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

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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 $PM_{2.5}$ and adverse health effects, with limited information on the 24-hr PM_{10} standard of 150 µg/m3, which has not been revised since 1987. Although a new reference method for $PM_{10\text{-}2.5}$ 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 $PM_{10\text{-}2.5}$ indicator for thoracic coarse particles intends to characterize suspended dust from traffic, construction, and industrial sources, but it excludes rural windblown dust and soils generated from agriculture and mining sources. 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 $PM_{10\text{-}2.5}$ would be helpful to address the 2020 PM NAAQS evaluation. It should also be recognized that the $PM_{10\text{-}2.5}$ 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 an evaluation was made of more recent work on climate and material damage effects between June 2018 and March 2021.

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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 $PM_{2.5}$ 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?

<u>Characterizing Ambient $PM_{2.5}$ Concentrations for Exposure (Section 2.3.3)</u>

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 visibility impairment. 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 presented to illustrate the long term trend in fires and their potential impacts on ambient $PM_{2.5}$ and carbon concentrations.

$PM_{10-2.5}$ 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. Section 2.3.2.5 on "National Characterization of $PM_{10-2.5}$ Mass" (page 2-39) acknowledges the less distinct difference between the eastern and western U.S. (2017-2019) without elaborating on the increasing trend found 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 addition 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 found 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.

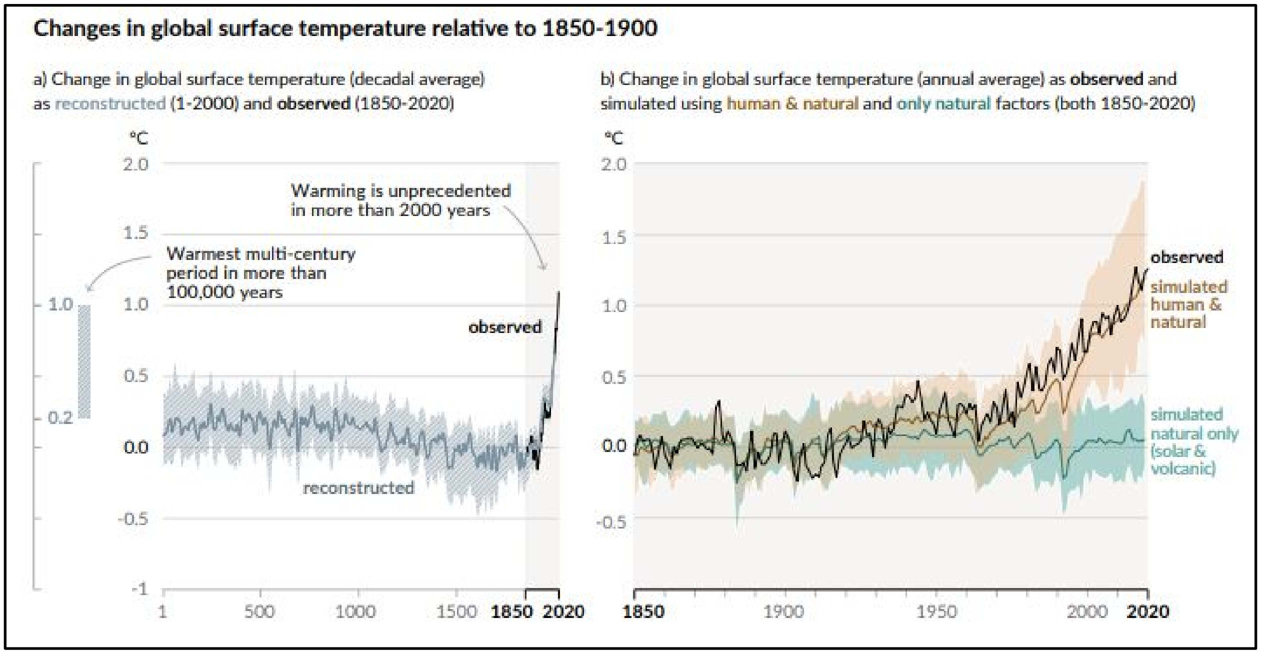

Figure SPM.1. a) Changes in global surface temperature reconstructed from paleoclimate archives (solid grey line, 1–2000) and from direct observations (solid black line, 1850–2020), both relative to 1850–1900 and decade-averaged. The vertical bar on the left shows the estimated temperature (very likely 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).

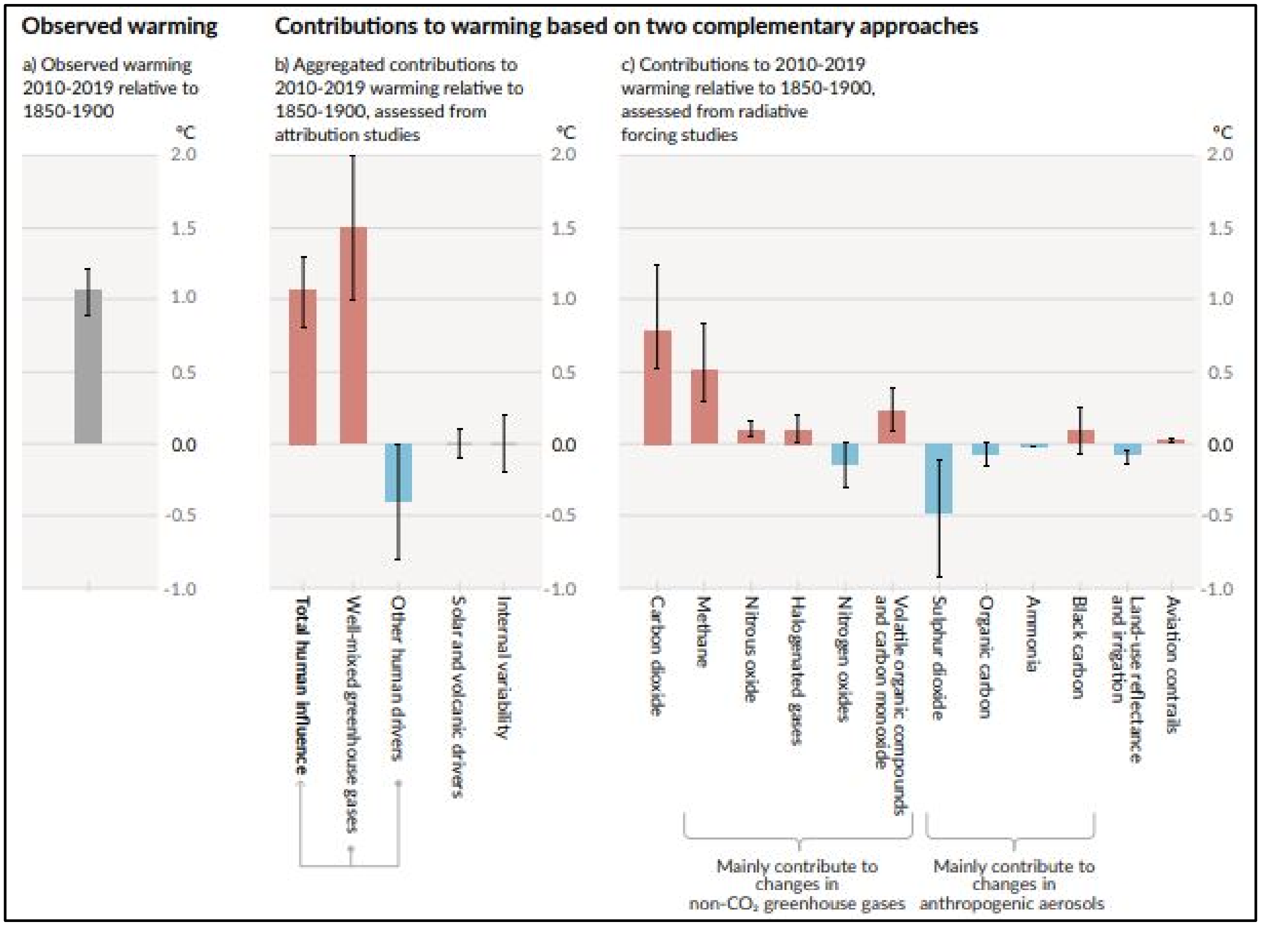

Figure SPM.2. a) Observed global warming (increase in global surface temperature) and its very likely range. b) Evidence from attribution studies, which synthesize information from climate models and observations. The panel shows temperature change attributed to total human influence, changes in well-mixed 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.

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 +0.10W/m^2 in addition to the +0.39W/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 ≥ 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.

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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 more detail on the previous ISA and PA review, specifically the major advice from CASAC on the draft PA, and the Agency's responses in the final PA.

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 PM2.5 effects on nervous system and cancer.

Introduction, Page 1-17, top. "Additionally, for these health effect categories the recent studies evaluated are limited to: o U.S. and Canadian epidemiologic studies o Epidemiologic studies that employed causal modeling methods or conducted accountability analyses…". This text states that the studies were limited to those epi studies using causal modeling or accountability analyses; that is obviously not the case.

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."

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?

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.

Additional comments are warranted on 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. 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".

Page 3-22, line 10. "For example, Bennett et al. (2019) reported that PM2.5 concentrations above the lowest observed concentration (2.8 µg/m3) 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 PM2.5 concentrations >12 µg/m3 to participants living in areas with PM2.5 concentrations < 12 µg/m3 and reported that the number of years of life lost due to living in areas with higher PM2.5 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 PM2.5 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 PM2.5 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 PM2.5 exposure is associated with cancers in other organ systems, but there is some evidence that PM2.5 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 PM2.5 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-hr standard. Human studies should not be used as the primary justification that the 24-hr standard is adequately protective, without caveats.

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?

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 and weight in the summation.

There are clearly presented and convincing justifications for maintaining the current indicator, averaging time, and form for both the 24-hr 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 PM2.5 standard, without revision, in this reconsideration?

Yes, a generally convincing case is made that it is appropriate to retain the current level of the 24-hr standard, given the protection that would be provided by a more stringent annual standard. This is based on the estimated reductions in mortality and morbidity. As noted above, it is suggested that less emphasis be placed on the human controlled exposure studies in making this determination, because of the reasons already discussed.

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 PA provides a clear and comprehensive summary of the evidence that the current annual PM2.5 standard is not adequately protective of the public health.

Dr. Christina H. Fuller

Chapter 3

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?

Section 3.6 - AREAS OF FUTURE RESEARCH AND DATA COLLECTION

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.

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 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.

Comment on language:

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. I encourage the consideration of different language when discussing race/ethnicity in the 2019 PM ISA Supplement. The summaries and conclusions within this document use the term White and non-White as the broadest categories. I suggest the Supplement refer to the group non-White as People of Color (POC) or Communities of Color (COC), as appropriate.

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. 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 $\mu g/m^3$ 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-hr 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

Chapter 3

- 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.
- The comparison of the four methods and the comparison of 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.

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?

- 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 suggest references, many of which fall within the period of the literature review for the supplement.

Subsection 2.1.1.2 Sources contributing to Primary PM_{10} Emissions

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

Subsection 2.2.3.2 Chemical Speciation and IMPROVE networks

- 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. This could be clarified.

Subsection 2.2.3.3 Recent Changes to $PM_{2.5}$ Monitoring Requirements

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

Subsection 2.3.1 Trends in Emissions of PM and Precursor Gases

- Line 23 states that "emissions from dust and fires have increased over this time", but the time period is not clear. 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?

Subsection 2.3.2 Trends in Monitored Ambient Concentrations

- 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.

Subsection 2.3.2.2.2 $PM_{2.5}$ Near Major Roadways

- 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 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).

Subsection 2.3.2.6 UFP

- 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.

Section 2.4 Background PM

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

Minor Edits

- 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.

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

- 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

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

- 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.

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 strong synthesis of the evidence on PM-related visibility effects presented in the 2019 PM ISA and the 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.
- In the section addressing information on spatial and temporal variation in the factors affect light extinction across the U.S. it would be good to show a figure from the original source (Hand et al. 2020).

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 ISA Supplement. While there is a clear causal relationship between PM and direct and indirect climate effects, there remain large uncertainties in relationships between PM and climate impacts at regional scales and interactions and feedbacks in the climate system make determining relationships between PM and such processes as cloud formation highly uncertain.

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 int eh 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.
- Results are sound and clearly communicated.
- I appreciated the division of each section into a subsections organized by various questions related to the available evidence, changes in scientific understanding, recent studies, uncertainties and so forth.
- 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". Also, more treatment of the coarse fraction is relevant in light of the research by Kok et al. on coarse dust and light absorbing effects.

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 fields. 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. In fact, 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, there do not appear to be new studies demonstrating that locations meeting the daily $PM_{2.5}$ standard experience visibility index values above 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 visibility preference studies, including the fact that many of these were conducted 15-30 years ago and may no longer reflect current preferences.
- The need for current research on visibility preferences is especially relevant in light of two additional factors. First, both wildfire and dust emissions are increasing in several regions, especially in the US West where Class I Areas are concentrated. Second, national park visitation has increased considerably in recent years and spikes in visitation have been reported for many western US Class I Areas following COVID-19 shutdowns (NPCA 2021). It is unclear how changes in the frequency of high/extreme PM episodes coupled with increased visitation and the desire to experience outdoor environment influence visibility preferences, making this an area ripe for further research.
- Given the discussion of the IPCC AR5 in the context of PM-related climate effects, it may be worth noting and citing the IPCC Sixth Assessment Report, the first part of which was published in 2021.

- 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

<u>Chapter 3</u>

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?

Conclusions made in the draft PA are generally justified, although there are studies from the ISA or draft ISA supplement that should be added. Specific comments on the text are provided below.

Page 3-42, line 6 – It is not necessarily a limitation of the studies of air pollution and birth outcomes that an individual window of susceptibility during pregnancy is identified. It may be that there are multiple windows, and different effects of exposures in different windows. This should be removed as a limitation.

Page 3-77 and 3-78 - Figure 3.6 – CV Morbidity – Studies from the ISA and draft ISA supplement studying PM2.5 and myocardial infarction, specifically STEMI, are missing but should be included here. US and Canadian studies examining this association are 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.

Page 3-78, Figure 3.6 – Other papers studies 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/should 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.

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 and actions in the state and region. PM2.5 concentrations were <12 $\mu g/m^3$ in several of the locations. Health effects associated with these low PM2.5 concentrations are provided in several papers provided above. The Squizzato et al (2018) paper could/should 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.

Page 3-128, line 21 – "…while epidemiologic studies indicate associations between PM2.5 and health effects, they do not identify particular PM2.5 exposures that cause effects." Please clarify what feature(s) of "exposure" you are referring to here? Duration? Location? Composition or source of PM?

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 PM2.5 mass" – For this topic, the draft PA is missing several papers all from 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 these source-specific PM2.5 contributions. Although this study and these papers from it are not enough to justify a change away from regulating PM2.5 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.

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 choice for 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 above). A description of the design and potential confounders controlled for by design or in their analytic models should be provided.

Page 3-167, lines 25-27: "How do the study-reported PM2.5 concentrations corresponding to the 25th and 10th 25 percentiles of health data or exposure estimates provide insight to inform our 26 consideration of the level of the current annual PM2.5 standard?" - It is not clear from the description provided below this what is meant by "the 25^{th} and 10^{th} percentiles of health data or exposure estimates". Of what variable(s) are you examining the distribution and noting the 25^{th} and 10^{th} percentile? Is this the PM2.5 concentration distribution of concentrations used in a study, and the 25^{th} and 10^{th} percentiles from that distribution. Please redraft this to make it clearer what this is.

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 PM2.5 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 $PM_{2.5}$.

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?

A few future additional areas should be highlighted. First, the discussion of accountability studies should include studies that address both changes and trends in pollutant concentrations, but also changes in PM composition and changes in PM sources. 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 ug/m3 increase in PM2.5 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 in PM2.5 mass, but also how those effects may simultaneously be affected by the composition of the PM.

Second, similar to PM2.5, such studies on UFP should examine trends in different size bins 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.

Last, 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 exposures. These could/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 birth 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 $PM_{2.5}$

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.
- Uncertainties regarding the shape of the C-R function at low concentrations is both critical and currently unresolvable. In the Supplement to the PM ISA, the approaches for estimating the shape of the C-R curve, for a range of endpoints including mortality, were clearly presented. 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'.
- The inclusion of analyses and risk estimates for at-risk populations, especially non-White and low SES communities, is a welcome and overdue addition to this PA and the ISA process, generally.

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

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:

- Section 3.4.1.2: How studies from Table 3-13 were considered (or used) when developing the risk assessment model (or were they not? Did these studies just informed that it should be done?). For example, a more detailed explanation of how studies were used to inform risk across racial-ethnic groups was included (page 3-135, ln 3-36, page 3-136, ln 1-3).
- 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.
- What is the main geographic unit of analysis? 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.
- 3-133, ln 10-12: Appreciate the inclusion of two methods that would lead to reduction in PM2.5. The rationale (or the expected outcome difference on health) as to why two adjustment approaches were considered would be helpful. My assumptions is that a

reduction in secondary PM2.5 would potentially have greater health benefit given that the reduction would be more evenly distributed. However, I'm not entirely sure this is the correct conclusion.

- 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.

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 3-153, 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.

<u>Chapter 4 – Reconsideration on PM_{10}</u>

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.

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 uncertainties in the emissions estimate uncertainties are overstated, as are the impacts of anthropogenic emissions on secondary organic aerosol formation from biogenic VOCs. 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.
- Budisulistiorini, S.H., Canagaratna, M.R., Croteau, P.L., Marth, W.J., Baumann, K., Edgerton, E.S., Shaw, S.L., Knipping, E.M., Worsnop, D.R., Jayne, J.T. and Gold, A., 2013. Real-time continuous characterization of secondary organic aerosol derived from isoprene epoxydiols in downtown Atlanta, Georgia, using the Aerodyne Aerosol Chemical Speciation Monitor. Environmental science & technology, 47(11), pp.5686-5694.
- 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 entirely natural either, although perhaps largely accidental. 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?

Page 2-69: I agree that since the 2012 review "our scientific understanding of organic aerosol formation has 4 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 and upperbound.

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?

It captures key aspects well.

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?

The technical approach to comparing monitor concentrations, hybrid model concentrations and design values is sound. However, even though I understand the design value concept, I found Figure 3-5 to be confusing.

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 approach is appropriate, except that I note that locations where there is substantial home heating by woodstoves are excluded because those areas are also affected by periodic wildfires in the summer (i.e. the Northwest). How does this omission alter the results of the analysis, including the assessment of whether the 24 h standard is adequate. I note that the 24 h standard is more likely to be the controlling standard in the Northwest than in the East.

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 makes a strong case for retaining the current primary 24 h standard. However, I remain concerned that the risk assessment may not adequately consider the population of Americans living in locations with wintertime stagnation and woodsmoke, where the 24 h standard is controlling.

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, with the exception of the concern I raised in 5, above.

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.

Page 5-21: The text states, "In the 5 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.

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?

I agree with the assessment that a causal relationship exists between PM2.5 and visibility, climate change and material damage. I am not convinced that the Policy Assessment fully considered new research explaining regional differences in visibility preferences that was presented in the ISA Supplement.

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 50^{th} percentile preferences of Denver residents (Fig 5-3). 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.

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

<u>Chapter 3</u>

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?

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

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?

Are the several papers identifying associations with 24-hour PM2.5 at levels below the current standard being adequately considered?

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?

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.

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?

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)?

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?

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

<u>Larger comments:</u>

1) I feel a little uncomfortable with the strong focus on mean levels in studies being used to set key 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—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, it is not clear to me that averaging all the means of the different studies to determine limits is the correct 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 limits 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 hybrid model-determined exposure levels in Canada and what the design value at a monitor in Canada would be, to me, that is not the issue. The issue is if the hybrid 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.
4) An issue I would like more clarity on is the relation between study specific PM2.5 concentrations vs design values. If the point is to consider the effects on the overall population, then I understand that taking the difference between model-based estimates (that tend to be lower because they get at areas away from monitors) and design values makes sense since the meeting standards at the monitor should then translate to lower concentrations in areas further from the monitor. But if the idea is to protect everyone, then setting the limit higher simply because it is measured at a monitor does not protect

people who live close to the monitor as these are areas with typically higher exposure levels.

<u>Other points:</u>

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 25^{th} 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

<u>Chapter 3</u>

1. Chapter 3 of the revised PA provides very useful context relating to the 2020 PA and the Administrator's stated reasoning for retaining the annual and 24hr PM2.5 standard. In relation to the Administrator's comments about epidemiologic studies' failure to "identify particular PM2.5 exposures that cause effects," there may be opportunity to more explicitly connect these statements with the newly-considered "causal modeling" studies as well as the the initial motivation for the weight of evidence causality determinations in the ISA Preamble.
2. 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 public comments in the 2020 review." This is very helpful context.
3. I appreciate that page 3-22 refers to causal modeling methods like GPS and IPW and DID as "reduce[ing] uncertainties related to confounding bias in the association between long-term PM2.5 exposure and mortality." This is appropriate framing of the role of these studies in the policy assessment, and is emphasized later in the PA (e.g., when describing Table 3-11 on page 3-122).