) Observed global warming (increase in global surface temperature) and its very likely range. b) Evidence from attribution studies, which synthesize information from climate models and observations. The panel shows temperature change attributed to total human influence, changes in well-mixed greenhouse gas concentrations, other human drivers due to aerosols, ozone and land-use change (land-use reflectance), solar and volcanic drivers, and internal climate variability. Whiskers show likely ranges. c) Evidence from the assessment of radiative forcing and climate sensitivity. The panel shows temperature changes from individual components of human influence, including emissions of greenhouse gases, aerosols and their precursors; land-use changes (land-use reflectance and irrigation); and aviation contrails. Whiskers show very likely ranges. Estimates account for both direct emissions into the atmosphere and their effect, if any, on other climate drivers. For aerosols, both direct (through radiation) and indirect (through interactions with clouds) effects are considered. From IPCC (2021a)

Trend analysis over the last 30 years (1988-2017) by Requia et al. (2019b) identified weather-associated changes in $PM_{2.5}$ composition, termed as "weather penalty". Increased temperature in the industrial Midwest and Northwest during the warm and cold seasons, and in the upper Midwest and West during the cold season, along with increased relative humidity and decreased wind speeds, resulted in large changes in $PM_{2.5}$ chemical composition. Weather penalties on sulfate were apparent in the warm season with minimal influence in the cold season, whereas nitrate concentrations were higher in the cold season. Weather penalties for organic and elemental carbon were greatest in the West Coast, reflecting influences from wildfires (Requia et al., 2019a), consistent with observed- and model-estimated OC by Meng et al. (2018) that found OC spikes during 2011, 2012, and 2015.

Revell et al. (2021) note the increasing levels of microplastic particles in suspended particulate matter and perform limiting calculations to estimate effects on the Earth's radiation balance. These show that microplastic particles of different composition and shapes have strong infrared absorbing properties, as well as strong scattering cross-sections at visible and ultraviolet wavelengths. Although their calculations demonstrate a balance between absorption and scattering, Revell et al. (2021) emphasize the preliminary nature of their bounding calculations and uncertainties in the measurement methods. They call for greater efforts to determine microplastic concentrations, compositions, shapes, and sizes to better estimate their effects on climate.

Section 6.3.5.3 of IPCC (2021b) mentions brown carbon (BrC), but it does not elaborate on it. There is a growing number of published articles examining the effects of brown carbon on climate and visibility. As an example, Zhang et al. (2020) used a global model to estimate that BrC has a net warming effect of $+0.10 W/m^2$ in addition to the $+0.39 W/m^2$ attributed to black carbon (BC). Other modeling efforts find that BrC can contribute +0.22 to $+0.57 W/m^2$ of radiative forcing, corresponding to 27-70% of the BC absorption (Brown et al., 2018; Budisulistiorini et al., 2017; Lin et al., 2014; Liu et al., 2015). These estimates are much higher than radiative forcing estimates shown in Figure 13-24 of the ISA (page 13-62) for black carbon and biomass burning and in Figure 13-26 (page 13-64) for biomass burning (U.S.EPA, 2019). As biomass burning is an important contributor to direct aerosol radiative forcing, their association with climate change warrants additional research.

3. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related materials effects?

Section 13.4 of ISA on "Effects on Materials" discusses the soiling and corrosion caused by PM deposition to exposed surfaces and provides dose-response relationships and damage functions for PM-related materials effects. New information on materials damage by PM is not included in the ISA supplement (U.S.EPA, 2019). Section 5.3.2.1.2 on "Materials Effects" addresses studies of soiling on cultural heritage and photovoltaic panels, corrosion of steel, and degradation rates of stone materials. These reviews show that causal relationships exist between PM and effects on materials. However, most of these studies were published in 2010-2011 with a few studies in 2015-2017. More recent research regarding PM impact on structural materials (e.g., Al-Thani et al., 2018; Vidal et al., 2019) may provide additional insights.

Christodoulakis et al. (2018) used satellite observations (i.e., MODIS [Moderate Resolution Imaging Spectrometer] on board Terra and Aqua; AIRS [Atmospheric Infrared Sounder] on board Aqua; and OMI [Ozone Monitoring Instrument] on board Aura) to examine material deterioration and establish dose-response functions. In addition to ground-based measurements, the satellite data processing provides additional information and can add to the weight-of-evidence in understanding the corrosion/soiling distribution, especially for areas where ground-based monitoring is not available.

Vidal et al. (2019) discuss forms of degradation, physical and chemical mechanisms of deterioration, and analytical approaches to quantify pollution effects on materials. They summarize time-independent dose-response functions for metals (e.g., carbon, steel, copper, zinc, and aluminum) to estimate annual corrosion rates. Al-Thani et al. (2018) reviews the direct effect of PM pollution on materials and potential mitigations for environmental sustainability. This review highlights the role of process management, fuel choices, and implementation of clean technologies to control PM pollution.

4. What are the Panel's views on the interpretation of the evidence for PM-related welfare effects for the purpose of evaluating the adequacy of the current secondary PM standards? Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

Organic carbon (OC) and BC play key roles in visibility impairment, materials damage, and the radiation balance. The positive and negative signs of the radiative forcing are inconsistent among model simulations, reflecting uncertainties in optical properties of carbonaceous aerosols (e.g., primary vs. secondary organic carbon, fresh vs. aged combustion emissions) and their roles in PM-related welfare. The regional-segregated relationship between the recent three-year (2017-2019) light extinction (90 percentile) and 24-hour $PM_{2.5}$ design value (98 percentile) in Figures 5-3 and 5-4 (page 5-29 and page 5-31) demonstrate the visibility metrics are below 30 deciview (consistent with levels are acceptable by $\geq$ 50% of the participants in the preference studies). These types of analyses are helpful to determine the causal relationship for secondary PM NAAQS. No quantitative associations are given for PM-related materials and climate effects. Additional discussions of recent findings may provide some perspectives.

5. What are the Panel's views on conclusions regarding support for new or updated quantitative analyses? What are the Panel's views of the technical approach taken to conduct updated analyses to inform our understanding of the relationship between PM in ambient air and visibility impairment?

So et al. (2015) demonstrated that standard air quality and meteorological measurements (i.e., hourly $PM_{2.5}$, NO_2, relative humidity) and monthly averaged PM chemical composition can be applied to estimate hourly light extinction in regions where direct optical measurements are not available. Performance statistics suggest that this hybrid model can be applied to estimate a range of air quality and relative humidity conditions. Variations in aerosol composition and ambient conditions may result in intramonthly and seasonal variabilities in the light scattering and absorption efficiencies. This modeling approach may be tested, verified, and considered as a tool for setting future visual air quality standard. This approach, originally proposed by So et al (2015) applied the hybrid model developed by Pitchford (2010) to several visual air quality management scenarios. This type of policy-related scenario analysis aims to inform visual air quality management in impacted regions. It better characterizes the temporal and spatial differences in visibility for a given region and provide improved quantification of relationship between $PM_{2.5}$ concentrations and visibility impairment.

6. What are the Panel's views on preliminary conclusions regarding adequacy of the current secondary PM standards and on the public welfare policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current secondary PM standards, without revision, in this reconsideration?

The draft PA intends to summarize state-of-the-art measurement techniques. Section 5.3.1 on "Visibility Effects" acknowledges the "Direct measurements of PM light extinction, scattering, and absorption are considered more accurate for quantifying visibility impairment than PM mass-based estimates…" (Lines 6-7, page 5-17), the only listed methods are the transmissometer, nephelometer, teleradiometer, and telephotometers. More recent advanced techniques that can be used to estimate visibility, radiation balance, or climate change need to be added. For example, photoacoustic extinctometer (PAX, Droplet Measurement Technologies [DMT], Boulder, CO) is a sensitive, fast response high resolution instrument that provides optical measurements at multiwavelengths (e.g., 405, 532, and 870 nm). The single particle soot photometer (Droplet Measurement Technologies) can measure black carbon in individual particles, whereas dual (370 and 880 nm) and seven wavelength (370 to 950 nm) aethalometers (AE22 and AE33, Magee Scientific, Berkeley, CA) estimates both black carbon and brown carbon (BrC) that absorb lights at lower wavelength (~300-450 nm). Although not technically nephelometers (Ouimette et al., 2021), there is a plethora of light scattering sensors that provide values that are highly correlated with in-situ light scattering.

BrC is most prominent in the smoldering emissions from open fires and residential wood combustion and can persist in the atmosphere for several days. The IMPROVE network reports seven wavelength (i.e., 405-980 nm) optical measurements along with the OC and EC analysis (e.g., Chen et al., 2015; Chen et al., 2021; Chow et al., 2015; Chow et al., 2018; Chow et al., 2019; Chow et al., 2021; June et al., 2020) since 2016 that evaluate effects of BrC during fire episodes.

7. What are the Panel's views on the areas for additional research that are identified in Chapter 5? Are there additional areas that should be highlighted?

Forello et al. (2020) demonstrates the knowledge gained in estimating source contributions to aerosol optical absorption properties and organics by coupling optical (e.g., seven wavelength aerosol absorption coefficients) with chemical speciation measurements in a receptor model. A combination of optical and chemical measurements can be used to address changes in OM/OC ratios; further refine IMPROVE algorithms; improve emissions inventory estimates; and provide data for climate assessments. Additional data analysis can assist in determining natural visibility conditions related to the U.S. Regional Haze Rule; examining the effectiveness of emission reduction strategies; and identifying exceptional events that can cause exceedances of air quality standards.

The increased frequency and intensity of wildfires lead to increased atmospheric BrC levels. A more detailed treatment of BrC and its effects on visibility and global warming is needed. BrC plays an important role in hydrologic cycle and photochemistry, especially for areas influenced by biofuel consumption and biomass burning.

The growing amounts of microplastic emissions and presence in airborne particles, with potential effects on the Earth's radiation balance a well as deposition onto materials, soils and waterways merits further research into their concentrations, chemical compositions, optical properties, and size ranges.

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Dr. Jane Clougherty

CQ 3. What are the Panel's views on conclusions related to the full body of currently available epidemiologic literature, and in particular, the technical approach taken to conduct new analyses to inform our understanding of the relationship between mean PM2.5 concentrations reported in epidemiologic studies and annual PM2.5 design values? What are the Panel's views on the interpretation of that information and evidence for the purpose of evaluating the adequacy of the current primary PM2.5 standards?

Chapter 3 – Epidemiology, design values

Overall, the draft PA is well-written, and presents a cogent summary of the literature.

- The document does, of course, repeat a lot of the information in the ISA and Supplement to the ISA, which does feel repetitive and challenging to find the new, critical information.
- It was, as noted by others, a bit unclear where to focus in the chapter to answer this charge question.

Many of my prior comments on the ISA supplement apply to this document as well.

- In particular, I have some hesitance regarding *co-pollutant adjustment* and *spatial scale* in the PM2.5 epidemiology literature to date.
    - There is an assumption throughout the document that la*rger studies constitute better epidemiology,* though this is not necessarily the case, as larger studies often have greater exposure misclassification, as compromises are made in estimating exposures across larger populations/ regions.
    - Further, these studies are often implemented at larger spatial scales (e.g., 1 km x 1 km or larger), which is much larger than the scale of variance for many important co-pollutants (i.e., NOx can vary at 100 m or less); as such, studies at larger almost necessarily imperfectly adjust for co-pollutants.
        - *P. 3-101 states that "the determination of what spatial scale to use to estimate PM2.5 concentrations does not inherently affect the quality of the epidemiology study." – I don't believe this to be quite true*. Though larger scales may reasonably capture spatial variation in PM2.5 concentrations, they do not fully capture variation in important co-pollutants, so these studies may well not accurately adjust for co-pollutant exposures.

There could be a bit more acknowledgement of the potentially very important modification by PM2.5 composition – although there may not be adequate evidence to date to determine casual components with certainty.

Page 3-57 – emphasis on controlled characteristics of controlled human exposure or animal toxicology studies.

- Seems important to note here that real exposures vary drastically & be much higher, given personal activities, work exposures, commutes, etc. – simply underscoring that such controlled studies can actually underestimate exposures, and are short-term, by their very nature.

***I am a bit uncomfortable with the emphasis on *<u>mean</u>* exposures in epidemiology studies (justified on p. 3-66 to 3-67) (e.g., Table 3-5 to 3-8).**

- Necessarily over-estimates the range to which the observed (usually linear) association applies.
    - Would be far more comfortable with a table/ summary that includes the exposure interval assessment (e.g., IQR, 10 ug/m3, etc.)
    - Though I recognize that relatively few studies (surprisingly) have reported the 10^{th} percentile or 25^{th} percentile of the exposures distribution in the cohort under study (Figs 3-8 to 3-14).
    - This may be an important call for future epidemiologic studies to better characterize the exposure distribution under study.

Overlap in years of exposure data and health data (p. 3-79):

- "Key epidemiologic studies" are identified as those in which the years of exposure data and health data overlap in their entirety. Contrast is made to studies in which exposure data exists for only the LATER years of follow-up.
- But – for purposes of understand CHRONIC exposure impacts, an exposure metric may very reasonably be measured *prior to, or very early in, the follow-up period*.
- This is particularly true for longer etiologic processes or long-latency outcomes (e.g., cancers).

Epi studies reveal either there is no threshold, or very low.

Very good depiction of the relationships among model-based exposure estimates across varying regions/scales, monitoring-based exposure estimates, and design values.

- The example shown for the Atlanta region is useful and depicts these relationships nicely.
- However, the take-away seems to be that design values consistently over-estimate "actual" cohort exposures.

- I don't believe this necessarily implies that design values over-estimate TRUE population exposures, and therefore anticipated health effects, given:
  - Most regulatory monitors are at rooftop height (not ground level).
  - Most are further away from key sources (e.g., highways) than are many populations, including commuters, bicyclists, and pedestrians.
  - Do not account for personal activities, workplace exposures etc. (noting that indoor and personal exposure estimates are consistent higher than ambient concentrations).

Finally, very striking that those relatively few analyses restricted to exposures below the current standard (Table 3-10) appear to find consistently stronger concentration-response functions

- Despite smaller sample sizes and reduced statistical power, and plausibly greater exposure misclassification at low end of the distribution of estimated exposures.

CQ 6. In the Panel's view, has the evidence and risk information, including limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative annual PM2.5 standards?
Does the discussion provide an appropriate and sufficient rationale to support preliminary conclusions regarding alternative primary annual PM2.5 standard levels that are appropriate to consider?

Section 3.3.4: Uncertainties in the Health Effects Evidence (p. 3-125)

- Heterogeneity across cities and geographic regions:
- I am happy to see this issue discussed here, which was examined in terms of effect modification in the ISA Supplement. I would like to see a bit clearer statement that it remains very much unclear whether variation in observed associations between cities or regions may be owing to differential exposure misclassification, true variation in PM2.5 composition, presence of co-pollutants (which may be confounders or effect modifiers of PM2.5 health effects), or due to population differences and variation in underlying population susceptibilities.

Section 3.5.2.4. Uncertainties

It appears a key point on p. 3-177 that the choice of concentration-response function used had only a small impact on risk estimates (lines 28-30).
- p. 3-185: Also, that studies restricted to exposures below the current standard generally report effect estimates greater in magnitude (lines 14-17, also p. 3-199 lines 36-42).
- Together, these observations support using steepest justifiable concentration-response function in risk assessment.

p. 3-178: Unclear why risk modeling scenarios are based only on "across-the-board" changes in primary PM2.5 or NOx/ SO2 from anthropogenic sources by fixed percentages. This seems unrealistic in regard to policy implementation (e.g., Clean Air Act SO2 regulations targeting highest-emitting power plants).

p. 3-180: At-risk populations are defined here as children, older adults, or those with pre-existing respiratory or cardiovascular disease). Race/ ethnicity is discussed in subsequent paragraph. Should SES not be addressed as well?

Relationships between mean concentrations and design values (p. 3-194 to 3-195):

- Important to be clear that, although design values run higher than other monitoring values (by definition, as highest) and mean of regional exposure models,
  - This does NOT mean that some population exposures won't be higher than design value (lines 1-12, p. 3-195)
  - Design value is just highest AMONG THOSE LOCATIONS monitored by EPA.

Critical point on p. 3-197 (line 3-6): "meeting a revised annual standard with a lower level may also proportionally reduce exposure and risk in Black populations slightly more so than in White populations in simulated scenarios just meeting alternative annual standards."

- As such, reducing the annual standard would produce GREATER proportional exposure reductions for Blacks than Whites.
- Thus, this represents an opportunity to reduce overall population risk, and to *reduce a known disparity*, which is an important & valuable opportunity, and should be emphasized.

Alternative annual standard levels (starting on p. 3-197):

- Lines 27-34: The justification for considering alternative levels argues that linear associations are well-established down to 8 ug/m3.
  - Below which there is more uncertainty in shape of concentration-response function.
  - But then presents risk analyses only down to 10 ug/m3.
  - This seems a disjuncture, and begs the question of why a risk assessment down to 8 ug/m3 are not presented here?

- Lines 35-38 appear to continue to make the mistake of interpreting the observed concentration-response function in epidemiologic studies to principally apply <u>at the mean</u>, rather than for a larger range of exposures around the mean - which begins, by definition, at a lower concentration.

Future research directions:

- Section should call for more detail in epidemiologic studies on statistical distribution of exposure estimates.
  - This is listed as a call for more descriptive statistics, but seems such a critical limitation in EPA's ability to perform informed risk assessment & identify lower alternative standards, that it seems to merit some emphasis.
  - Incl. tests for non-linearity, targeted analyses of linearity below current standards.

- Section should also further underscore identification and elucidation of impacts of specific PM2.5 components on health effects (e.g., metals).

- To reduce exposure disparities, possibly some consideration of exposure variability across a region, to consider, for example, exposure disparities as a metric? (as in a Gini coefficient)?

Dr. Deborah Cory-Slechta

Charge Question 2 - What are the Panel's views on the interpretation of the human exposure and animal toxicologic studies for short- and long-term PM2.5 exposures for the purpose of evaluating the adequacy of the current primary PM2.5 standards? To what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

In the view of this reviewer, the interpretation of the evidence is presented in a fair and unbiased manner, with the outcomes of the studies accurately described. This includes statements as to whether the results themselves of various studies are consistent or inconsistent with the literature to date. In addition to that, the studies are described in terms of their contribution to further understanding co-pollutant impacts, accountability analysis, and with specific attention to the methods used for characterizing the exposure levels and how this influences outcomes as well as strength of the evidence.

Charge Question 5 **-** *What are the Panel's views on preliminary conclusions regarding adequacy of the current primary PM2.5 standards and on the public health policy judgments that support those preliminary conclusions?*

a. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary 24-hour PM2.5 standard, without revision, in this reconsideration?

Yes, the presentation and discussion of the evidence is appropriate to supporting the preliminary conclusions to retain the current primary 24 hr PM2.5 standard, particularly given that its overall impact would be far less impactful than would revision of the primary annual standard. This conclusion is well supported by the arguments presented with respect to the consequences of what would be achieved through revisions of various sizes that are described.

b. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider revising the current primary annual PM2.5 standard in this reconsideration?

Yes, in the view of this reviewer, the data clearly support the preliminary conclusion to consider revising the current primary annual PM2.5 standard in this reconsideration. In the view of this reviewer, such a conclusion would be warranted just based on the long-term exposure and mortality data, which is highly compelling, particularly given the fact that these studies can markedly differ in their populations and other conditions, as well as handling of confounders. In addition, the differences in locations means both similarities and differences in compositions/speciation of the PM. The PA does an excellent job of describing the various consequences of changes to the standard levels, and how this would affect different sociodemographic groups as well as consequences for groups with identified co-morbidities that are enhanced by PM2.5 exposures.

Dr. Mark W. Frampton

General Comments

Chapter 1

It would be helpful to provide additional background on the CASAC review of the 2019 ISA and the 2020 PA, including the key advice from CASAC and the Agency's responses.

Page 1-14 of the current PA states, "In response to the CASAC's comments, the 2020 final PA incorporated a number of changes (U.S. EPA, 2020), as described in detail in section I.C.5 of the 2020 proposal (85 FR 24100, April 30, 2020)." With regard to causality determinations, this page of the Federal Register (FR2100) states, "Changes in the text to reflect the change in the final ISA's causality determination from ''likely to be causal'' to ''suggestive of, but not sufficient to infer, a causal relationship.'' This account in the FR does not specify what PM fraction or health effect was changed. As noted in my comments on the ISA Supplement, the Final 2019 ISA accepted CASAC's advice with regard to UFP nervous system effects, but did not accept advice on $PM_{2.5}$ effects on nervous system and cancer.

Introduction, Page 1-17, top. "Additionally, for these health effect categories the recent studies evaluated are limited to:

- U.S. and Canadian epidemiologic studies
- Epidemiologic studies that employed causal modeling methods or conducted accountability analyses…".

While the first bullet is correct, the second is not. The considered studies were obviously not "limited to" those using causal modeling methods or accountability analyses; these types of studies were highlighted.

Section1.4.3, last sentence, contradictory. "The court has not yet acted on the EPA's motion, which the court granted on October 1, 2021."

Charge Questions, Chapter 3

CQ1. To what extent does Chapter 3 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on $PM_{2.5}$-related health effects?

Chapter 3 provides an excellent summary and characterization of the health effects evidence assessed in the 2019 ISA and draft ISA Supplement.

Chapter 3, and the document in general, have considerable redundancy in the text, with the same points being made repeatedly in different sections and contexts.

More consideration is needed of the limitations of human controlled exposure studies in determining effects at near-ambient concentrations, and in determining exposure thresholds of effects. In general, human studies require levels higher than ambient to elicit effects, in order to provide a contrast with continuous pollutant exposures experienced in daily life. In addition, numbers of subjects are usually relatively small, less than 30 or 40 subjects, and exposure durations relatively short, less than 6 hours, in part because of the difficulty and expense involved. Subjects are generally healthy, or have mild and stable cardiac or respiratory disease. Children and frail elderly, as well as other at-risk groups, are generally not studied. Regardless of the pollutant being studied, in order to elicit effects, human studies generally require concentrations considerably higher than ambient, and higher than those found to have effects in epidemiology studies. Furthermore, many human PM exposure studies have used particle concentrators. While this technology has advantages, the concentrated particles are not a perfect reproduction of $PM_{2.5}$ in the ambient air from which they are concentrated. Particles in the ultrafine size range are not concentrated in the fine particle concentrators, and the process of passage through sequential impactors may alter particle surface chemistry. For all of these reasons, absence of an effect at a given concentration in human studies should not be interpreted to represent a no-effect threshold in the "real world". And conversely, elicitation of effect at concentrations in or near the upper range of ambient should not be interpreted as evidence that the current standard is protective. In general, in this PA, too much reliance is placed on the human exposure studies in arriving at the conclusion that the 24-hour $PM_{2.5}$ standard is adequately protective.

Page 3-22, line 10. "For example, Bennett et al. (2019) reported that $PM_{2.5}$ concentrations above the lowest observed concentration (2.8 $\mu g/m^3$) were associated with a 0.15 year decrease in national life expectancy for women and 0.13 year decrease in national life expectancy for men (U.S. EPA, 2021a, section 3.2.2.2.4, Figure 3-25). Another study compared participants living in areas with $PM_{2.5}$ concentrations >12 $\mu g/m^3$ to participants living in areas with PM2.5 concentrations < 12 $\mu g/m^3$ and reported that the number of years of life lost due to living in areas with higher $PM_{2.5}$ concentrations was 0.84 years over a 5-16 year period (Ward-Caviness et al., 2020; U.S. EPA, 2021a, section 3.2.2.2.4)." This section discusses new accountability studies, but the two studies cited above are not actually accountability studies, if defined as reduction in health effects with reductions in PM exposure, within a given population. The two cited studies are life expectancy studies, and that is the context in which the ISA presents them.

Page 3-33, "…the draft ISA Supplement continues to indicate an immediate effect of $PM_{2.5}$ on cardiovascular-related outcomes primarily within the first few days after exposure,…". Immediate is defined as within 1 day. A few days would be a delayed effect. Also page 3-49, line 22-24: "…studies provide evidence of an immediate effect of short-term-related $PM_{2.5}$ exposure on cardiovascular-related outcomes, especially during the first few days following exposure."

Page 3-39. "A subset of the studies focusing on lung cancer incidence also examined histological subtype, providing some evidence of positive associations for adenocarcinomas, the predominate subtype of lung cancer observed in people who have never smoked (U.S. EPA, 2019, section 10.2.5.1.2)." It should be noted that adenocarcinoma is the most common type of lung cancer in smokers, as well, so this findings is of questionable significance.

3.3.1.4 Cancer. Page 3-40. "Overall, there is limited evidence that long-term $PM_{2.5}$ exposure is associated with cancers in other organ systems, but there is some evidence that $PM_{2.5}$ exposure may reduce survival in individuals with cancer (U.S. EPA, 2019 section 10.2.7; U.S. EPA, 2021a, section 5 2.1.1.4.1)." Few of the epi studies of supposed cancer incidence have long enough lead times to assure incident cancer rather than reduced survival in those with cancer. See previous CASAC comments on the draft 2019 ISA, including the advice that the evidence was insufficient to move the causality determination from suggestive to likely to be causal, given the remaining uncertainties, including negative data in long-term animal studies.

Page 3-49, line 34, "…reductions in heart rate…" presumably should be "heart rate variability".

Table 3-4, Lucking et al. 2011, exposure was to diesel exhaust.

Page 3-180: "Similarly, adults over the age of 65 also have a greater prevalence of respiratory diseases, particularly COPD reported as chronic bronchitis or emphysema,…". Chronic bronchitis and emphysema are subsets of COPD. This statement seems to exclude people with COPD that are not described as chronic bronchitis or emphysema. This would be better worded: "particularly COPD, including chronic bronchitis and emphysema".

Page 3-196. "While there is no specific point in the air quality distribution of any epidemiologic study that represents a "bright line" at and above which effects have been observed and below which 12 effects have not been observed,…". The "bright line" is the same as a threshold, so this repeats the statement in the previous bullet point.

Page 3-202. "Human clinical studies support the occurrence of effects following single short-term exposures to $PM_{2.5}$ concentrations that correspond to the peak of the air quality distribution, though these concentrations are well above those typically measured in areas meeting the current standards, suggesting that the current standards are providing protection against these exposures." The concerns raised previously in these comments, about using human studies to determine lower exposure thresholds, has most relevance to the 24-hour standard. Human studies should not be used as the primary justification that the 24-hour standard is adequately protective, without caveats.

CQ5. What are the Panel's views on preliminary conclusions regarding adequacy of the current primary $PM_{2.5}$ standards and on the public health policy judgments that support those preliminary conclusions?

The framework for this important section is established using a series of questions, which is clear and effective. These questions are appropriately phrased for this reconsideration, asking whether newer information alters previous conclusions.

This section accurately summarizes both the evidence and the remaining uncertainties.

Findings from the animal toxicology studies, and the human controlled exposure studies, are given appropriate context in the summation. However, too much emphasis is placed on the findings from human exposure studies

There are clearly presented justifications for maintaining the current indicator, averaging time, and form for both the 24-hour and annual standards.

Page 3-160 to 3-161. This is a discussion of the human studies, and compares ambient 2 hour concentrations with those used in human studies. It is important here to add a caveat about the limitations of human studies in identifying minimum concentrations at which health effects are elicited.

a. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary 24-hour $PM_{2.5}$ standard, without revision, in this reconsideration?

No, the rationale for retaining the current level of the 24-hour standard is not convincing. First, too much emphasis is placed on the findings of human exposure studies, which, for the reasons discussed above, should not be used to identify a no-effect threshold. Second, the epidemiology studies provide strong evidence for mortality and morbidity at short-term concentrations well below the current standard of 35 $\mu g/m^3$. Third, the risk assessment excluded locations with exposures related to wildfires, and this is inappropriate. Wildfires, like air pollution, are mostly of human origin, and their exposure effects should be included in the risk assessment. While a more stringent annual standard will reduce peak exposure levels, it will not be sufficiently protective of the adverse health effects of peak short-term exposures.

b. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider revising the current primary annual $PM_{2.5}$ standard in this reconsideration?

Yes, the PA provides a clear and comprehensive summary of the evidence that the current annual $PM_{2.5}$ standard is not adequately protective of the public health.

Dr. Christina H. Fuller

Chapter 3

1. To what extent does Chapter 3 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on PM2.5-related health effects?

Recommendations:

Add language that describes the reasoning why $PM_{10-2.5}$ studies were used to evaluate the PM_{10} standard. Explain why it is appropriate and any impact on the interpretation of results.

I suggest the PA refer to the group non-White as People of Color (POC) or Communities of Color (COC), as appropriate. There are multiple terms utilized to describe the span of races and ethnicities in the United States, which is reflected by the studies included in this Supplement. Race/ethnicity is a fluid concept that is relevant by time, country, region, population and government. Therefore, the most useful terminology for the purpose of protecting public health has changed over time.

Given the multiple differences between $PM_{2.5}$ and UFP I suggest separating UFP into its own-subsection when presenting the results from the PM ISA. It will make it easier to identify the gaps in research and conclusions relevant to UFP when compared to $PM_{2.5}$. It's important to distinguish and clarify the relationship between UFP number and $PM_{2.5}$ mass.

Specific comments related to the recommendations:

Page 3-3, Lines 17 – 20. The draft Supplement ISA provides evidence that populations of color (POC) are at increased risk for exposure and health effects. Add POC to this sentence before "populations of low socioeconomic status".

Page 3-6, lines 1-26. There is a lot of redundancy in this paragraph. Please make it more concise.

Page 3-7, first paragraph. It is important to note that the standards are insufficient if monitoring sites are in low PM areas. As noted in Section 2, near-roadway $PM_{2.5}$ is often higher than other monitors in urban areas.

Page 3-19, Table 3-1. It is apparent from the table that there is data missing. Add a sentence here describing why UFP has not evaluated for all effects.

Page 3-43. UFP-Nervous System Effects. Include references to articles by Lilian Calderón-Garcidueñas who has contributed significant work in this area. Dr. Calderón-Garciduenas has reported results from cohorts in Mexico evaluating UFP exposure and cognitive effects.

Page 3-45. Lines 10 – 12. I recommend changing this sentence to read, "Since the 2009 ISA, there have been additional studies published…" I would not consider the UFP-CVD publications through 2019 to be limited. They are less numerous than $PM_{2.5}$, but continue to increase.

Page 3-46, 3.3.1.6.3 COVID-19 Infection and Death. Include text that states the disproportionate burden on populations of color (POC) of COVID death and severe cases.

Air pollution levels can be higher than monitored data and design values. Include text in the document that acknowledges this fact.

4. What are the Panel's views on the technical approach taken to update the risk assessment, including the approach to evaluating impacts in at-risk populations? To what extent does the draft PA accurately and clearly communicate the results of these analyses? What are the Panel's views on staff's interpretation of these results for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ standards?

Recommendations:

There is good language here regarding the uncertainties regarding the risk estimates and at-risk analyses. An additional uncertainty to include is the existence (or lack of) monitors in high exposure areas where at-risk populations reside. The current risk estimates are very good, however, they could be improved with additional monitoring in key locations. Chapter 2 provided data on the $PM_{2.5}$ concentrations comparing near-road monitors to those away from monitors, finding that those near roads were higher. The limited number of near-road sites would impact both epidemiological findings and risk estimates. The draft PA should include language detailing this complex relationship.

The term at-risk has not been used as consistently in this Chapter as in the draft ISA supplement. We recommend that Section 3.4.1.6 provide explicit detail and/or a citation to the use of this term as described in the ISA preamble.

Specific comments related to the recommendations:

Page 3-135, lines 29 – 33. As in previous replacing the term non-White with people/populations of color (POC) is most appropriate at the current time. Therefore, please replace nonwhite populations with populations of color (POC) in these two sentences.

Explanation of the categorization of the selected urban study areas (CBSAs) is well-described. I recommend revising Figure 3-16 to distinguish between those just meeting the standard to those exceeding the standard. That information is a good accompaniment to the text given in the previous paragraph (pages 3-133 to 3-134). It also appears that one of the numbers may be incorrect. Sixteen CBSAs exceeding plus 30 meeting totals 46 and not 47.

Page 3-135, lines 29 – 33. As in previous replacing the term non-White with people/populations of color (POC) is most appropriate at the current time. Therefore, please replace nonwhite populations with populations of color (POC) in these two sentences.

Page 3-136, lines 1-2 and line 7. Replace “non-white populations” with “populations of color in both sentences”.

Page 3-138, line 2. I believe that the term “at-risk” should simply be “risk”. It is my understanding that the 47 CBSAs were used to estimate risk for the full populations residing in those locations, not simply the at-risk populations.

Table 3-17. Replace the term “delta” with change, because it would be more familiar to readers.

Page 3-147, lines 10 – 12. Change this sentence to read, “Evidence strongly supports that people of color and Hispanic populations have higher $PM_{2.5}$ exposure than White, non-Hispanic populations, thus contributing to increased risk of PM-related effects.”

Page 3-148, line 28. It is most correct to include both race and ethnicity in this sentence, because the accompanying Figure includes categories of race as well as Hispanic identify. Change the term race-specific to race/ethnicity-specific and race-stratified to race/ethnicity-stratified.

Page 3-149, Figure 3-20. This figure gives excellent data broken down by race and ethnicity. I suggest making the change to this figure and the others in Section 3 (Figure 3-21) to organize the data alphabetically. Therefore, the comparison of all race/ethnicities is more balanced, because there is not a focus on White as the referent category. Remove obesity and diabetes (line 20), because this would be included in the previous statement concerning pre-existing diseases. Also, this paragraph would benefit a few sentences discussing how the aforementioned factors are often correlated with each other.

Page 3-159, lines 14 - 21. I conclude that the 2019 draft ISA supplement provides additional evidence of higher exposures for some at-risk populations, in particular populations of color and especially Black populations. Therefore, the sentence beginning on line 14 should state that current evidence improves our understanding of increased risk for some at-risk populations

Page 3-169, lines 25 – 28. It would be helpful to readers to provide the variation explained by the model in the Di et al 2017 article.

Page 3-173, lines 1-2. More specificity in this sentence would better represent current evidence. Replace "such as" with "specifically" in line 1. Remove and from line 2 so that it reads "White, non-Hispanic populations".

Page 3-179, line 13. Replace non-White with people of color.

Page 3-180, lines 10 – 23. Refine this sentence to align with the broader definition of at-risk populations in the draft ISA.

Suggestions for future PAs:

A suggestion for this or future Policy Assessment is to consider morbidity-based risk assessment. The focus solely on mortality does not incorporate the massive burden of chronic disease that is distributed disproportionately in the country. Including morbidities (such as ischemic heart disease) would also invite the inclusion of other studies that may include more diversity with regards to race, ethnicity, income and other at-risk populations. There are many studies in this realm that are just as well-designed and valid as their larger, long-running counterparts.

Section 3.5.2.3. Another suggestion is to better integrate the at-risk analyses into the risk assessment instead of having the analysis in a separate subsection. This would support the EPA's stated mission to determine requisite standards that are protective of the most sensitive in the U.S. population.

There has been no adjustment for auto-correlation between demographic, socioeconomic or built environment factors. I suggest that examination of these impacts be included in the next review. Autocorrelation may result in modeling errors and inaccurate estimates. (Page 3-173, lines 1 – 18)

7. What are the Panel's views on the areas for additional research that are identified in Chapter 3? Are there additional areas that should be highlighted?

This Section provides a comprehensive list of the scientific gaps in the literature that through inclusion in future reviews would allow for a more precise and thorough assessment of the spatial breadth of $PM_{2.5}$ exposure as well as health impact. I have edits to the existing bulleted items as outlined below.

Recommendations and specific comments:

I recommend the PA refer to the group non-White as People of Color (POC) or Communities of Color (COC), as appropriate. There are multiple terms utilized to describe the span of races and ethnicities in the United States, which is reflected by the studies included in this Supplement. Race/ethnicity is a fluid concept that is relevant by time, country, region, population and government. Therefore, the most useful terminology for the purpose of protecting public health has changed over time.

The inclusion of robust research in the identified areas would enhance the characterization of $PM_{2.5}$ over space and time as well as identify and estimate disproportionate burdens and susceptibilities of vulnerable subsets of the U.S. population. Therefore, sentence two in this paragraph (page-3-203, lines 13-14) should be expanded to include this additional text.

Page 3-204, lines 14-15: The assessment of this area of research (UFP and cognitive function) would be improved by the inclusion of research from ongoing studies in children and adults in Mexico City led by Lilian Calderón-Garcidueñas. A recent article of her relevant work can be found here (Calderón-Garcidueñas et al. 2021).

Page 3-204, lines 27-29: Understanding linkages between pollutant levels, physical predictors and demographic factors are key to better understand spatial and temporal variation in ambient $PM_{2.5}$ concentrations. It also important to state the underlying auto-correlation between these factors, which may vary by metropolitan area and has been relatively unexplored in rural areas. I would specifically state the assessment of auto-correlation here.

Page 3-204, lines 30-33: I suggest this paragraph be separated into two parts beginning with "as well as the temporal and spatial variability…" in line 32. In this new paragraph add that research is needed in the assessment of sensor technologies for use in estimating spatial and temporal variation of $PM_{2.5}$ exposure and epidemiologic studies. Especially those studies that compare validated regulatory measurement methods with sensors in long-term studies.

Page 3-204, lines 34-36. I would also add to this paragraph with its focus on exposures during the life course (beginning in utero) language about the need for studies that include intergenerational vulnerabilities that stem from parental exposure to elevated levels of $PM_{2.5}$.

Page 3-204, lines 40-42: Also include in this bullet the need for epidemiologic authors to report the estimation of autocorrelation between variables and any necessary adjustments, if needed.

Suggestion for future policy assessments:

I suggest future policy assessments of PM include evaluation of both long-term and short-term UFP studies and health effects. Outcomes of particular interest include cardiovascular, respiratory, and cognitive disease; and adverse pregnancy/birth outcomes.

References

Calderón-Garcidueñas L, Stommel EW, Rajkumar RP, Mukherjee PS, Ayala A. 2021. Particulate air pollution and risk of neuropsychiatric outcomes. What we breathe, swallow, and put on our skin matters. International journal of environmental research and public health 18.

Dr. Terry Gordon

Chapter 2

The wildfire issue is so large and impactful, that EPA must clearly address this issue either in the PM ISA or PM PA. Given the consistent nature of these wildfire events, this is the 'elephant in the room' consideration for EPA and CASAC.

Coarse PM measurements are critical to understanding the association of $PM_{10-2.5}$, relative to $PM_{2.5}$, with adverse health effects. Additionally, speciation of $PM_{10-2.5}$ is also important to understanding PM toxicity and should not be ignored in terms of research objectives.

Chapter 3, Charge Question 1

An excellent chapter in terms of clarity, there were some redundancies. Perhaps these repeated sections were intentionally included if EPA staff thought readers of the PA document may read only certain sections?

Chapter 3, Charge Question 2

What are the Panel's views on the interpretation of the human exposure and animal toxicologic studies for short- and long-term $PM_{2.5}$ exposures for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ standards? To what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

The interpretations of the human and animal exposure studies are appropriate. Although the exposure concentrations are relatively high compared to ambient exposure concentrations, the mechanistic data support the epidemiology-based associations that evaluate the adequacy of the current primary $PM_{2.5}$ standards. Because of the lower exposure concentrations in the human exposure studies, they are more relevant in terms of support of revising the current 24 hr $PM_{2.5}$ standard, in particular because of the responses of healthy subjects in those studies when ambient $PM_{2.5}$ may adversely affect sensitive individuals to a greater extent.

The consideration of the evidence and uncertainties are excellent and clearly communicated, although, to be honest, even though my career was built upon inhalation toxicology, it is unclear how much these mechanistic studies can actually impact this or future PM NAAQS. This reviewer believes that it would be more impactful to focus toxicology research on the associations of individual sources with adverse health outcomes, so that states/regions could perhaps focus on the 'worst' polluters. In particular, more research is needed on the contribution(s) of traffic (i.e., pollution vs. noise/stress; environmental justice), coal, and wildfire emissions to adverse health effects.

<u>Chapter 3, Charge Question 4</u>

What are the Panel's views on the technical approach taken to update the risk assessment, including the approach to evaluating impacts in at-risk populations? To what extent does the draft PA accurately and clearly communicate the results of these analyses? What are the Panel's views on staff's interpretation of these results for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ standards?

Regarding at-risk populations, the discussion was clear but this reviewer believes that there could be some additional separation and clarity on the at-risk/susceptible populations being due to innate host factors or because of exposure scenarios. Regardless of EPA's 'current' definitions of susceptibility or vulnerability, the different reasons for being at-risk are very important in evaluating why a subpopulation may be at increased risk. This 'why' is critical in understanding whether a current NAAQS needs revision.

<u>Chapter 3, Charge Question 5</u>

What are the Panel's views on preliminary conclusions regarding adequacy of the current primary PM2.5 standards and on the public health policy judgments that support those preliminary conclusions?

a. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary 24-hour $PM_{2.5}$ standard, without revision, in this reconsideration?

The discussion is appropriate and while it provides a solid rationale to support retaining the current 24 hr $PM_{2.5}$ standard, the discussion, however, could expand upon an alternative rationale supporting a revision (i.e., lowering) of the 24 hr $PM_{2.5}$ standard. The controlled human exposure studies provide evidence that a few hours of exposure at $PM_{2.5}$ concentrations that are fairly relevant to real-life exposure scenarios, can produce signs of cardiopulmonary changes in <u>healthy</u> research subjects. Although the number of studies supporting these findings is somewhat limited at this time (reproducibility of research is important), this evidence strongly suggests that susceptible individuals may respond to $PM_{2.5}$ at the current 24 hr standard. This possibility is supported by animal and human exposure studies that demonstrate susceptible individuals (e.g., whether due to pre-existing disease or genetic) respond to inhalation exposure challenges to particles or gases at concentrations lower than what is observed in 'healthy' individuals. Thus, consideration of revision of the 24 hr $PM_{2.5}$ standard is warranted to protect susceptible individuals.

b. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider revising the current primary annual $PM_{2.5}$ standard in this reconsideration?

The rationale is appropriate and on target for supporting a revision of the annual $PM_{2.5}$ standard. Perhaps one of the key topics for justification of revising the current primary annual $PM_{2.5}$ standard is brought up in Section 3.3.1.1 on page 3-23: "indicating that risks are not disproportionately driven by the upper portions of the air quality distribution". Thus, despite the uncertainties in the lower end of the C-R association curves, there is evidence to consider lowering the current annual standard. Similarly, the consideration of the recent Canadian epidemiology studies is paramount to assessing the 'low end' of the C-R curves. If not used directly in a decision to revise the current annual $PM_{2.5}$, the Canadian data, despite some differences in the target populations and hybrid modeling, relative to U.S. epidemiology studies, strongly support an association of adverse health effects below the current annual standard for $PM_{2.5}$.

Chapter 4 – Reconsideration of the Primary Standard for PM_{10}

1. To what extent does Chapter 4 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on $PM_{10-2.5}$-related health effects?

Chapter 4 does an excellent job of characterizing the key points of evidence regarding coarse PM's association with adverse health effects.

This reviewer is confused, however, on the extent of the discussion of adverse health effects that do not rise to the level of 'likely to be causal' or 'causal' (as evaluated in the PM ISA), which were stated to be used as the criteria for discussing $PM_{2.5}$'s contribution to adverse health effects in this Supplemental PA. This becomes particularly unclear in the last paragraph of page 4-16. Perhaps this Chapter could be greatly reduced in length if these criteria were used more consistently in this Supplemental PA.

Chapter 4 also needs some clarity in repeatedly discussing $PM_{10-2.5}$ whereas the NAAQS says PM_{10}. Perhaps a sentence or 2 should be added to address this issue.

2. What are the Panel's views on the interpretation of the health evidence for short- and long-term $PM_{10-2.5}$ exposures for the purpose of evaluating the adequacy of the current primary PM10 standard? Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

The Chapter's interpretation of the health evidence described in the PM ISA was on target. In particular, the descriptions of the uncertainties in evaluating the health effects of coarse PM were well written. These uncertainties include the more limited number of epidemiology studies, compared to $PM_{2.5}$ studies, with positive statistically significant findings and the difficulty in extracting the sole contribution of coarse PM to observed adverse health effects in light of the causal evidence for $PM_{2.5}$ which acts as a confounder in a majority of studies.

3. What are the Panel's views on conclusions regarding support for new or updated quantitative analyses?

Quantitative analyses are beyond the scope of this reviewer.

4. What are the Panel's views on preliminary conclusions regarding adequacy of the current primary PM_{10} standard and on the public health policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary PM_{10} standard, without revision, in this reconsideration?

The preliminary conclusion of retaining the current PM_{10} standard is appropriate in the eyes of this reviewer. Sufficient rationales were appropriately given to support the retention.

5. What are the Panel's views on the areas for additional research that are identified in Chapter 4? Are there additional areas that should be highlighted?

The sampling design for both epidemiology and toxicology studies are generally inadequate to properly evaluate the contribution of $PM_{10-2.5}$ to adverse health effects relative to that of $PM_{2.5}$ (e.g., dichotomous sampling is superior to estimation of coarse PM by subtraction of $PM_{2.5}$). Separation of the mass concentration of the coarse fraction compared to $PM_{2.5}$ is very important in such studies. Similarly, there is not a sufficient research effort to speciate coarse PM and therefore the potential overlap with $PM_{2.5}$, or lack thereof, in compositionally-driven toxicity has not been established.

Dr. Michael T. Kleinman

Chapter 1 – Introduction: *Chapter 1 provides introductory information including a summary of the legislative requirements for the NAAQS, an overview of the history of the PM NAAQS and the decisions made in prior reviews, and a summary of the scope and approach for the reconsideration of the 2020 final decision.*

1. *To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for this reconsideration?*

   - The information is clearly presented.
   - The PA brings out the following points which limited the range of considerations:
     - The draft ISA Supplement was narrowly focused on health effects evidence where the 2019 ISA concluded a "causal relationship" existed, e.g cardiovascular outcomes and total mortality.
     - The PA recognized "that the evaluation does not encompass the full multidisciplinary evaluation presented within the 2019 ISA that would result in weight-of-evidence conclusions on causality (i.e., causality determinations)"
   - Importantly the PA notes that despite the 2020 decision to retain the PM NAAQS without revision, "the scientific evidence and information supported revising the level of the primary annual PM2.5 standard to below the current level of 12 μg/m^3"

Chapter 2 – Air Quality: *Chapter 2 describes the major PM emissions sources; the atmospheric chemistry related to PM in ambient air; the PM monitoring network; PM ambient air quality trends and relationships; an overview of hybrid modeling methods used to estimate $PM_{2.5}$ concentrations; analyses to inform our understanding of mean $PM_{2.5}$ concentrations from monitors and hybrid models and their relationships with design values; and background PM.*

1. *What are the Panel's views on the technical approach taken and analyses completed to inform our understanding of how $PM_{2.5}$ concentrations calculated using composite monitors and area averages from hybrid modeling approaches compare to area design values?*

   - The hybrid methods have promise and may eventually be applied to fill in where there are clear deficits in monitor coverage which could greatly improve coverage in at risk communities.
   - Research in hybrid modeling should be continued.

- It was not explicit as to how this discussion fit into the overall thinking for the current PA.

2. *To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for this reconsideration?*

- This is a complex area and the overview of Hybrid Methods jumps in with little explanation or reference and a lot of 'jargon'. The non-modelers would benefit from some additional explanatory material and maybe some simple examples (perhaps added as an appendix).
- It was not clear where hybrid methods fit into the overall thinking for the current PA.

Chapter 3 – Reconsideration of the Primary Standards for $PM_{2.5}$: *Chapter 3 summarizes key aspects of the health effects evidence and evaluates mean $PM_{2.5}$ concentrations reported in key epidemiologic studies that are particularly relevant to considering the adequacy of the current primary $PM_{2.5}$ standards. Chapter 3 also summarizes the risk assessment and at-risk analyses to inform preliminary conclusions on the primary $PM_{2.5}$ standards. Finally, Chapter 3 presents the preliminary conclusion that, collectively, the scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as supporting retention of the 24-hour $PM_{2.5}$ standard, while calling into question the adequacy of the public health protection afforded by the current primary annual $PM_{2.5}$ standard, and presents alternative annual $PM_{2.5}$ standards that could be supported by the available scientific and technical information. Chapter 3 also identifies key areas for additional research and data collection, in order to inform future reviews.*

1. *To what extent does Chapter 3 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on $PM_{2.5}$-related health effects?*

- Chapter 3 clearly lays out the key questions and rationale for the approach
    - Does the sum of the new and old scientific evidence support the finding in the 2020 PA that revising the level of the primary annual PM2.5 standard to below the current level of 12 μg/m^3 would more adequately protect health?
    - The range of alternative primary standards that might be proposed that are requisite to protect public health.
    - Chapter 3 also emphasizes that in addition to the evaluation of the targeted recent studies, the full body of evidence from the 2019 ISA was considered.
    - More relevance could have been placed on cancer, nervous system effects and metabolic effects, all of which were demonstrated to show significant effects in the 2019 ISA but were not further examined in the supplement.

Nervous system long term exposure effects were not on the radar in the 2009 ISA but were found to be likely to be causal in 2019 could have profound impacts especially in our aging population where the cost of Alzheimer's disease may exceed costs for cardiovascular disease treatment.

2. *What are the Panel's views on the interpretation of the human exposure and animal toxicologic studies for short- and long-term $P_{M2.5}$ exposures for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ standards? To what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?*

- The selection and analysis of the human exposure and animal toxicology studies were reasonable (given the focus on biological outcomes related to causal relationships).
- The discussion of uncertainties broadly covers the topic but might have benefitted from a few concrete examples and some deeper discussion of the direction of bias, i.e. do the various uncertainties bias the effects towards the mean making it less likely that an outcome would be significant.

3. *What are the Panel's views on conclusions related to the full body of currently available epidemiologic literature, and in particular, the technical approach taken to conduct new analyses to inform our understanding of the relationship between mean $PM_{2.5}$ concentrations reported in epidemiologic studies and annual $PM_{2.5}$ design values? What are the Panel's views on the interpretation of that information and evidence for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ standards?*

- The focus on those outcomes that were deemed causal in the 2019 ISA is a useful way to assess the possibility that the NAAQS should be changed.
- It might be that if the mandate had been broadened addition significant outcomes could have been identified.

4. *What are the Panel's views on the technical approach taken to update the risk assessment, including the approach to evaluating impacts in at-risk populations? To what extent does the draft PA accurately and clearly communicate the results of these analyses? What are the Panel's views on staff's interpretation of these results for the purpose of evaluating the adequacy of the current primary $PM_{2.5}$ standards?*

- The focus on mortality is important, however PM-associated morbidity, especially in at-risk populations may affect a far greater number of individuals, be more disruptive to families and could have long term effects like inducing chronic diseases.

5. *What are the Panel's views on preliminary conclusions regarding adequacy of the current primary $PM_{2.5}$ standards and on the public health policy judgments that support those preliminary conclusions?*

    a. *Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary 24-hour $PM_{2.5}$ standard, without revision, in this reconsideration?*

        - No

    b. *Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider revising the current primary annual $PM_{2.5}$ standard in this reconsideration?*

        - Yes

6. *In the Panel's view, has the evidence and risk information, including limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative annual $PM_{2.5}$ standards? Does the discussion provide an appropriate and sufficient rationale to support preliminary conclusions regarding alternative primary annual $PM_{2.5}$ standard levels that are appropriate to consider?*

    - Yes

7. *What are the Panel's views on the areas for additional research that are identified in Chapter 3? Are there additional areas that should be highlighted?*

    - More studies of developmental toxicology and the role of PM in the etiology of cancer, chronic lung, nervous system and heart diseases, metabolic diseases including diabetes are needed.
    - The economic impact of morbidity, especially in at risk populations, on families should be given greater weight in assessing risks and evaluating efficacy of mitigation strategies.

Chapter 4 – Reconsideration of the Primary Standard for PM_{10}: *Chapter 4 summarizes key aspects of the health effects evidence that are particularly relevant to considering the adequacy of the current primary PM_{10} standard. Chapter 4 presents the preliminary conclusion that the available evidence does not call into question the adequacy of the public health protection provided by the current primary PM_{10} standard and that it is appropriate to consider retaining this standard in this reconsideration. Chapter 4 also identifies key areas for additional research and data collection, in order to inform future reviews.*

1. *To what extent does Chapter 4 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on $PM_{10-2.5}$-related health effects?*

    - Yes, but no recent studies were evaluated which could have weighed on the outcome. However, my brief review of recently published articles did not identify any seminal articles.

2. *What are the Panel's views on the interpretation of the health evidence for short- and long-term $PM_{10-2.5}$ exposures for the purpose of evaluating the adequacy of the current primary PM_{10} standard? Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?*

    - PM10-2.5 is enriched in some locations with Pb and As and may be an important route of exposure to these toxic elements. Those risks could be considered.

3. *What are the Panel's views on conclusions regarding support for new or updated quantitative analyses?*

    - More data are needed

4. *What are the Panel's views on preliminary conclusions regarding adequacy of the current primary PM_{10} standard and on the public health policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary PM_{10} standard, without revision, in this reconsideration?*

    - More data are needed

5. *What are the Panel's views on the areas for additional research that are identified in Chapter 4? Are there additional areas that should be highlighted?*

    - New studies of health effects should be encouraged
    - Better understanding of the risks associated with toxic component of PM10-2.5 might be useful.
    - Evaluate and expand the PM10-2.5 network, along with speciation of PM10-2.5 including 19 multi-elements, major ions, carbon (including carbonate carbon), and bioaerosols could be highlighted.

Chapter 5 – Reconsideration of the Secondary Standards for PM: *Chapter 5 summarizes key aspects of the welfare effects evidence that are particularly relevant to considering the adequacy of the current secondary PM standards. Chapter 5 also summarizes the quantitative assessment of visibility impairment to inform preliminary conclusions on the secondary PM standards. Chapter 3 presents the preliminary conclusion that the available evidence does not call into question the adequacy of the public welfare protection provided by the current secondary PM standards and that it is appropriate to consider retaining these standards in this reconsideration. Chapter 5 also identifies key areas for additional research and data collection, in order to inform future reviews.*

1. *To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on PM-related visibility effects?*

    - Treatment is appropriate

2. *To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related climate effects?*

    - This is an area that would benefit from additional research

3. *To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related materials effects?*

    - This is an area that would benefit from additional research

4. *What are the Panel's views on the interpretation of the evidence for PM-related welfare effects for the purpose of evaluating the adequacy of the current secondary PM standards? Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?*

    - This is an area that would benefit from additional research

5. *What are the Panel's views on conclusions regarding support for new or updated quantitative analyses? What are the Panel's views of the technical approach taken to conduct updated analyses to inform our understanding of the relationship between PM in ambient air and visibility impairment?*

    - PM is causally related to visibility reductions. It would be useful to evaluate the visibility co-benefit attributable to alternative PM NAAQS

6. *What are the Panel's views on preliminary conclusions regarding adequacy of the current secondary PM standards and on the public welfare policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current secondary PM standards, without revision, in this reconsideration?*

   - See comment in 5

7. *What are the Panel's views on the areas for additional research that are identified in Chapter 5? Are there additional areas that should be highlighted?*

   - The link between PM and climate is more than just the climate forcing effects of particles. There could be climate-mitigating effects of PM emission reductions for example by burning cleaner fuels or using more energy-efficient processes.

Dr. Stephanie Lovinsky-Desir

General Comments Chapter 3:

Overall, I believe the Approach section 3.1 is very well described and lays a nice foundation for the subsequent discussion. The Evidence-based considerations section 3.2 was a comprehensive and thorough review of the scientific evidence that supports a causal or likely causal relationship between $PM_{2.5}$ and several health outcomes. Table 3-1 was a nice visual representation of the differences in the key findings since the last PM ISA.

The ISA supplement provided a substantial amount of data regarding the increased risk of exposure and poor health outcomes in racial and ethnic minorities as well as persons with low socioeconomic status. However, it is unclear how this knowledge was incorporated, if at all, in the risk assessment models. There is a brief mention of potential at risk populations in section 3.2.2. Yet the chapter does not describe the potential additional benefit that vulnerable populations may receive from a reduction in the current air quality standards. A more thorough discussion of how a revised annual standard would impact specific vulnerable populations is warranted based on the results presented in the Draft ISA supplement.

Based on the information provided I agree with the interpretation of the results for evaluating the adequacy of the current primary $PM_{2.5}$ standards and find the results and interpretation to be compelling.

Specific Comments:

Table 3-4 refers to the epidemiologic study, Thurston 2016 and other tables refer to Thurston 2015. Please clarify which study is being referenced and consider reorganizing Table 3-4 to match the study order for the subsequent tables.

Tables 3-5 and 3-6 very nicely illustrate the point that reducing the annual average $PM_{2.5}$ concentration will have a greater impact on health related outcomes compared to reducing the 24-hour standard.

Figures 3-12 and 3-13: It would be helpful to provide additional explanation about the risk reduction that is illustrated in these 2 figures. This panel member is interpreting the findings to mean that geographic areas that currently have annual $PM_{2.5}$ concentrations within a certain range will see greater risk reductions in $PM_{2.5}$-associated mortality for the different alternative annual standards. But I am still confused about how figure 3-12 adds to this story. Please consider providing additional information in figure legends or text that clarifies how these models and figures should be interpreted.

Figure 3-13: consider adding information in the footnote regarding the significance of the different colors used in the table.

General Comments Chapter 4:

The chapter does a nice job of communicating the key aspects and limitations in the literature regarding $PM_{10-2.5}$-related health effects. The consideration of the evidence including uncertainties is both technically sound and clearly communicated. This panel member feels that the preliminary conclusions regarding the adequacy of the current primary PM_{10} standard and the public health policy judgments are supported by the data reviewed in this draft PA.

I appreciate the inclusion of section 4.5 that describes areas for future research and data collection as it has the potential to not only influence future research but also funding agencies that support air pollution research. In addition to the areas noted, I believe it would be important to specifically design and execute studies that identify the risk of exposure to PM_{10} in vulnerable populations, including children. I recommend adding research specifically targeting exposure risk and health effects in vulnerable populations as an area for future research in section 4.5.

Minor Comments:

It would be helpful if short-term and long-term exposure durations were briefly defined at the start of Chapters 3 and 4.

Dr. Jennifer Peel

Charge Question 1 Draft PA:

- Chapter 3: considering incorporating the following publications in the sections discussing experimental evidence at near-ambient concentrations:
  - Cole-Hunter T, Dhingra R, Fedak KM, Good N, L'Orange CL, Luckasen G, Mehaffy J, Walker E, Wilson A, Balmes J, Brook RD, Clark ML, Devlin RB, Volckens J, Peel JL. Short-term differences in cardiac function following controlled exposure to cookstove air pollution: the subclincal tests on volunteers exposure to smoke (SToVES) study. Env Int. 2021
  - Walker ES, Fedak KM, Good N, Balmes J, Brook RD, Clark ML, Cole-Hunter T, Dinenno F, Devlin R, L'Orange C, Luckasen G, Mehaffy J, Shelton R, Wilson A, Volckens J, Peel JL. Acute Differences in Pulse Wave Velocity, Augmentation Index, and Central Pulse Pressure Following Controlled Exposures to Cookstove Air Pollution in the Subclinical Tests of Volunteers Exposed to Smoke (SToVES) Study. Environmental Research, 2020. https://doi.org/10.1016/j.envres.2019.108831
  - Fedak KM, Good N, Walker ES, Balmes J, Brook RD, Clark ML, Cole-Hunter T, Devlin R, L'Orange C, Luckasen G, Mehaffy J, Shelton R, Wilson A, Volckens J, Peel JL. Acute changes in lung function following controlled exposure to cookstove air pollution in the subclinical tests of volunteers exposed to smoke (STOVES) study. Inhalation Toxicology. 2020.
  - Fedak KM. Good N, Walker ES, Balmes J, Brook RD, Clark ML, Cole-Hunter T, Devlin R, L'Orange C, Luckasen G, Mehaffy J, Shelton R, Wilson A, Volckens J, Peel JL. Acute effects on blood pressure following controlled exposure to cookstove air pollution in the SToVES study. J Am Heart Assoc. 2019. 8:e012246. https://doi.org/10.1161/JAHA.119.012246

Charge Question 3 Draft PA:

- Based on a robust and comprehensive evaluation of the literature, the draft PA presents a clear evaluation of relationship between new concentrations reported in epidemiologic and the annual $PM_{2.5}$ design values.
- Section 3.3 presents the relevant evidence regarding the entire body of literature of the health effects of $PM_{2.5}$ relevant for this consideration.
- The draft PA presents a clear approach to using the mean values from the newer hybrid modeling approaches.

- Particularly given the large and virtually complete samples included in the recent US and Canada studies, the focus on statistical significance on the measures of association, even in those restricting to below a specific concentration, could be emphasized less, with the focus on the continued positive association observed at those concentrations.
- The evaluation of current and alternative standards is clear and well-justified.
- Figure 3-21 presents compelling information about the heterogeneity in $PM_{2.5}$ exposure reduction and $PM_{2.5}$- attributable mortality risk estimates by race and ethnicity, with much larger reductions experienced by Black populations compared to other race/ethnicity groups.
- The risk assessment appropriately and clearly discussed sources and magnitude of uncertainty in relevant scenarios.
- The key area where evidence has been strengthened in this section is evidence available at lower $PM_{2.5}$ concentrations. In particular, the evidence from evaluations restricting concentrations below a specific threshold has been strengthened as well as accountability studies that start with concentrations below 12 ug/m3.
- Although the evidence presented for consideration of alternative annual standards of 10ug/m3 and 8 ug/m3 is strong and compelling, the evaluations rely on evidence that includes more uncertainty than the evidence at higher concentrations (e.g., the shape of the C-R down to 8 and the relative uncertainty of the estimates a lower concentrations). Thus, these sections may be benefit from a thorough discussion of the different approaches of the various studies to estimate the shape of the C-R function.

Dr. Alexandra Ponette-González

Comments on Section 1: Introduction

- Section 1 provides a useful summary of the changes in the NAAQS standards over time and a brief history of the NAAQS review process.

Comments on Section 2: Air Quality

1. *What are the Panel's views on the technical approach taken and analyses completed to inform our understanding of how $PM_{2.5}$ concentrations calculated using composite monitors and area averages from hybrid modeling approaches compare to area design values?*

- Section 2.3.3 provides a concise explanation of the types of hybrid modeling approaches used as well as comparisons among these methods and variations in their performance by season, region, and concentration level.
- Given the various hybrid modeling approaches and the limited number of intercomparison studies, the more explicit, in-depth comparison of the two approaches utilized in epidemiologic studies reviewed in the 2019 ISA and draft ISA is appropriate.
- Results from the comparison involving four and two-methods are ultimately in agreement: performance and predictions are weaker for the western US, at lower concentrations, and in areas with sparse monitoring, and both data resolution and scale of analysis influence PM estimates.

To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for this reconsideration?

- Overall, the information on major PM emissions sources, PM monitoring, PM trends and relationships, modeling approaches, and background PM is clear and well presented. However, there are some areas where additional details would improve the clarity of the text. I also provide a few references, many of which fall within the period of the literature review for the supplement.

Subsection 2.1.1.1 Sources Contributing to Primary $PM_{2.5}$ Emissions

- Fires alone represent 43% of $PM_{2.5}$ national emissions.
- Giving the increasing frequency, extent, and magnitude of wildfires in many US regions, this section on $PM_{2.5}$ sources would benefit from expanded discussion of changing wildfire regimes over the past decade both for context and to highlight impacts on PM and its components.

- Although the relative importance of $PM_{2.5}$ sources differs by location, with fires more important at the national level and mobile sources more important in urban areas, increasing contribution of smoke from wild and prescribed fires to $PM_{2.5}$ in urban counties and associated effects on urban residents is worth mentioning (i.e., smoke at the wildland-urban interface). As an example, Colin L. et al. (2021) found a more than 100% increase in population growth between 1990 and 2010 in areas at the wildland-urban interface designated as high fire danger areas. This finding underscores the growing number of people who will be affected by smoke in the future.
- It also raises the question of whether the exceptional events rule will protect public health and welfare in the future (David et al. 2021).

<u>Subsection 2.1.1.2 Sources Contributing to Primary PM_{10} Emissions</u>

- In this section, it would be worthwhile to repeat that dust PM_{10} emissions include those from agricultural, construction, and road dust, while fire PM_{10} emissions include those from wildfires, prescribed fires, and agricultural fires.

<u>Subsection 2.2.3.2 Chemical Speciation and IMPROVE networks</u>

- There are numerous networks and stations monitoring $PM_{2.5}$ across the US. It is unclear how many sites in total are monitoring fine particle components across the CSN, NCore, and IMPROVE networks. A summary of this information in a simple table would be helpful (consisting of the name of the network, the numbers of monitors, locations in rural and urban areas).

<u>Subsection 2.2.3.3 Recent Changes to $PM_{2.5}$ Monitoring Requirements</u>

- After mentioning the addition of $PM_{2.5}$ monitoring at near-road locations, I suggest adding "within 50 m of roads" in parentheses.

<u>Subsection 2.3.1 Trends in Emissions of PM and Precursor Gases</u>

- Line 23 states that "emissions from dust and fires have increased over this time", but the time period is unclear. Two time periods are reported in Table 2-1. Is it 1990-2017? Or 2002-2017?
- Why are emissions from wildfires (reported in the NEI) not included in Figure 2-14 and Table 2-1?

<u>Subsection 2.3.2 Trends in Monitored Ambient Concentrations</u>

- Page 2-27: The highest ambient $PM_{2.5}$ concentrations are in the West, where wildfires continue to limit improvements particulate matter air quality (McClure et al. 2018). The McClure and Jaffe 2018 reference provides support for this statement.

<u>Subsection 2.3.2.2.2 $PM_{2.5}$ Near Major Roadways</u>

- This subsection states that "$PM_{2.5}$ is expected to exhibit less spatial variability on an urban scale than UFP or coarse PM". Although outside the scope of the review, recent research highlights differences in the spatial and temporal profiles of UFP and co-emitted pollutants on very fine spatial scales (Gani et al. 2021).

- It is also important to recognize the growing body of knowledge on spatial and temporal variability in atmospheric $PM_{2.5}$ and PM_1 concentrations derived from mobile monitoring campaigns (Apte et al. 2017; Li et al. 2019; Chambliss et al. 2020). Several of these studies reveal disparities in PM exposure and risk by race and ethnicity at fine spatial scales (Southerland et al. 2021; Chambliss et al. 2021). Note that some of the cited studies fall outside of the scope of the review period for this PM supplement (i.e., Chambliss et al. 2021).

<u>Subsection 2.3.2.6 UFP</u>

- A few additional references on UFP include Li et al. (2019) and Presto et al. (2021).
- Figure 2-27 should indicate in the figure caption and/or figure that these data refer to UFP.
- Lines 7-8 are confusing. "Particle number concentrations at this site (which site? Bondville?) are closer to those of the background site in Figure 2-27 (which background site)". This sentence needs to be clarified.

<u>Section 2.4 Background PM</u>

- How many sites were used to determine the annual background $PM_{2.5}$ concentrations in the 2012 review?

<u>Minor Edits</u>

- Page 2-4, Line 18: change "mobiles sources" to mobile sources.
- Page 2-25, Line 21: remove "a" before Table 2-1.
- Page 2-60. Add a period at the end of the first sentence.

<u>Additional references within the time frame of the PM Review (January 2018 through March 2021)</u>

- McClure, C. D., & Jaffe, D. A. (2018). US particulate matter air quality improves except in wildfire-prone areas. *Proceedings of the National Academy of Sciences*, 115(31), 7901-7906.
- Apte, J. S., Messier, K. P., Gani, S., Brauer, M., Kirchstetter, T. W., Lunden, M. M., ... & Hamburg, S. P. (2017). High-resolution air pollution mapping with Google street view cars: exploiting big data. *Environmental Science & Technology*, 51(12), 6999-7008.
- Li, H. Z., Gu, P., Ye, Q., Zimmerman, N., Robinson, E. S., Subramanian, R., ... & Presto, A. A. (2019). Spatially dense air pollutant sampling: Implications of spatial variability on the representativeness of stationary air pollutant monitors. *Atmospheric Environment: X*, *2*, 100012.
- Chambliss, S. E., Preble, C. V., Caubel, J. J., Cados, T., Messier, K. P., Alvarez, R. A., ... & Apte, J. S. (2020). Comparison of mobile and fixed-site black carbon measurements for high-resolution urban pollution mapping. *Environmental Science & Technology*, 54(13), 7848-7857.
- Southerland, V. A., Anenberg, S. C., Harris, M., Apte, J., Hystad, P., van Donkelaar, A., ... & Roy, A. (2021). Assessing the Distribution of Air Pollution Health Risks within Cities: A

Neighborhood-Scale Analysis Leveraging High-Resolution Data Sets in the Bay Area, California. *Environmental Health Perspectives*, 129(3), 037006.

- Presto, A. A., Saha, P. K., & Robinson, A. L. (2021). Past, present, and future of ultrafine particle exposures in North America. *Atmospheric Environment: X*, *10*, 100109. for the section on UFP
- Miller, C., O'Neill, S., Rorig, M., & Alvarado, E. (2019). Air-quality challenges of prescribed fire in the complex terrain and wildland urban interface surrounding Bend, Oregon. *Atmosphere*, 10(9), 515.
- Bowman, D. M., Daniels, L. D., Johnston, F. H., Williamson, G. J., Jolly, W. M., Magzamen, S., ... & Henderson, S. B. (2018). Can air quality management drive sustainable fuels management at the temperate wildland–urban interface? *Fire*, 1(2), 27.
- David, L. M., Ravishankara, A. R., Brey, S. J., Fischer, E. V., Volckens, J., & Kreidenweis, S. (2021). Could the exception become the rule? 'Uncontrollable' air pollution events in the US due to wildland fires. *Environmental Research Letters*, 16(3), 034029.

<u>Additional references outside the time frame of the PM PA Review (January 2018 through March 2021)</u>

- Gani, S., Chambliss, S. E., Messier, K. P., Lunden, M. M., & Apte, J. S. (2021). Spatiotemporal profiles of ultrafine particles differ from other traffic-related air pollutants: lessons from long-term measurements at fixed sites and mobile monitoring. *Environmental Science: Atmospheres*.
- Chambliss, S., Pinon, C., Messier, K., LaFranchi, B., Upperman, C., Lunden, M., ... & Apte, J. (2021). Local and Regional-Scale Racial and Ethnic Disparities in Air Pollution Determined by Long-Term Mobile Monitoring.
- Peterson, G. C. L., Prince, S. E., & Rappold, A. G. (2021). Trends in Fire Danger and Population Exposure along the Wildland–Urban Interface. *Environmental Science & Technology*.

Comments on Section 5: Reconsideration of the Secondary Standards for PM

1. *To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on PM-related visibility effects?*

- Chapter 5 provides a good synthesis of the evidence on PM-related visibility effects presented in the 2019 PM ISA and the draft ISA Supplement. There is a clear causal relationship between PM and visibility effects. However, there are limited new data on the relationship between PM and light extinction or on methods for directly measuring light extinction. The accuracy of the IMPROVE algorithm for estimating light extinction in the context of changing PM composition has been assessed and studies suggest that inputs to the equation may need to be region specific.

- More information on the effects of coarse PM on light extinction would be beneficial in this section given that impacts are higher in some areas, such as the Southwest, than in others. The text simply describes that coarse PM has a "modest impact".

2. *To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related climate effects?*

- As with visibility effects, Chapter 5 characterizes well the evidence on PM-related climate effects presented in the 2019 PM ISA and the drat ISA Supplement. While there is a clear causal relationship between PM and climate effects, there remain large uncertainties in relationships between PM and climate impacts at regional scales. Moreover, interactions and feedbacks in the climate system make it difficult to establish clear relationships between PM, radiation, and cloud processes.
- Given the discussion of the IPCC AR5 in the context of PM-related climate effects, it may be worth citing the IPCC Sixth Assessment Report, the first part of which was published in 2021.

3. *To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM-related materials effects?*

- Chapter 5 offers a good summary of the current evidence on PM-related materials effects. There is a causal relationship between the deposition of PM and soiling and corrosion of materials, but quantitative information on these relationships is lacking, and new information is from outside the US where PM levels are generally higher than in the US.

4. *What are the Panel's views on the interpretation of the evidence for PM-related welfare effects for the purpose of evaluating the adequacy of the current secondary PM standards? Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?*

- This section of the assessment is comprehensive in its review of the evidence, including limitations and uncertainties in the existing data.
- Figure 5-2 presents a graph of the relationship between light extinction and viewer acceptability ratings. The graph shows acceptability below 50% at deciviews ranging from 20-30. Figures 5-3 and 5-4 show that most areas meeting the $PM_{2.5}$ 24-hour standard have light extinction estimates below 30 dv. Despite the uncertainties and limitations of the visibility preference studies, it is not clear why 30 dv was selected as the appropriate target rather than 20 dv or 25 dv, the midway point between 20-30 dv.

5. *What are the Panel's views on conclusions regarding support for new or updated quantitative analyses? What are the Panel's views of the technical approach taken to conduct updated analyses to inform our understanding of the relationship between PM in ambient air and visibility impairment?*

- For climate and materials effects, it was concluded that new quantitative analyses were not warranted due to the limitations and uncertainties in the evidence in both areas. The conclusions are sound.
- With respect to visibility, comparisons of the relationship between the 98th percentile of daily $PM_{2.5}$ and the 90th percentile daily light extinction using the original IMPROVE equation and revisions of the equation are useful for understanding visibility effects under current air quality conditions and how relationships between PM and light extinction vary depending on the inputs to the IMPROVE equation.
- I am unsure why Figure D-2 was placed in the Appendix rather than in the main text. A three-panel figure including the analyses with the original, revised, and Lowenthal and Kumar equation would be better.

6. *What are the Panel's views on preliminary conclusions regarding adequacy of the current secondary PM standards and on the public welfare policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current secondary PM standards, without revision, in this reconsideration?*

- The preliminary conclusions for visibility, climate, and materials effects are sound.
- Given current scientific understanding of quantitative relationships between PM, visibility impairment, climate impacts, and materials damage, and given limited new evidence since the last review, it is appropriate to consider retaining the secondary PM standards.
- For visibility, specifically, most locations meeting the daily $PM_{2.5}$ standard experience visibility index values below 30 deciviews, the target level of protection for visibility-related welfare effects.

7. *What are the Panel's views on the areas for additional research that are identified in Chapter 5? Are there additional areas that should be highlighted?*

- Chapter 5 highlights several limitations with visibility preference studies, including the fact that many of these were conducted 15-30 years ago and may no longer reflect current preferences.
- There is a clear need for more research on visibility preferences, especially in the context of: (1) increasing wildfire and dust emissions across several US regions, especially in the US West; (2) the rise in national park visitation in many western US Class I Areas prior to and following

COVID-19 shutdowns (NPCA 2021); and (3) the documented need for greenspace and outdoor recreation in urban areas during COVID.

- Understanding how changes in the frequency of high/extreme PM episodes coupled with increased desire to experience outdoor environments influence visibility preferences is an area ripe for further research.
- Given the rapidly growing body of knowledge on airborne microplastics, this represents an important area of future research with respect to effects both on visibility and climate.

Minor Edits

- Page 5-7, Line 10: delete the word “in” which is repeated twice.
- Page 5-21, Line 36: delete the word “during” before “from”
- Page 5-25, Line 33: Remove the “7” from “t7he”
- Page 5-34, Line 18: The Ban-Weiss et al. paper was published in 2014. Delete the word “recent” at the beginning of the sentence.
- Page 5-41, Line 6: Delete “under”

References

NPCA. Accessed 12 November 2021. https://www.npca.org/articles/2919-position-on-the-impacts-of-covid-19-and-visitation-to-the-national-park

Dr. David Rich

What are the Panel's views on conclusions related to the full body of currently available epidemiologic literature, and in particular, the technical approach taken to conduct new analyses to inform our understanding of the relationship between mean PM2.5 concentrations reported in epidemiologic studies and annual PM2.5 design values? What are the Panel's views on the interpretation of that information and evidence for the purpose of evaluating the adequacy of the current primary PM2.5 standards?

Conclusions made in the draft PA are generally justified, although there are studies from the ISA or draft ISA supplement that should be added. Further, more justification for restricting this supplement to only studies conducted in the US and Canada should be added to the document. Specific comments on these and other comments on the draft PA text are provided below.

1. Page 3-42, line 6 – A minor comment, but it is not necessarily a limitation of the previous studies of air pollution and birth outcomes that an individual window of susceptibility during pregnancy has not been identified across studies. It may be that there are multiple windows, and different effects of exposures in different windows. This should be removed as a limitation.
2. Page 3-77 and 3-78 - Figure 3.6 – CV Morbidity – Studies from the ISA and draft ISA supplement studying $PM_{2.5}$ and myocardial infarction, specifically STEMI, are missing and should be included here. US and Canadian studies examining this association are listed below. There are also other studies in Europe and Asia that could be included, even if the average $PM_{2.5}$ concentrations in those studies are higher that those listed below.

   *Evans, KA, et al***.** *Triggering of ST-elevation myocardial infarction by ambient wood smoke and other particulate and gaseous pollutants. Journal of Exposure Science and Environmental Epidemiology 2017;27(2):198-206.*

   Gardner B, et al. Ambient fine particulate air pollution triggers ST-elevation myocardial infarction, but not non-ST-elevation myocardial infarction. Particle & Fibre Toxicology 2014;11(1):1

   Pope CA, et al. Short-term exposure to fine particulate matter air pollution is preferentially associated with the risk of ST-segment elevation acute coronary events. J Am Heart Assoc 2015;4(120): e002506.

Wang M, et al. Triggering of ST-elevation myocardial infarction by particulate air pollution in Monroe County, New York; before, during, and after multiple air quality policies and economic changes. Environmental Health 2019;18(1):82.

Wang X, et al. Air pollution and acute myocardial infarction hospital admission in Alberta, Canada: A three-step procedure case-crossover study. PLoS One 2015;10(7). :e0132769.

3. Page 3-78, Figure 3.6 – Other papers from the NY accountability study examined $PM_{2.5}$ and the rate of hospitalizations and emergency department visits for asthma and respiratory infection, and could be included in this figure and the text describing it.

   Croft D, et al. Triggering of respiratory infection by air pollution: impact of air quality policy & economic change. Annals of the American Thoracic Society 2019;16(3)321-330.

   Hopke PK, et al. Changes in the acute response of respiratory diseases to $PM_{2.5}$ in New York State from 2005 to 2016. Science of the Total Environment 2019;677:328-339.

4. Page 3-124, line 7+ - Squizzato et al (2018) describes changes and trends in $PM_{2.5}$ and other pollutant concentrations at several sites in New York State from 2005-2016, and how they changed relative to several air quality policies/actions and an economic recession in the state and region. $PM_{2.5}$ concentrations were <12 μg/m^3 in several of the locations. Health effects associated with these low $PM_{2.5}$ concentrations are provided in several papers provided above. The Squizzato et al (2018) paper could be added and described in the text here.

   Squizzato S, et al. $PM_{2.5}$ and gaseous pollutants in New York State during 2005-2016: spatial variability, temporal trends, and economic influences. Atmospheric Environment 2018;183:209-224.

5. Page 3-128, line 21 – *"…while epidemiologic studies indicate associations between $PM_{2.5}$ and health effects, they do not identify particular $PM_{2.5}$ exposures that cause effects*." Please clarify what feature(s) of "exposure" you are referring to here? Duration? Location? Composition or source of PM? Further, what is required for a "particular $PM_{2.5}$ exposure" to cause an effect?
6. Page 3-158, line 1-4 – "*While some studies evaluate the health effects of particular sources of fine particles, or of particular fine particle components, evidence from these studies does not identify any one source or component that is a better predictor of health effects than $PM_{2.5}$ mass*" – For this topic, the draft PA is missing several papers from our group (listed below). They are part of a study in NY State examining trends in PM and other pollutants at 6 urban sites and 2 background sites, conducting source apportionment at those 6 urban sites, and epidemiology studies examining changes in the rate of total and cause-specific cardiovascular, respiratory, and

respiratory infectious disease hospitalizations and emergency department visits associated with $PM_{2.5}$ and source-specific $PM_{2.5}$ contributions. Although this study and these papers from it are not enough to justify a change away from regulating $PM_{2.5}$ for PM mass, they could/should be discussed more fully in the ISA supplement and discussed in the PA alongside other accountability studies.

Croft D, et al. Triggering of respiratory infection by air pollution: impact of air quality policy & economic change. Annals of the American Thoracic Society 2019;16(3)321-330.

Croft D, et al. Associations between source-specific particulate matter and respiratory infections in New York State adults. Environmental Science & Technology 2020;54(2):975-984.

Hopke PK, et al. Changes in the acute response of respiratory diseases to $PM_{2.5}$ in New York State from 2005 to 2016. Science of the Total Environment 2019;677:328-339.

Hopke PK, et al. Changes in the hospitalizations and emergency department visits for respiratory diseases to source-specific PM2.5 in New York State from 2005 to 2016. Environmental Research 2020;181:108912.

Masiol M, et al. Long-term trends (2005-2016) of source apportioned $PM_{2.5}$ across New York State. Atmospheric Environment 2019;201:110-120.

Rich DQ, et al. Triggering of cardiovascular hospital admissions by source specific fine particle concentrations in New York State. Environment International 2019;126:387-394.

Squizzato S, et al. $PM_{2.5}$ and gaseous pollutants in New York State during 2005-2016: spatial variability, temporal trends, and economic influences. Atmospheric Environment 2018;183:209-224.

Squizzato S, et al. A long-term source apportionment of $PM_{2.5}$ in New York State during 2005 to 2016. Atmospheric Environment 2018;192:35-47.

Wang M, et al. Triggering of ST-elevation myocardial infarction by particulate air pollution in Monroe County, New York; before, during, and after multiple air quality policies and economic changes. Environmental Health 2019;18(1):82.

Zhang W, et al. Triggering of cardiovascular hospital admissions by fine particle concentrations in New York State: before, during, and after implementation of multiple environmental policies and a recession. Environmental Pollution 2018;242(Pt B):1404-1416.

7. Page 3-162, lines 14-19 & Page 3-169, lines 20-25: "Key epidemiology" study designs (time-series and cohort) are discussed and what confounders are traditionally included in the design provided. However, case-crossover studies, which are frequently the study design of studies examining short-term associations between air pollutant concentrations and cardiovascular morbidity outcomes including myocardial infarction, are not described. These studies are reviewed in the draft ISA supplement, and should be included in this PA as well (see Comment #2 above). A description of the design and potential confounders controlled for by design (e.g., non-time varying confounders including genetic characteristics, demographics, and disease/health history) and those typically included in their analytic models (e.g., factors that vary within a few days such as ambient temperature and relative humidity) should be provided.
8. Page 3-167, lines 25-27: *"How do the study-reported $PM_{2.5}$ concentrations corresponding to the 25th and 10th percentiles of health data or exposure estimates provide insight to inform our consideration of the level of the current annual PM2.5 standard?"* - It is not clear from the description provided what is meant by "*the 25th and 10th percentiles of health data or exposure estimates"*. Of what variable(s) are you examining the distribution and noting the 25th and 10th percentile? Is this the $PM_{2.5}$ concentration distribution of concentrations used in a study, and the 25th and 10th percentiles from that distribution? Please redraft this to make it clearer what this is.
9. Page 3-190, lines 7-10: "*While some studies evaluate the health effects of particular sources of fine particles, or of particular fine particle components, evidence from these studies does not identify any one source or component that is a better predictor of health effects than $PM_{2.5}$ mass*". What would be used to judge whether an individual source or component is a better predictor of health effects? What are you looking for in studies examining sources and components? Here and throughout the PA draft, what would define a "better predictor" should be described. I expect this has been defined in previous ISA's. However, it should be included with each statement of this conclusion regarding whether individual sources or components are "better predictors" of health effects than $PM_{2.5}$.

What are the Panel's views on the areas for additional research that are identified in Chapter 3? Are there additional areas that should be highlighted?

1. A few future research areas should be highlighted. First, the discussion of accountability studies should include studies that address both changes and trends in pollutant concentrations, but also studies that examine changes in PM <u>composition</u> and changes in PM <u>sources</u>. In addition to accountability studies that assess whether a policy results in reductions in PM concentration, such studies should also evaluate whether any changes in PM composition alter the rate of health effects associated with each incremental increase in PM concentration (e.g., is there any change over time in the rate of a health effect associated with each 10 μg/m^3 increase in $PM_{2.5}$

concentration in a population, and are there also simultaneous changes in PM sources and PM composition in the same population?). Future research should be conducted to provide both information on health effects associated with changes/reductions in $PM_{2.5}$ concentrations, but also how those effects may simultaneously be affected by concomitant changes in the composition of PM.

2. Second, similar to $PM_{2.5}$, studies on UFP should examine trends in the concentrations of different sizes of particles <100nm, and conduct source apportionment of UFP in multiple areas in the US. This work is very limited now, due to the lack of continuous UFP measurements at US monitoring sites.
3. The draft PA and draft ISA supplement describe studies examining potential mechanisms by which $PM_{2.5}$ and other pollutants may lead to cardiorespiratory health events. Studies examining health effects of air pollution exposure during pregnancy and associations with adverse pregnancy outcomes (e.g., fetal growth restriction, preterm birth) as well as outcomes in childhood (e.g., neurodevelopment) should also include examination of potential mechanisms mediating and modifying such effects. These should be done in epidemiology and toxicology studies, and again would provide biologic justification for previous studies finding associations between PM exposure during pregnancy and adverse pregnancy and childhood outcomes.

Dr. Jeremy Sarnat

Chapter 2 – Air Quality

1. What are the Panel's views on the technical approach taken and analyses completed to inform our understanding of how PM2.5 concentrations calculated using composite monitors and area averages from hybrid modeling approaches compare to area design values? 2. To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for this reconsideration?

2. In the Panel's view, has the evidence and risk information, including limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative annual PM2.5 standards? Does the discussion provide an appropriate and sufficient rationale to support preliminary conclusions regarding alternative primary annual PM2.5 standard levels that are appropriate to consider?

Chapter 2 of the Policy Assessment is clear, comprehensive, and well-written, generally following a similar template used in previous ISA.

- 2-30. The issue of correlations among PM concentrations using varying averaging times has substantial policy implications and Figure 2-17 is useful for assessing the suitability of the current temporal averaging time and design values. Small point, but were non-parametric correlations examined (i.e., Spearman correlations)? I would think that the differences won't be great, but given the right-skewed PM distributions, which is clearly presented throughout this chapter, I would prefer to use non-parametric descriptive statistics and metrics of association.
- A similar comparison of temporal correlations among various sub-daily PM metrics (i.e., mean, median, peaks, 25/75 pctl, rush hour/non-rush hour)) would also be useful as it relates to observed health effects when evaluating varying exposure windows.
- There is too little attention given to biogenic PM, especially SOA, other than noting that the source contributions and chemistry are complex and uncertain. While this continues to be an active area of research, I think this chapter can devote a bit more attention to contextualizing the scale of these contributions, whether EPA believes this to be a substantial source relative to other sources, and the chemistry and potential toxicity of biogenic PM. While it is likely that this PM source is far less important from burden of health standpoint, a more thorough treatment of biogenic PM may preemptively assuage concerns about exposure and health risk.

Chapter 3 – Reconsideration of $PM_{2.5}$

CQ 6. In the Panel's view, has the evidence and risk information, including limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative annual PM2.5 standards? Does the discussion provide an appropriate and sufficient rationale to support preliminary conclusions regarding alternative primary annual PM2.5 standard levels that are appropriate to consider?

- I support the EPA's general summary that the evidence provided in the supplement to the 2019 PM ISA and policy implication outlined in the current Policy Assessment 'support and in some instances strengthen' the evidence relating to causal determination for many of the health outcome categories considered. Specifically, I believe the additional epidemiologic evidence conducted in locations with mean fine PM concentrations below the current standards, the causal modeling findings, and the results from the cited accountability studies firmly support a reconsideration of the current PM NAAQS and their ability to adequately protect human health. The comments below largely focus on minor observations not likely to impact my overall impression of this chapter or collective summary for the Policy Assessment.

- I also agree with the conclusion that the annual standard probably serves as the controlling standard, especially given the averaging time and mortality outcomes considered within the risk assessment. I also accept, although with more reservations, that the form of the 24h standard, which is based on the 98^{th} percentile of the distribution, probably does capture and hopefully provides protection against peak exposures. I'd be curious to results from a sensitivity analysis varying the form in risk assessments for morbidity outcomes. In any case. I strongly support the statement on 3-201 that more research is probably needed on sub-daily exposures and response on a population level. (See comments below on what specific endpoints might be considered).

- I'd also suggest including panel-based designs as a means and method for elucidating these short-term exposures and response. While lacking rigorous controls of experimental or controlled exposure designs, I do believe that there is an increasing body of critical mass data from panel studies to inform this issue, warrant discussion within this section, and deserve greater attention in future ISA drafts.

- Uncertainties regarding the shape of the C-R function at low concentrations is both critical and currently unresolvable. In this PA, the EPA authors take and clearly articulate what I feel is an appropriately cautious view of these observed functions at low concentrations due to the '[r]elatively low data density in the lower concentration range, the possible influence of exposure measurement error, and variability among individuals with respect to air pollution health effects. These sources of variability and uncertainty tend to smooth and "linearize" population-level concentration-response functions and thus could obscure the existence of a threshold or nonlinear relationship'. This language is good and differs somewhat from the corresponding interpretation of the science found In the Supplement to the PM ISA. (see Fig 3-17 and discussion from the Supplement to the ISA).

- The inclusion of analyses and risk estimates for at-risk populations, especially communities-of-color and low SES communities, is a welcome and overdue addition to this PA and the ISA process, generally.

CQ 7. What are the Panel's views on the areas for additional research that are identified in Chapter 3? Are there additional areas that should be highlighted?

With regard to averaging time, I generally agree with the EPA's conclusion in the PA that the observational and experimental evidence currently available do not support consideration of a sub-daily PM standard. However, I do believe that a growing number of studies will provide information in the near future on exposure to PM from 1 to 6 hours and associations with clinical effects, including MI's, out of hospital cardiac arrest, and cardiac arrhythmias. Section 3.5.1.3 alludes to these outcomes and the current state-of-the-science and Section 3.5.3.2.2 adequately justifies the EPA's decision to retain the existing averaging times.

Dr. Neeta Thakur

Chapter 3 – Reconsideration of $PM_{2.5}$

4. What are the Panel's views on the technical approach taken to update the risk assessment, including the approach to evaluating impacts in at-risk populations?

General Comments:

The main document text of the technical approach could improve by increasing the level of detail to better understand the **rationale** of the approach taken for the risk assessment, below I've highlighted areas where this could improve:

- Why limited to mortality? Section 3.4.1.2 starts by stating "consistent with the overall approach for this reconsideration, this risk assessment has a targeted scope that focuses on mortality", yet the ISA supplement to the 2019 ISA presents health effects for cardiovascular morbidity. The rationale for not including cardiovascular morbidity as part of the risk assessment needs to be added as this has had reached the level of causality based on the 2019 ISA. It may be that there is enough evidence with mortality that cardiovascular morbidity does not need be considered; if this is the case, this rationale should be included in this section (3.4.1.2).
- Section 3.4.1.2: How were the studies from Table 3-13 were considered (or used) when developing the risk assessment model for different levels of exposure. Were these the studies for which lower concentration-response effects were observed? Making extrapolation easier? Additionally, while the PA states that concentration-response were estimated from the effects observed from these studies, it is less clear how the population structures of those studies were considered in the models over the 47 urban study areas. I only began to understand some of this nuance after reading the appendix, some of the text there should be moved to this section, specifically how population structure variables are considered.
- Section 3.4.1.2: For mortality, the level of analysis is not mentioned in the main text. I was only able to locate this in Appendix C which reports this at the county level for baseline data. Given the variability within each urban area, rational as to why this area unit selected is needed. Would also consider refining to the zip code level within each of the 47 urban areas as a sensitivity analysis (in addition to the analysis at the 12km grid cell level). This would allow both the variability in exposure and variability in the outcome over the 47 urban areas to be consider simultaneously. One limitation to this approach would be if the mortality data is not available at the zip code level (currently states that baseline mortality data is at the county level, however these data are likely available at the zip code level).

- 3.4.1.3 Additional information on the rationale for assuming (or deciding to use) a linear relationship at lower concentration levels is needed. This may include a statement that "the threshold effect is likely at very low levels, i.e. < 8ug/m3."
- 3-133, ln 10-12: Appreciate the inclusion of two methods that would lead to reduction in PM2.5. The rationale (and the expected outcome *differences* on health with each method) as to why two adjustment approaches were considered would be helpful.
- Page 3-135, Lines 16-22 identify that the following demographics may increase health risk from PM2.5: lifestage, race/ethnicity, and SES. The rationale for why risk assessments were only considered for race/ethnicity followed; however, this rationale is a bit diffuse and could benefit from tightening up the language to allow the reader to more clearly understand why lifestage and SES were not considered. For example – for older populations, hastened mortality may be an important end-point, but accounting for the multitude of confounders here (e.g. pre-existing disease, frailty, etc), this assessment would be difficult. For SES, my assumption is that this was not pursued given that lack of conclusion that there is "adequate evidence" for a causal relationship with PM2.5.

**While the variability and uncertainty associated with some of the choices listed above is noted in section 3.4.2.5, we still do not have insight as to the rationale for these choices.

To what extent does the draft PA accurately and clearly communicate the results of these analyses?

-The results of the analyses are easy to follow, especially with main takeaways being bulleted text. Agree with the suggestion by Dr. Fuller to reorganize figures 3-19 & 3-20 to have the race/ethnicity data presented alaphabetically
- More of a comment, while the gap in mortality decreases as the standard goes down, it persists. More explanation of why this persists and what future efforts are needed better understand the persistence of this disparity are critical.

What are the Panel's views on staff's interpretation of these results for the purpose of evaluating the adequacy of the current primary PM2.5 standards?

-The interpretation is appropriate cautious in its interpretation while still definitely highlighting the reduction in mortality estimates modelled with decreasing the annual PM2.5 standard. EPA staff also does a nice job of summarizing the sources for uncertainty in the results presented.

<u>Specific Comments</u>

- Page 3-133 ln 32 (Appendix C-47 ln 6-8, Figure C-26-28 & C-31) states the 47 urban study areas but the PM2.5 modeling is occurring over a 12km grid (section 3.4.1.4). In Appendix C, risk assessment analyses are also presented at the grid level. If would be helpful to include in the main document that additional/sensitivity analyses were repeated at this area unit and reference this section.

- Page 3-153, ln 1-10: EPA staff highlight the wide CI for mortality estimates derived for the short-term PM2.5 exposure and the variability across studies (e.g., CI for estimates derived using the Zanobetti study were narrower), was this variability (and direction of variability) expected? EPA staff provides very generic statements as to the source of the variability. The confidence in the risk assessment results would improve if, when selecting the studies to include, there already understanding of how these different studies would perform in the model.

- Unable to locate Table C-32 in Appendix C

7. What are the Panel's views on the areas for additional research that are identified in Chapter 3? Are there additional areas that should be highlighted?

Overall, the EPA staff summarized well the areas highlighted for additional research. Would emphasize that for many of these areas, including a focus on health equity, which includes ensuring adequate sample size across sub-populations, examining for exposure burden (both short-term and long-term) and health effects.

- Page 3-203 ln 25-27: In addition to health impacts would include "physiologic measures", these include lung function testing and blood pressure
- Page 3-204, ln 1-3: Does this include measuring health effects of PM2.5 components?
- Other areas of research needed are:

  - Continued development of models that take into account low-cost sensor data (e.g. purple air) to improve granularity of measurement and decrease misclassification of exposure
  - Understanding how different composition of PM2.5 is distributed over populations and the health effects of these sub-components? This would improve understanding of which PM2.5 sources should be prioritized and how these sub-components may contribute to disproportionate exposure and health effect (even if two communities have similar annual PM2.5 exposure)
  - Understanding of how annual PM2.5 exposure changes susceptibility to short-term exposure.
  -

Chapter 4 – Reconsideration on PM_{10}

1. To what extent does Chapter 4 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA on PM10-2.5-related health effects?

2. What are the Panel's views on the interpretation of the health evidence for short- and long-term PM10-2.5 exposures for the purpose of evaluating the adequacy of the current primary PM10 standard?

Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

The summary of health effects come from the 2019 ISA with no new studies to consider. The EPA staff summarizes the general findings in the 2019 ISA and highlight areas of uncertainty. This includes potential confounding by copollutants that may be driving the PM10 associated risk for health and issues related to measurement. The summary was clearly written, and it was easy to follow the rationale for retaining the PM10 standards.

3. What are the Panel's views on conclusions regarding support for new or updated quantitative analyses?

- Health effects are summarized from the 2019 ISA, no new studies are included in this PA.
- For each health effect, the same conclusions were drawn and there was concern raised regarding confounding with copollutants, particularly with PM2.5. There doesn't appear to be a "re-look" of the studies included in the 2019 ISA.
- I agree that the same concerns raised in the 2019 ISA are still present.

4. What are the Panel's views on preliminary conclusions regarding adequacy of the current primary PM10 standard and on the public health policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary PM10 standard, without revision, in this reconsideration?

- Given that no new studies have resulted since the publication cutoff for the 2019 ISA, the rationale for retaining the current primary PM10 standard is adequate and appropriated based on the degree of evidence provided.

5. What are the Panel's views on the areas for additional research that are identified in Chapter 4? Are there additional areas that should be highlighted?

- Page 4-18, ln 30-34: Would expand to include development of low-cost sensors that provide direct measurement would additionally fill in the sparse PM10-2.5 monitoring network. This would also improve understanding of disproportionate burden of exposure across communities (this also aligns with the area identified on page 4-19 ln 9-18)
- Similar to above, would emphasize a focus on health equity, which includes ensuring adequate sample size across sub-populations, examining for exposure burden (both short-term and long-term) and health effects.

Dr. Barbara Turpin

Chapter 1 – Introduction: *Chapter 1 provides introductory information including a summary of the legislative requirements for the NAAQS, an overview of the history of the PM NAAQS and the decisions made in prior reviews, and a summary of the scope and approach for the reconsideration of the 2020 final decision.*

1. To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for this reconsideration?

I think Chapter 1 of the Policy Assessment is clearly presented and provides useful context.

Chapter 2 – Air Quality: *Chapter 2 describes the major PM emissions sources; the atmospheric chemistry related to PM in ambient air; the PM monitoring network; PM ambient air quality trends and relationships; an overview of hybrid modeling methods used to estimate PM2.5 concentrations; analyses to inform our understanding of mean PM2.5 concentrations from monitors and hybrid models and their relationships with design values; and background PM.*

1. What are the Panel's views on the technical approach taken and analyses completed to inform our understanding of how PM2.5 concentrations calculated using composite monitors and area averages from hybrid modeling approaches compare to area design values?

The approach taken is thorough, appropriate and informative. Another issue that should be discussed is comparison of concentrations between FRM and FEM samplers.

2. To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for this reconsideration?

The material in Chapter 2 is generally clearly presented and provides useful context for consideration. As noted below, the limitations posed by emissions estimate uncertainties are overstated, and the understanding of anthropogenic emissions on secondary organic aerosol formation from biogenic VOCs is not adequately recognized. See comments below.

Page 2-3 line 25: calls “oxidation of biogenic hydrocarbons such as isoprene and terpenes to produce secondary organic aerosol” a natural source of SOA. However, biogenic SOA is not necessarily natural. For example, SOA formation from isoprene oxidation products (i.e., isoprene epoxydiol) is dependent on the acidity (and liquid water) associated with sulfate, and sulfate is largely anthropogenic. Thus, IEPOX SOA is formed as a result of reactions with anthropogenic emissions and is not natural. Field studies and modeling suggest that it is a major source of aerosol in the southeastern US in both rural and urban locations and that it is controllable by reducing sulfate.

- Budisulistiorini, S., Li, X., Bairai, S.T., Renfro, J., Liu, Y., Liu, Y.J., McKinney, K.A., Martin, S.T., McNeill, V.F., Pye, H.O.T. and Nenes, A., 2015. Examining the effects of anthropogenic emissions on isoprene-derived secondary organic aerosol formation during the 2013 Southern Oxidant and Aerosol Study (SOAS) at the Look Rock, Tennessee ground site. Atmospheric Chemistry and Physics, 15(15), pp.8871-8888.
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- Marais, E. A., Jacob, D. J., Jimenez, J. L., Campuzano-Jost, P., Day, D. A., Hu, W., Krechmer, J., Zhu, L., Kim, P. S., Miller, C. C., Fisher, J. A., Travis, K., Yu, K., Hanisco, T. F., Wolfe, G. M., Arkinson, H. L., Pye, H. O. T., Froyd, K. D., Liao, J., and McNeill, V. F.: Aqueous-phase mechanism for secondary organic aerosol formation from isoprene: application to the southeast United States and co-benefit of SO_2 emission controls, Atmos. Chem. Phys., 16, 1603–1618, https://doi.org/10.5194/acp-16-1603-2016, 2016.

Page 2-3: likewise, wildfires are not exactly natural either. This reference says "Humans ignited four times as many large fires as lightning, and were the dominant source of large fires in the eastern and western U.S."
Nagy, R., Fusco, E., Bradley, B., Abatzoglou, J. T., & Balch, J. (2018). Human-related ignitions increase the number of large wildfires across US ecoregions. Fire, 1(1), 4.

Page 2-13: "It is not clear how uncertainties in emission estimates affect air quality modeling, as there are no numerical empirical uncertainty estimates available for the NEI. However, by comparing modeled concentrations to ambient measurements, overall uncertainty in model outputs can be characterized." -- This language overstates the uncertainities. Comparison of top down and bottom up approaches can and do provide bounds on emissions uncertainty, and varying emissions within those bounds in sensitivity analyses in chemical transport models inform us as to how uncertainties in emissions estimates result in variability in air quality modeling results.

Page 2-34 line 2. Implies that the high 2-yr concentrations during April – September are due to wildfires. That may be true, but it is also the photochemical smog season, so other explanations are also possible.

Page 2-42 section 2.3.3: Not stated, but hybrid exposure models also do a better job of covering the exposure of rural residents, which are not as well represented by monitors, and thus better represent the diversity of exposures experienced by all Americans.

I agree that "Hybrid PM2.5 modeling methods have improved the ability to estimate PM2.5 exposure for populations throughout the conterminous U.S. compared with the earlier approaches based on monitoring data alone. Excellent performance in cross-validation tests suggests that hybrid methods are reliable for estimating PM2.5 exposure in many applications."

Page 2-64: "However, SOA formation from biogenic emission sources can also be facilitated by the presence of anthropogenic precursors (Xu et al., 2015). More work characterizing the interactions of anthropogenic and biogenic emissions is needed to determine the implications of such processes for background PM concentrations." See Marias et al., regarding the importance of (anthropogenic sulfate) to the formation of SOA from biogenic VOCs.

Marais, E. A., Jacob, D. J., Jimenez, J. L., Campuzano-Jost, P., Day, D. A., Hu, W., Krechmer, J., Zhu, L., Kim, P. S., Miller, C. C., Fisher, J. A., Travis, K., Yu, K., Hanisco, T. F., Wolfe, G. M., Arkinson, H. L., Pye, H. O. T., Froyd, K. D., Liao, J., and McNeill, V. F.: Aqueous-phase mechanism for secondary organic aerosol formation from isoprene: application to the southeast United States and co-benefit of SO_2 emission controls, Atmos. Chem. Phys., 16, 1603–1618, https://doi.org/10.5194/acp-16-1603-2016, 2016.

Page 2-65: wildfire smoke is an increasing contributor to high PM2.5 concentrations over extended periods of time. These events risk eroding the progress that has been made in air quality and health in the US. Will the exceptional events designations extend throughout the warm months over much of the west in the future? Will a substantial portion of the US population no longer be protected from $PM_{2.5}$ due to wildfires?

Wildfire exceptional events are no longer exceptional. The chapter should acknowledge the wildfire trends and public health and wealfare impacts and explain briefly how these are handled with respect to NAAQS attainment.

Page 2-69: I agree that since the 2012 review "our scientific understanding of organic aerosol formation has evolved." And modeling to better assess background aerosol with this new scientific undertstanding is needed. EPA can do this now in the CMAQ model. The assessment of background organic PM provided here is undoubtedly an upperbound. This must be stated clearly.

Pg 2-7 through 2-10. Ammonium should be identified as a significant component of PM2.5 and ammonia as an important precursor.

Chapter 3 – Reconsideration of the Primary Standards for PM2.5: *Chapter 3 summarizes key aspects of the health effects evidence and evaluates mean PM2.5 concentrations reported in key epidemiologic studies that are particularly relevant to considering the adequacy of the current primary PM2.5 standards. Chapter 3 also summarizes the risk assessment and at-risk analyses to inform preliminary conclusions on the primary PM2.5 standards. Finally, Chapter 3 presents the preliminary conclusion that, collectively, the scientific evidence, air quality analyses, and the risk assessment can reasonably be viewed as supporting retention of the 24-hour PM2.5 standard, while calling into question the adequacy of the public health protection afforded by the current primary annual PM2.5 standard, and presents alternative annual PM2.5 standards that could be supported by the available scientific and technical information. Chapter 3 also identifies key areas for additional research and data collection, in order to inform future reviews.*

1. To what extent does Chapter 3 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on PM2.5-related health effects?

The material concerning long term $PM_{2.5}$ exposure is very clear about what the new evidence is, and that it strengthens the understanding regarding causality and that it provides clear evidence for $PM_{2.5}$-associated mortality at levels below the annual standard.

A similar communication approach should also be used for short term (24-hr) exposures.

I recommend that EPA use the term "people of color" as a descriptor rather than "non-white."

4. What are the Panel's views on the technical approach taken to update the risk assessment, including the approach to evaluating impacts in at-risk populations? To what extent does the draft PA accurately and clearly communicate the results of these analyses? What are the Panel's views on staff's interpretation of these results for the purpose of evaluating the adequacy of the current primary PM2.5 standards?

Risk assessment uses sound risk assessment principles consistent with that used previously, and appropriately, the number of locations has been expanded compared to past risk assessment. This is appropriate, except that I note that locations where there is substantial wintertime stagnation and home heating by woodstoves are excluded because those areas are also affected by periodic wildfires in the summer (i.e. the Northwest). How does omitting wintertime data in areas affected by summertime wildfires alter the results of the analysis, including the assessment of whether the 24 h standard is adequate? I am concerned that excluding these areas also excludes areas where the 24 h standard is controlling. The risk assessment is being used to argue that revision of the 24 h standard is not necessary because the annual standard is controlling. I am not convinced this is a sound argument.

In the future, can conduct the risk assessment over the entire country rather than 47 locations. This is now quite possible.

5. What are the Panel's views on preliminary conclusions regarding adequacy of the current primary PM2.5 standards and on the public health policy judgments that support those preliminary conclusions?

a. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current primary 24-hour PM2.5 standard, without revision, in this reconsideration?

No. Epidemiologic associations with 24 h concentrations below 35 ug/m^3, including short term studies with analyses restrictied to 24 h concentrations below 25 ug/m^3 call into question the adequacy of the 24 h standard.

The discussion makes a case for retaining the current primary 24 h standard because monitoring suggests that the annual standard is usually controlling. I remain concerned that the risk assessment may not adequately consider the population of Americans living in locations where the 24 h standard may be controlling, e.g. areas with wintertime stagnation and local primary sources (heating with woodsmoke, primary industrial emissions, commercial vehicle emissions) (includes urban areas in narrow valleys, and both rural residents and EJ areas).

Placing less weight on the risk assessment and more on the short term epidemiological evidence, argues for a lower level for the 24 h standard.

b. Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider revising the current primary annual PM2.5 standard in this reconsideration?

Yes. the discussion provides an appropriate and sufficient rationale to conclude that the annual standard is not currently adequate and should be revised.

6. In the Panel's view, has the evidence and risk information, including limitations and uncertainties, been appropriately characterized and interpreted for the purpose of considering potential alternative annual PM2.5 standards? Does the discussion provide an appropriate and sufficient rationale to support preliminary conclusions regarding alternative primary annual PM2.5 standard levels that are appropriate to consider?

Yes, the discussion is appropriate to support preliminary conclusions regarding the annual standard and alternative levels, particularly between 9 and 11 ug/m^3. Note that while estimated health risks for Black communities are still higher than for majority White communities, the risk assessment predicts a substantial risk reduction for Black residents with a decrease in the annual standard to 9 μg/m^3 or lower (Figure 3-21). Thus, I would support a level of 9 μg/m^3 in consideration for health equity.

Regarding the level of the daily standard: Short term studies restricted to below 25 ug/m^3 provided in Table 3-10 support reducing the 24 h standard. A level of 25-30 ug/m^3 will not eliminate risk but is supported by the data.

7. What are the Panel's views on the areas for additional research that are identified in Chapter 3? Are there additional areas that should be highlighted?

Chapter 3 provided a fairly comprehensive list. Here is one more:

> PM2.5 background - As an upperbound, background was estimated by assuming all biogenic secondary organic aerosol (SOA) is natural. Even though it is made from biogenic hydrocarbons, biogenic SOA is not necessarily natural. There have been substantial improvements in the CMAQ model's ability to predict the anthropogenic influences (e.g. NOx and acidic sulfate) on biogenic SOA. New model predictions of background PM2.5 should reflect this new knowledge.

Chapter 5 – Reconsideration of the Secondary Standards for PM: *Chapter 5 summarizes key aspects of the welfare effects evidence that are particularly relevant to considering the adequacy of the current secondary PM standards. Chapter 5 also summarizes the quantitative assessment of visibility impairment to inform preliminary conclusions on the secondary PM standards. Chapter 3 presents the preliminary conclusion that the available evidence does not call into question the adequacy of the public welfare protection provided by the current secondary PM standards and that it is appropriate to consider retaining these standards in this reconsideration. Chapter 5 also identifies key areas for additional research and data collection, in order to inform future reviews.*
1. To what extent does Chapter 5 capture and appropriately characterize the key aspects of the evidence assessed and integrated in the 2019 ISA and draft ISA Supplement on PM-related visibility effects?

Page 5-20: The authors should consider that an increasing portion of sulfate in the southeast is organosulfate rather than inorganic sulfate. Organosulfates have different water uptake and optical properties. Changing ratio of inorganic sulfate to organosulfate (and related changes in hygroscopicity) will affect visibility predictions and should be considered.

Page 5-21: The text states, "In the Northwest, POM was the largest contributor to annual average bext, up to 70%, in most urban and rural regions with the greatest contributions in the fall. This seasonal contribution of POM may be related to wildfires." Is the peak contribution from wildfires expected in the fall? Certainly wildfires are a major issue in the west, but there are other major sources of POM in the northwest, including woodburning for home heating, which tends to occur when temperature inversions trap emissions near the surface. This source should be acknowledged.

4. What are the Panel's views on the interpretation of the evidence for PM-related welfare effects for the purpose of evaluating the adequacy of the current secondary PM standards? Specifically, to what extent is the consideration of the evidence, including uncertainties, technically sound and clearly communicated?

5. What are the Panel's views on conclusions regarding support for new or updated quantitative analyses? What are the Panel's views of the technical approach taken to conduct updated analyses to inform our understanding of the relationship between PM in ambient air and visibility impairment?

I agree with the assessment that a causal relationship exists between PM2.5 and visibility, climate change and material damage.

I suggest that the Policy Assessment more fully consider new research explaining regional differences in visibility preferences, which was presented in the ISA Supplement. Visibility preferences are better explained by contrast than concentration.

6. What are the Panel's views on preliminary conclusions regarding adequacy of the current secondary PM standards and on the public welfare policy judgments that support those preliminary conclusions? Does the discussion provide an appropriate and sufficient rationale to support the preliminary conclusion that it is appropriate to consider retaining the current secondary PM standards, without revision, in this reconsideration?

It appears to me that the current standard adequately addresses visibility for residents of many cities including Washington DC. It looks like the 24 h standard would have to be much lower to meet the 50th percentile preferences of Denver residents (Fig 5-3) – probably more research is needed. Reasonably, residents of western cities with beautiful mountain views prefer to have adequate contrast to enjoy them, as explained in ISA Supplement Fig 4-2. What about other western cities with mountain views (e.g. Seattle, Portland)?

7. What are the Panel's views on the areas for additional research that are identified in Chapter 5? Are there additional areas that should be highlighted?

Changes in PM2.5 composition are resulting in an increasing "closure" gap between light extinction and light extinction predicted from particle composition (as sulfate and organic PM decrease). One plausible hypothesis is that this is caused by a change in wildfire PM2.5. It also might be caused by an increase in the organosulfate/inorganic sulfate ratio (and associated differences in hygroscopicity and light extinction). Research is needed to understand and reduce this closure gap.

Research: There is a potential to develop alternative preference studies that may be more quantitative in assessing the value of good visibility, for example: a method that uses perceived value of a "property with a view" (as a function of PM2.5 concentration) in visibility preference studies.

Dr. Marc Weisskopf

Charge Q3: See my larger comments below for some issues with the way the data are being used and interpreted.

Charge Q5a: Are the several papers identifying associations with 24-hour PM2.5 at levels below the current standard being adequately considered? There are several (many newer) studies showing associations at concentrations below current standards. This would seem to argue for *not* retaining the current 24-hour PM2.5 standard.

Charge Q5b: See my larger comments for some issues regarding this. I think the available discussion of the evidence absolutely provides sufficient rationale to consider lowering the current standard.

Charge Q6: How were the starting alternatives of 10 and 30 arrived at? Is it appropriate to use estimates from just one paper for risk analysis inputs (Di et al., 2017b or Turner et al., 2016)?

Charge Q7: Difference in Difference studies that account for changes in co-pollutants at the same time.

Larger comments:

1) I do not agree with the strong focus on mean levels in studies being used to set key standard levels. Relationships at the mean are meaningless (and can't be defined) without variation around that mean. So to me that implies you must consider levels below the mean, although I understand some degree of attention to where the bulk of the data lie is needed (although note the bulk of the data is NOT always at the mean [and in fact is typically lower than the mean when concentrations skew to the high side]—this idea seems to come from looking at the confidence bands of splines, but that may not be saying the same thing).
    a. Related to this, averaging all the means of the different studies to determine standards to me is the incorrect approach (see text on 3-7 and 3-8). If there is enough data in lower ranges that indicate an effect there, then the fact that other study settings don't have such low levels is irrelevant.
2) Uncertainties (e.g. text on p. 3-8, ll. 6-10): Note that the uncertainty of measurement error most likely (and papers have addressed this, e.g. Hart et al., 2015; Kioumourtzoglou et al., 2014; Willis et al., 2003; Kloog et al., 2013) leads to an underestimation of effects and therefore be unlikely to create false associations. As a corollary, it contributes to more uncertainty in lower ranges of exposures and therefore leads to likely setting standards higher than might otherwise have been set.

3) Use of Canadian studies: While I understand that data may not exist to define the relation between model-determined exposure levels in Canada and what the design value in Canada would be, to me, that is not the issue. The issue is if the models are done in the same way as in US studies, and they show effects at some given level, then the issue is: had we seen that level in a US setting, what would the design value be that corresponds to that level. And that we know from the US studies. So, to me, Canadian studies ***should*** contribute to the consideration of levels at which effects are seen.
4) If we believe all people should be protected from PM2.5 exposure above some level X (based on the evidence in the literature), then setting a PM2.5 standard at a level higher than X because design values are higher than area averages, ignores the fact that people living around the design value monitor will be exposed to levels closer to the design value than the area average and that they will suffer health consequences consistent with the level at the design value monitor (which is higher than X). Furthermore, the populations that live closer to design value monitors are not randomly distributed and likely skew to more disadvantaged populations who are then more likely to not be protected to the level X.

Other points:

3-7, ll. 16-22: I don't quite get how this conclusion is reached. Many short-term studies showing associations were done in settings with exposure levels well below 35ug/m3 (see Supp ISA 3.2.1.2.1).

3-7, ll. 30-31: I'm not clear on what is meant by "did not identify particular PM2.5 exposures that cause effects" – is this meant to be did not identify specific levels at which effects are seen? (see also 3-8, ll. 20-21)

3-21, ll. 24-26: I don't see why the fact that before only stratified analyses were done is a limitation other than possibly if that meant smaller numbers.

3-26, ll. 31-33: I'm not sure this is a great argument against confounding by co-pollutants given the smallish effect estimates.

3.3.1.5: I may have missed something, but there are several papers on PM2.5 and cognitive decline or dementia that I would have thought would be in the time frame of articles reviewed for this ISA. Did I miss them or is there a reason they were not considered?

3-65, ll. 19-30, Fig. 3-2: (see larger comment 1 above): I don't believe this interpretation of the figure is correct. The smallest confidence bands are a function of the way the spline is run and are defaulted to the mean as that is set as a sort of reference point. It is NOT determined by the data. In fact, the bulk of the data will be below the mean because the levels are right skewed.

3-66, ll. 13-16: see the point above and larger comment 1. Considering a lower point in the distribution I think is more appropriate.

3.5.1.2: Given determination that there are populations at increased risk, why does the risk assessment not consider effects on the most vulnerable sub-populations?

3-167, l. 35: Not 25th percentile of the deaths, but of the exposure distribution, correct?

3-195, ll. 11-17: See larger comment 1 about relying in the mean.

3-197: Several of my larger comments above relate to issues in the bullets beginning here.

3-199, l. 20: Something is missing for the last range of concentrations.

Dr. Corwin Zigler

The Draft 2021 Policy Assessment for the Reconsideration of the NAAQS for PM (henceforth "Draft PA") incorporates ample discussion of so-called "causal modeling methods" that constitute important additions to the body of evidence that has appeared since the 2019 PM ISA. I have provided more detailed thoughts on the role of these methods in my comments to the Draft Supplement to the 2019 PM ISA, but reiterate here that I believe the emergence of these studies is novel to the PM ISA and PA and that they reduce key uncertainties in the body of evidence, in particular many uncertainties specifically highlighted by members of previous CASAC and the previous Administrator in the 2020 decision to retain the PM standards. I have several comments on the Draft PA, most of which relate to discussions of causality.

- The background material on the current standard in Chapter 3.1.1, particularly that related to the annual standard, highlights previous CASAC advice on interpretation of the epidemiological evidence. My read of this background material is that previous CASAC advice was not consistent with the weight of evidence causality determinations outlined in the 2015 ISA Preamble. The advice appeared to entirely sidestep the causality determinations in the 2019 ISA and instead focus on particularities of only the epidemiologic studies, most notably whether they "identify PM2.5 exposures that cause effects" and the mean exposure levels reported in those studies relative to the current standard. Both of these specific features of the epidemiologic evidence have been thoroughly addressed in the Draft Supplement to the PM ISA, and I feel the body of evidence in support of lowering the standard has been strengthened as a consequence. More generally, I do not believe that the general premise of the weight of evidence causality determinations should be confused with or replaced by more specific discussions of causality in the context of certain types of studies, at least not without serious justification. A change to the ISA process of this magnitude may or may not be warranted, but would certainly involve much more thorough consideration than what was provided by previous CASAC, Administrator, and public comments. In short, while I feel that key advances in the scientific literature (highlighted in the draft PM ISA Supplement) provide specific evidence that counters much of the stated justification of the 2020 decision to retain the standard, I also believe that the apparent efforts to disregard the causality determinations in the ISA was unjustified. The Draft PA could reiterate the intended role of the weight of evidence causality determinations in relation to the 2020 decision to retain the standard.
- Page 3-17 explicitly notes that the draft ISA Supplement considered studies that employed causal modeling methods, "given that such studies were highlighted by the CASAC and identified in pub- lic comments in the 2020 review." Future sections (e.g., Page 3-22) continue to describe specific methodologies (e.g., generalized propensity scores, inverse probability weighting, and difference- in-difference) in terms of uncertainties that they reduce in the body of evidence. This

is appropriate framing of the role of these studies in the policy assessment, and is emphasized at other points in the PA (e.g., when describing Table 3-11 on page 3-122).

3. In Table 3-7, the study by Wu et al. [2019] has its study design listed as "Causal modeling study (MEDICARE)" but several other studies using the Medicare cohort have their study designs listed as "Cohort study (Medicare)" or similar, including the study by Wu et al. [2020], which uses "causal modeling." I do not think this is a productive labeling of study designs in the context of Table 3-7, as the "causal" label here would relate more to the analysis conducted and not to the overall description of the study design.
4. Page 3-122 explicitly cites that Wu et al. [2020] considered three novel causal modeling approaches alongside two more traditional statistical methodologies and found consistent results across all analyses. This is a key point, and should serve to underscore the role of "causal modeling" to reduce uncertainties in the existing body of evidence, and not somehow replace evidence gleaned from studies that use more traditional modeling approaches.
5. Acknowledging the complexities of conducting air quality modeling under different emissions scenarios, I think it is adequate for the PA to consider the *Reductions in primary PM2.5 (Pri-PM)* and *Reductions in secondary PM2.5 (Sec-PM)* adjustment approaches to simulate air quality surfaces just meeting current and alternative standards. However, as PM2.5 levels continue to reduce and the evidence of toxicity related to different sources or trace chemicals evolves, it would seem that some more refined ways to model reductions at different sources or source categories should be explored for future PAs. This may be particularly important for addressing the 24-hour standard.

<u>References</u>

X. Wu, D. Braun, J. Schwartz, M. A. Kioumourtzoglou, and F. Dominici. Evaluating the impact of long-term exposure to fine particulate matter on mortality among the elderly. *Science Advances*, July 2020. doi: 10.1126/sciadv.aba5692. URL https://www.science.org/doi/abs/10.1126/sciadv.aba5692. Publisher: American Association for the Advancement of Science.

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