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EPN Comments on the Reconsideration of the National Ambient Air Quality Standards for Particulate Matter

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Founded in 2017, the Environmental Protection Network (EPN) harnesses the expertise of more than 550 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

I. **Introduction**

On January 27, 2023, in its "Reconsideration of the National Ambient Air Quality Standards for Particulate Matter," EPA proposed a range for the annual $PM_{2.5}$ primary standard, from 9.0 $\mu g/m^3$ to 10.0 $\mu g/m^3$, inviting comment on levels above and below this range. EPA proposed to retain the 24-hour primary standard without change, inviting comment on an alternative 24-hour standard level as low as 25 $\mu g/m^3$. In these comments, EPN first addresses the annual standard and then the 24-hour standard.

EPN believes that EPA's proposed range for the level of the annual standard is flawed. Section II of our comments discusses the flaws in the framework that EPA used to select a proposed range of levels for the annual standard. Unlike the framework applied in the 2012 Review, EPA's current approach fails to protect all of the at-risk groups in an area, including critically the at-risk group exposed to the highest levels in an area as measured by an area's design value monitor. Instead, EPA largely focused on general or area-wide levels of exposure in an area and related issues concerning the design value of studies. EPA's obligation is to select a NAAQS that protects all of the at-risk groups in an area with an adequate margin of safety, including those exposed to the highest levels in an area and cannot place primary focus on general or area-wide exposures. EPA's current proposed framework takes a step backwards compared to the approach taken in the 2012 Review. In addition, EPA did not explain that its current approach is a major change from prior reviews and did not explain why this change is appropriate.

Section III of our comments reviews the assessment of epidemiology studies presented in the proposal, finding a number of flaws in the process. The proposal incorrectly placed less emphasis on a number of important studies reporting mean levels on the basis of uncertainty in identifying the studies' peak design values as well as other problematic reasons. Section III also explains that EPA did not report some key results in studies included in the EPA review documents and omitted some studies recommended by CASAC. Section III shows that the reasoning behind EPA's decision to place limited if any weight on certain studies or kinds of studies is either weak, incorrect, contrary to CASAC's advice, or in some cases nonexistent. The section concludes that the limited group of U.S. study results that EPA relied upon in the proposal for selecting the level of the annual standard was too narrow, given the breadth of robust scientific evidence before EPA.

Section IV of our comments brings together the large group of study results that the proposal should have considered, in a manner similar to that done in prior reviews. From this perspective, EPN shows that important evidence from studies given too little weight by EPA shows effects at levels somewhat to well below EPA's proposed range. For this reason as well as the erroneous design value approach, EPA's range

would fail to protect all of the population in an area with an adequate margin of safety, including the at-risk subgroups exposed to the highest levels in an area. The failure to properly weigh the large body of evidence before EPA amplifies and increases the concerns discussed in Section II. The result runs counter to EPA's goal of addressing environmental inequities stemming from disparate exposures to levels of air pollution. Section IV concludes that if EPA would apply a proper framework to the large body of evidence before it, like the framework applied in the 2012 Review, it would reject a level of 10.0 $\mu g/m^3$. In addition, it would be difficult to justify a standard of 9.0 $\mu g/m^3$ based on the evidence. As a result, EPN recommends that EPA should seriously consider selecting a standard of 8.0 $\mu g/m^3$, a level within the range recommended by CASAC.

Section V addresses the 24-hour standard. EPN discusses the reasoning provided by EPA to retain the current level of the 24-hour standard, focusing on EPA's decisions to place little weight on certain air pollution studies with analyses restricted to 24-hour concentrations below 25 $\mu g/m^3$ and controlled human exposure studies. Like the majority of CASAC, EPN disagrees with EPA's reasoning and shows that EPA should consider revising the level of the 24-hour standard to a level between 25 and 30 $\mu g/m^3$.

II. **The Decision-Making Framework Used to Justify EPA's Proposed Range for the Annual Standard is Deeply Flawed and Illogical.**

EPA proposed a range for the annual $PM_{2.5}$ standard from 9.0 $\mu g/m^3$ to 10.0 $\mu g/m^3$, inviting comment on levels above and below this range. This proposed range is based on a flawed rationale and logic, and on its own terms clearly fails to protect all of the at-risk people in an area, including subgroups of sensitive, at-risk people that are exposed to the highest levels in an area, the levels measured by an area's design monitor.

In the 2012 Review, EPA applied a decision-making framework that took into account the need to protect all of the people in an area, not just the overall population on average. EPA recognized that the people exposed to the higher, design monitor levels in an area were likely to be at greater risk because of factors such as minority status, age, and/or low socioeconomic status (SES). This subgroup needed to be protected with an adequate margin of safety, calling for setting the standard at a level "somewhat below" that of the lowest mean in a group of studies EPA treated as key studies. This approach would ensure that the at-risk subgroup would be exposed to levels below those associated in the studies with serious adverse health effects, including mortality. EPA recognized that this approach would also protect the overall population in an area, as the average levels in an area were expected to be lower than the level measured at the design monitor. In the 2012 Review, EPA explained in great detail the importance of protecting all of the at-risk people in an area, including the at-risk subgroup exposed to the highest levels in an area.

EPA's current proposal has provided only a cursory and superficial discussion of this approach and proceeds to propose a range of levels in direct conflict with this approach. EPA proposed a range in which almost all levels are <u>at or above</u> the lowest means of the studies EPA focused on, not <u>below</u> the lowest mean. EPA appears to justify this largely by claiming the proposed range is enough below the projected design values of the studies it focuses on such that in general the level of exposure in an area would be at or below the means of these studies. This focuses on the general levels across an area and fails to address the higher than average levels experienced by the at-risk people exposed to the highest levels in an area.

This is a dramatic departure from the decision-making framework relied on in the 2012 review. EPA fails to explain that its approach is a major change from prior reviews and fails to explain why its change is appropriate.

The proposal fails to protect all of the at-risk people in an area with an adequate margin of safety, including the at-risk subgroups exposed to the highest levels in an area. The proposal amounts to a major step backwards in protection from the serious adverse effects of $PM_{2.5}$ exposure, including mortality.

This section describes the core concern identified by EPA in the 2012 Review – protecting the at-risk subgroups in an area exposed to the higher levels measured at the area's design monitor - and the decision-making framework relied upon to address this concern. The section then shows that EPA's current proposed range and its rationale is deeply flawed and fails to address these concerns. Instead, EPA's proposal runs directly counter to protecting these at-risk subgroups with an adequate margin of safety.

A. ***Background on EPA's decision in the 2012 Review to reject spatial averaging and set a level protecting all of the at-risk people in an area from well documented health risks.***

In promulgating the first fine particle standards in the 1997 review, EPA adopted a form of the $PM_{2.5}$ annual standard called spatial averaging. Spatial averaging allowed compliance to be determined by comparing the average of air quality levels measured across multiple community-based monitors to the annual level of the $PM_{2.5}$ NAAQS. This was allowed if the area met certain conditions. If the conditions were not met, the level at the highest monitor in the area would be compared to the NAAQS to determine compliance.[1] The use of spatial averaging was unique to the PM NAAQS; no other NAAQS allowed this approach. EPA tightened the conditions on use of spatial averaging in the 2006 review and removed the use of spatial averaging altogether in the 2012 review.[2]

From the inception of spatial averaging, EPA expressed concern that it would not provide adequate protection for the subgroup of the general population in an area exposed to the higher levels measured at the highest monitor. The 2012 final NAAQS decision applied a decision framework that is straightforward and logical and properly focuses on ensuring that all at-risk people in an area are protected with an adequate margin of safety, including at-risk subgroups exposed to higher levels in an area.

In the 2012 Review the Administrator stated:

> "[E]ven when the annual $PM_{2.5}$ standard was **first set in 1997, the spatial averaging provisions included constraints intended to ensure that inequities in the level of protection would not result.** These constraints on spatial averaging were tightened in the last review, based on an analysis showing the **potential for spatial averaging to allow higher $PM_{2.5}$ concentrations in locations where subgroups within the general population were potentially disproportionately exposed and hence, at disproportionate risk (e.g., low income and minority communities)**. … As discussed above and in the proposal (77 FR 38924), these analyses showed that the current **constraints on spatial averaging may be inadequate in some areas to avoid**

[1] 88 FR at 5565, note 10.
[2] 88 FR at 5566, and note 12.

substantially greater exposures for people living near monitors recording the highest $PM_{2.5}$ concentrations. Such exposures could result in disproportionate impacts to at-risk populations, including low-income populations as well as minority groups.

On this basis, the Administrator concludes that **public health would not be protected with an adequate margin of safety in all locations**, as required by law, **if disproportionately higher exposure concentrations in at-risk populations such as low income communities as well as minority communities were averaged together with lower concentrations measured at other sites in a large urban area**. … In reaching this conclusion, the Administrator further notes that her **concern over possible disproportionate $PM_{2.5}$-related health impacts in at-risk populations extends to populations living near important sources of $PM_{2.5}$, including the large populations that live near major roadways."** (emphasis added)[3]

In setting the level of the standard, the Administrator took into account that spatial averaging would no longer be allowed.[4] The Administrator described her main focus in determining the level of the annual standard as being a level somewhat below the lowest mean concentration from key studies in order to protect public health with an adequate margin of safety:

"Regarding an appropriate focal point for selecting the level of the annual standard, as discussed in the proposal and as advised by CASAC, **the EPA has focused on $PM_{2.5}$ concentrations somewhat *below* the lowest long-term mean concentrations from *each* of the key studies of both long- and short-term exposures of effects for which the evidence is causal or likely causal,** as considered by the EPA (i.e., the first two sets of studies shown in Figure 4). **If the level of the annual standard was set just somewhere *within* the range of the long term mean concentrations from the various long-term exposure studies, then one or more of the studies would have a long-term mean concentration below the selected level of the standard. Absent some reason to ignore or discount these studies,** which the commenter does not provide (and of which the EPA is unaware), **setting such a standard would allow that level of air quality, where the evidence of health effects is strongest, and its associated risk of $PM_{2.5}$-related mortality and/or morbidity effects to continue. Selecting such a standard level could not be considered sufficient to protect the public health with an adequate margin of safety**." (emphasis added)[5]

The combination of the approach for selecting the level of the annual standard and the rejection of spatial averaging reflects EPA's clear logic of protecting all of the at-risk people in an area, including the at-risk subgroups of the population exposed to the highest levels of air pollution measured at the area's design value monitor. The level of the standard needs to be set to protect with an adequate margin of safety, and everyone in the area, including the people exposed to the highest levels, needs to be protected to this degree. Protecting on average or overall is not enough – sensitive, at-risk subgroups need to be protected with an adequate margin of safety.

[3] 78 FR at 3126-27.
[4] 78 FR at 3127.
[5] 78 FR at 3147.

EPA's decision on the level of the annual standard worked hand-in-hand with its decision to reject spatial averaging. EPA determined that the epidemiology studies used to set the level of the standard had mean exposure levels ranging from 13.4 to 12.8 (short-term studies) and 14.5-13.6 $\mu g/m^3$ (long-term studies).[6] EPA set 12.0 $\mu g/m^3$ as the level, because:

> **"An annual standard level of 12 $\mu g/m^3$ is below the long-term mean $PM_{2.5}$ concentrations reported in *each* of the key multi-city, long- and short-term exposures studies** providing evidence of an array of serious health effects (e.g., premature mortality, increased hospitalization for cardiovascular and respiratory effects). As noted above, **the importance of considering a level somewhat below the lowest long-term mean concentration in the full set of studies considered is to set a standard that would provide appropriate protection against the observed effects in *all* such studies."** (emphasis added)[7]

Combined with the rejection of spatial averaging, this meant that all people in the area, including subgroups of the general population with the highest exposures, would be exposed to no higher than 12.0 $\mu g/m^3$. This was especially important as the highly exposed subgroups were also most likely at greater risk based on factors such as low SES, age, and minority status.

EPA recognized that average exposures across an area would in many cases be lower than the levels measured at the highest monitor, given variability of levels across an area. But the core of EPA's decision focused on ensuring that (1) no subgroups, including the highest exposed groups, would be exposed to levels greater than the standard, and (2) the standard would be set at such a level that no subgroups in the area would be exposed to levels that had been shown in key studies to be associated with serious adverse health effects. This was the direct result of selecting a level of the standard starting with the long-term means of the studies, with the level somewhat below the lowest reported mean, and requiring that all monitors, including the highest monitor, meet this level.

Under this logic, a level of 13.0 $\mu g/m^3$ would not provide adequate protection, as it would leave some people potentially exposed to 13.0 $\mu g/m^3$ (those at the highest monitor) and others exposed to levels below 13.0 $\mu g/m^3$ but still at or above 12.8 $\mu g/m^3$. These persons would be exposed to levels shown in one or more of the key studies to be associated with serious health risks. A level of 13.0 $\mu g/m^3$ would provide inadequate protection, with no apparent margin of safety from the risks identified in that study. The proper approach was to make sure that all people in the area would be exposed to levels lower than 12.8 $\mu g/m^3$, in this case, the lowest mean level in the group of key studies with health endpoints that were classified causal in the interim science assessment (ISA).

EPA explained its rejection of 13.0 $\mu g/m^3$:

> **"[A] standard level of 13 $\mu g/m^3$ or higher would be above the long-term mean concentrations reported in two well conducted, multi-city short-term exposure studies** reporting positive and statistically significant associations of serious effects (Burnett

[6] 78 FR at 3159.
[7] 78 FR at 3161.

et al., 2004[8] and Bell *et al.,* 2008). These important studies are fully consistent with the pattern of evidence presented by the large body of evidence in this review. As the Administrator recognized in the proposal, and as advised by CASAC, **the appropriate focus for selecting the level of the annual $PM_{2.5}$ standard is on concentrations somewhat *below* the lowest long-term mean concentrations from the set of key studies of both long term and short-term $PM_{2.5}$ exposures considered by the EPA** (i.e., as shown in Figure 4). Thus, **a standard level set at 13 $\mu g/m^3$ or higher would clearly not provide protection for the effects observed in the full set epidemiological studies** and, therefore, this standard level could not be judged to be requisite with an adequate margin of safety.

In addition, as noted above, **in recognizing that there is no evidence to support the existence of a discernible threshold below which an effect would not occur, the Administrator is mindful that effects occur around and below the long-term mean concentrations reported in both the short-term and long-term [ ]epidemiological studies**. A standard level of 13 $\mu g/m^3$ or higher would not appropriately take into account evidence from the two well-conducted, multi-city, short-term exposure studies reporting serious effects with long-term mean concentrations below 13 $\mu g/m^3$ noted above (Burnett *et al,* 2004; Bell *et al.,* 2008). Such a standard level would also not appropriately take into account additional population-level data from a limited number of epidemiological studies. This approach would ignore CASAC's advice to consider such information in order to better understand the concentrations over which there is a high degree of confidence regarding the magnitude and significance of the associations observed in individual epidemiological studies and where there is appreciably less confidence." (emphasis added)[9]

EPA's decision to remove spatial averaging, and the reasoning supporting the decision, were upheld in *National Ass'n of Mfrs. v. EPA*, 750 F.3d 921, 925 (D.C. Cir. 2014) ("EPA here fulfilled its obligation to reasonably explain its decision not to employ spatial averaging. As the agency stated, spatial averaging would enable some portions of a compliance area—particularly those areas where sensitive individuals are likely to live—to exceed the NAAQS for periods of time. *See* 78 Fed.Reg. at 3124–27. EPA reasonably concluded that allowing those excess emissions under all the circumstances here was inconsistent with EPA's goal of ensuring that the NAAQS provide requisite protection for all individuals. *Id.; see also id.* at 3168.").

The 2012 Review provided a clear framework that is straightforward and logical, and properly focused on ensuring that all people in an area are protected with an adequate margin of safety, including at-risk subgroups exposed to higher levels in an area. EPA's current proposal has departed from this framework, without explanation or justification, and is not supported by the scientific evidence and the necessity to protect at-risk subgroups.

B. ***EPA's proposed range backslides from the 2012 framework and fails to protect all of the at-risk people in an area with an adequate margin of safety.***

The following discussion shows the flaws in EPA reasoning, even if one limits the range of studies to those identified by EPA in the proposal. As discussed below in Section III, EPA improperly restricted its selection

[8] Burnett *et al*., 2004 is a multicity Canadian study.
[9] 78 FR at 3162.

of studies to focus on. This means the flaws in protection for the proposed range of 9.0 to 10.0 $\mu g/m^3$ are even worse than discussed below. The additional flaws or issues discussed in Section III need to be addressed, and a revised, proper decision-making framework needs to account for more studies than EPA currently relies upon.

EPA's proposal and supporting rationale appears to ignore the serious concerns expressed in the 2012 Review for the subgroups of at-risk people exposed to the highest levels in an area. EPA's core rationale for proposing a range of 9.0 to 10.0 $\mu g/m^3$ for the annual standard only briefly mentions people exposed to the highest levels in an area, and fails to account for the circumstances that place them at higher risk. In contrast, EPA has focused at some length on the general or average levels of exposure across an area. Nowhere does EPA place primary focus on the concerns expressed in the 2012 Review, the need to protect all of the at-risk people in an area from all of the mean levels associated in relevant studies with serious adverse health effects, including mortality.[10]

EPA stated that:

> "For the key U.S. monitor-based epidemiologic studies, the study reported mean concentrations range from 9.9–16.5 $\mu g/m^3$ and for the U.S. hybrid modeling based key epidemiologic studies, the mean concentrations range from 9.3– 12.2 $\mu g/m^3$." [11]

Following the approach used in 2012, one would expect EPA to proceed as follows:

(1) The main focus in determining the level of the standard would be the mean concentrations reported in each of these studies.

(2) EPA would not set the level <u>at or within</u> the range reported in these studies, as that would allow exposures to a level at or above that reported in one or more of the studies to be associated with serious adverse health effects. This would not provide an adequate margin of safety.

(3) Instead, the level would be set <u>somewhat below</u> the lowest reported mean concentration of the studies identified as most relevant to the decision. This would ensure that all at-risk persons in the area, and importantly the at-risk subgroups of the general population exposed to the highest levels in the area, would be protected from all of the levels shown by the key studies to be associated with serious adverse health effects, including mortality.

Under the 2012 framework, EPA would set the level somewhat below the lowest study reported mean in the group of U.S. studies EPA identifies. For the studies EPA relied upon in the proposal, this would mean a level somewhat below 9.3 $\mu g/m^3$. This would mean all people in the area would be protected from exposures to 9.3 $\mu g/m^3$ or above, the range of levels reported in the group of studies identified as most relevant to selecting the level of the standard. EPA would recognize that the variation in concentrations across an area would likely mean the average exposure across the area would be below the level of the

[10] EPA summarizes the decision making approach used in the 2012 Review in a relatively cursory and arguably misleading manner, with no explanation of or emphasis on the central concerns discussed in detail and driving the decision in that review. EPA nowhere explains that its proposed approach differs from and runs directly counter to the approach taken in 2012, and EPA nowhere explains why this change is appropriate. 88 FR at 5619, 5695-96.
[11] 88 FR at 5626.

standard, and critically a standard set somewhat below 9.3 $\mu g/m^3$ would ensure that the highest exposed subgroups of people, those likely to be more at risk from exposure, would not be exposed at or above 9.3 $\mu g/m^3$.

EPA did not take this approach. Instead, EPA proposed a range of 9.0 to 10.0 $\mu g/m^3$. EPA only briefly addressed the highest exposed subgroups in the population, stating:

> "[T]he Administrator observes that **a policy approach** for setting a standard level **that requires the design value monitor to meet study reported means** will generally result in lower concentrations of $PM_{2.5}$ across the entire area, **such that even those people living near an area design value monitor (where $PM_{2.5}$ concentrations are generally highest) will be exposed to $PM_{2.5}$ concentrations below the air quality conditions reported in the epidemiologic studies** where there is the highest confidence of an association." (emphasis added)[12]

EPA went on to state:

> "Based on the available air quality information, it would be expected that **an area with a study reported mean of 10 $\mu g/m^3$** would have a gradient of concentrations across the area, with higher concentrations near the design value monitor and lower concentrations away from it. **If the level of the standard were revised to 10.0 $\mu g/m^3$, then it would be expected that there would still be a gradient of concentrations, but the $PM_{2.5}$ concentrations across the area would be reduced in order to meet the revised standard at the design value monitor, and therefore areas away from the design value monitor would be expected to have a gradient of $PM_{2.5}$ concentrations at or below 10.0 $\mu g/m^3$ as well**." (emphasis added)[13]

EPA clearly recognized that people living near the design value monitor will be the subgroups likely exposed to highest $PM_{2.5}$ concentrations in the area. EPA stated that a level of the standard set to "meet the study reported means" should result in the highest exposed population being "exposed to $PM_{2.5}$ concentrations below the air quality conditions reported in the epidemiologic studies where there is the highest confidence of an association." There are important flaws in this approach.

First, EPA did not point to setting the level <u>somewhat below</u> the lowest reported study mean.

Instead, EPA referred to setting it to <u>meet the reported means</u>. While EPA was not clear, presumably it referred to setting the level at the lowest reported mean, a level of 9.3 $\mu g/m^3$. If that were the case, the population exposed to the levels measured at the highest monitor could be exposed to a level of 9.3 $\mu g/m^3$, a level shown in an important study to be associated with serious adverse health effects.[14] A level of 9.3 $\mu g/m^3$ clearly would fail to protect that higher exposed subgroup with an adequate margin of safety. EPA is incorrect to say that a standard <u>at</u> a level of a study-mean indicates that the most exposed subgroups would be exposed to levels "below the air quality conditions reported in the epidemiologic studies..."

[12] 88 FR at 5626.
[13] 88 FR at 5626, note 102.
[14] 88 FR at 5626.

EPA's reference to "requiring the design value monitor to meet the study reported means" is not clear, as EPA focused on several studies resulting in several different means. But it is clear that a range of 9.0 $\mu g/m^3$ to 10.0 $\mu g/m^3$ does not refer to setting a level somewhat below the lowest study reported mean. Perhaps EPA considered the proposed level of 9.0 $\mu g/m^3$ to be somewhat below the lowest reported mean of each of the key studies. Based on the limited group of studies EPA focused on, anything above 9.0 $\mu g/m^3$ clearly would not do this.

EPA discussed a level above 9.0 $\mu g/m^3$, stating that a standard level of 10.0 $\mu g/m^3$ would mean the average concentration in an area would likely be at or below 10.0 $\mu g/m^3$. While this is accurate, it ignores the exposure of the subgroups exposed to the higher levels measured by the design monitor. A level of 10.0 $\mu g/m^3$ would mean that the at-risk people exposed to the levels at the design monitor could be exposed to a level of 10.0 $\mu g/m^3$, yet in EPA's example, 10.0 $\mu g/m^3$ would be a level shown in a study associated with serious adverse health effects, and is clearly higher than the means reported in some of the studies, i.e. 9.6 and 9.3 $\mu g/m^3$. A level of 10.0 $\mu g/m^3$ would allow the highest exposed sub-groups to be exposed to levels <u>at or above</u> those found in important studies to be associated with serious adverse health effects. EPA ignored these subgroups and its obligation to protect these subgroups in its discussion of a level of 10.0 $\mu g/m^3$. EPA's statement noted that even the area-wide average concentration could be at a level of 10.0 $\mu g/m^3$, a level higher than the means of studies EPA relies on as key.

Any level above 9.0 $\mu g/m^3$ is clearly inconsistent with the logic of the 2012 decision, even using the set of studies EPA relied upon. A level above 9.0 $\mu g/m^3$ would allow the highest exposed subgroups in an area, likely at-risk populations, to be exposed to levels at or above those found in this group of studies to be associated with serious adverse health effects, including mortality. This would provide no margin of safety, much less an adequate margin of safety.

Second, EPA failed to discuss the risk attributes of the population likely to receive the highest exposures in an area, those measured by the design monitor.

In the 2012 review, EPA discussed in detail that subgroups of the general population exposed to the higher levels in an area were likely at greater risk because of factors such as lower SES, age, and minority status. EPA largely ignores these serious concerns in its discussion of the rationale for exposures that would be allowed by the proposed range of levels.

Third, EPA's use of the design values of studies as an important metric in setting the level of the annual standard NAAQS is flawed. This approach focuses on the average exposure across the whole area as a basis for justifying the proposed range, while ignoring the health risks of persons exposed to the highest levels measured by the design monitors in an area – a concern that was central in the 2012 Review.

In the proposal, EPA stated:

> "[The Administrator] specifically notes that **an annual standard level that is no more than 10–20% higher than the study reported means** in the U.S. monitor based studies (*i.e.,* for the lowest study reported mean value of 9.9 $\mu g/m^3$, this means an annual standard level of **approximately 10.9–11.9 $\mu g/m^3$**) **and no more than 15–18% higher for the U.S. hybrid modeling** with population weighting applied (*i.e.,* for the lowest study reported

> mean value of 9.3 μg/m^3, this means an annual standard level of **approximately 10.7–11.0 μg/m^3**), **would generally maintain air quality exposures at or below those associated with the study-reported mean $PM_{2.5}$ concentrations,** exposures for which we have the strongest support for adverse health effects occurring. **Based on this, the Administrator concludes that a revised standard level of 9.0 to 10.0 μg/m^3 would generally limit air quality exposures to levels well below those associated with the study-reported mean $PM_{2.5}$ concentrations in the key epidemiologic studies**." (emphasis added)[15]

Basically, EPA is saying that an annual standard level no higher than 10.9–11.9 μg/m^3 or 10.7–11.0 μg/m^3 would generally keep exposures below the mean levels reported in the studies EPA focused on. EPA provided no detailed discussion or clear explanation, but it's clear what EPA meant: a standard level below approximately 10.9 or 10.7 μg/m^3, which is met at an area's design value monitor, would keep the average concentration in an area below 9.9 or 9.3 μg/m^3. This appears to have been EPA's main justification for proposing a range up to 10.0 μg/m^3 – it would keep the average concentration in an area below the 9.9 or 9.3 μg/m^3 study reported mean levels.

This focus on the projected design values for the studies as a major justification for setting the level of the standard has ignored the health risk to the people exposed to the levels measured at an area's design monitor. These subgroups, typically at higher risk than the general population, would be exposed to levels up to and including 10.0 μg/m^3. They would not be protected from exposure to levels of 10.0 μg/m^3, and certainly would not be protected from exposures to levels of 9.9 or 9.3 μg/m^3. As discussed above, these subgroups would not be protected with an adequate margin of safety.

EPA's focus on the projected design values of the studies it identifies as "key" is flawed. EPA's logic appeared to be selecting the annual level of the NAAQS at or below the design values of these studies ("an annual standard level that is no more than 10–20% higher than the study reported means"). EPA justified this level as providing an adequate margin of safety because it will keep the general or average concentration across the area below the means reported in the key studies. This logic fails.

The goal of the NAAQS is not to protect the population on average. The NAAQS must protect <u>all</u> groups in the population, including those subgroups most at risk from higher, harmful exposures. EPA's use of the design values of studies as an important metric in setting the level of the standard fails to do this – it leaves at-risk subgroups of people, those exposed to the highest levels in an area, exposed to levels <u>higher</u> than the means of the studies. The fact the average exposure across an area is lower does not protect higher exposed subgroups.

As EPA said in the 2012 Review:

> **"[T]he Administrator concludes that public health would not be protected with an adequate margin of safety in all locations, as required by law, if disproportionately higher exposure concentrations in at-risk populations such as low income communities as well as minority communities were averaged together with lower concentrations measured at other sites in a large urban area.** See *ALA* v. *EPA,* 134 F. 3d 388, 389 (D.C. Cir., 1998) ("this court has held that 'NAAQS must protect not only

[15] 88 FR at 5626.

> average healthy individuals, but also sensitive citizens such as children,' and 'if a pollutant adversely affects the health of these sensitive individuals, EPA must strengthen the entire national standard'") and *Coalition of Battery Recyclers Association* v. *EPA,* 604 F 3d. 613, 617 (D.C. Cir., 2010) ("Petitioners' assertion that the revised lead NAAQS is overprotective because it is more stringent than necessary to protect the entire population of young U.S. children ignores that the Clean Air Act allows protection of sensitive subpopulations.")" (emphasis added)[16]

EPA's focus on the projected design value of the studies runs directly counter to protecting all at-risk members of the public. It would allow the highest exposed subgroups, those who are most at risk, to be exposed to levels above the means of these studies. It would allow them to be exposed to levels higher than those shown to be associated with serious adverse effects, including mortality. EPA justified this level of the standard because the average exposure in an area will be below the study means. That justification clearly fails to provide an adequate margin of safety for the at-risk subgroups exposed to the highest levels in an area.

Setting the NAAQS at a level "somewhat below" the design value of the key studies does not protect the higher exposed, at-risk subgroups, much less protect them with an adequate margin of safety. In contrast, setting the NAAQS "somewhat below" the lowest mean of the most relevant studies can be a valid approach to protecting these and other subgroups with an adequate margin of safety. [17]

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[16] 78 FR at 3127

[17] EPA's improper reliance on design values does not stop there. Over and over EPA relies on the importance of design values to justify rejecting or placing lower emphasis on otherwise credible and important studies. As discussed in section III, uncertainty over an otherwise important study's design value is used to ignore or place lower weight on the study and its reported means. EPA's logic in using the studies' design values in setting the level of the NAAQS is improper, and it is also not a valid reason to reject or under-emphasize important reported studies and their means.

EPA states over and over that the mean of the study has the most certainty in evaluating the health impacts of $PM_{2.5}$. In contrast, the design value of a study tells you nothing or next to nothing about the risk associated with exposure to $PM_{2.5}$. It is the tail end of the spectrum of data in a study. The mean of a study can provide critical information about the risk of serious health effects from exposure, risks that people need protection from. If a subgroup of people in an area are exposed at or above this mean level, then the study tells us that they are clearly at risk for the serious health effects identified in that study as associated with these levels. The design value may tell you something about expected average levels of exposure across an area, but it tells you nothing about the risk of serious adverse health effects for those people in an area exposed to the design value levels. It is the means of the reported studies and somewhat lower levels that tell you the most about the health risks for people exposed to the higher than average levels measured by the design value monitors.

That is why EPA previously required that the design value of an area be at or below the NAAQS (rejection of spatial averaging) and set the NAAQS at a level so the people exposed to the highest levels in an area (the design value) would only be exposed to levels somewhat below the lowest mean in the group of key studies. This protects the average or general population, such that the average area-wide exposure will be lower than these means. But it goes further and critically protects all subgroups in the area, especially those at the highest exposure levels and at most risk, ensuring that they are also exposed to levels somewhat below the lowest mean in the group of key studies.

EPA's use of design values to set the level of the NAAQS fails to do this. For the same reason uncertainty over design values is not a valid reason to reject or place less emphasis on important studies when determining the studies included in the group of studies most influencing the level of the NAAQS.

For these reasons, EPA's proposed range of 9.0 to 10.0 $\mu g/m^3$ is a major step backwards in protection in setting the level of the annual standard. The decision in the 2012 Review followed a clear and logical path, focused on protecting all of the at-risk people in an area. In contrast, the proposal's decision process was flawed:

- EPA failed to require the level of the standard to be at least "somewhat below" the lowest reported mean of the group of studies identified as most relevant to selecting the level of the standard.

- EPA's rationale briefly recognized and discussed the highest exposed population. However, the proposed range of levels, in all cases other than the very lowest level of the range, would leave the highest exposed subgroups of the general population exposed to levels above those that one or more of these studies found associated with serious adverse health effects, including mortality.

- EPA appeared to justify this by relying on the expected lower average levels of exposure across the entire area. This fails to take into account the disproportionate risk for populations in an area exposed at the higher-than-average design monitor levels.

In addition to failing to address the important concerns and rationales discussed in detail in the 2012 Review, EPA failed to make clear that its current approach differs dramatically from the approach taken in 2012, in ways that clearly appear to be backsliding in terms of public health protection. EPA failed to explain why it is rejecting the 2012 approach in favor of this new, unclear, and illogical approach that failed to protect all of the at-risk public from exposure to $PM_{2.5}$ with an adequate margin of safety.[18]

These serious flaws in EPA's proposal arise if you take as a given the limited group of studies EPA focuses on. Section III below explains that EPA's choice of studies to focus on in setting the level of the standard was too limited, exacerbating the flaws discussed in this section.

III. **The Proposal's Assessment of Epidemiology Studies Most Relevant to Selecting a Level of the Annual $PM_{2.5}$ Standard is Flawed.**

[18] *International Organization of Masters, Mates & Pilots, ILA, AFL-CIO v. National Labor Relations Board*, no. 21-1249 (D.C. Cir. March 3, 2023) (slip op. at 13, 15) ("When the Board fails to explain or acknowledge its deviation from established precedent, we vacate its decision as arbitrary and capricious. … While "[a]gencies are free to change their existing policies," they must "provide a reasoned explanation for the change**."** Encino Motorcars, LLC v. Navarro, 579 U.S. 211, 221 (2016); see NLRB v. CNN Am., Inc., 865 F.3d 740, 748 (D.C. Cir. 2017) (declining to enforce a Board order that "appear[ed] to be inconsistent with its precedents, without addressing those precedents or explaining why they do not govern"); see also Dupuy v. NLRB, 806 F.3d 556, 562 (D.C. Cir. 2015). The explanation **"**must at least display awareness that [the Board] is changing position and show that there are good reasons for the new policy**."** Encino Motorcars, 579 U.S. at 221 (cleaned up); see FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009).). Also see *National Ass'n of Mfrs. v. EPA*, 750 F.3d 921, 924 (D.C. Cir. 2014) ("In the 2013 Rule, … EPA selected the 12.0 $\mu g/m^3$ level because it was somewhat below the lowest long-term mean concentration shown by certain key epidemiologic studies to cause adverse health effects. *See* 78 Fed.Reg. at 3158–59, 3161. EPA followed a similar approach in earlier particulate matter NAAQS revisions, and we upheld those EPA decisions. *See American Farm Bureau Federation v. EPA,* 559 F.3d 512, 526–27 (D.C.Cir.2009) (EPA "reasonably decided to address long-term exposure with an annual standard somewhat below the long-term mean concentrations in the ACS and Six Cities studies"); *American Trucking Associations, Inc. v. EPA,* 283 F.3d 355, 372 (D.C.Cir.2002) (upholding particulate matter NAAQS where "EPA ultimately set the standard just below the range of mean annual [particulate matter] concentrations observed in studies showing a statistically significant association between fine particulate matter and health effects").")

EPA's ISA (EPA 2019) and ISA Supplement (EPA 2022) assessed a massive amount of scientific information relevant to evaluating the health effects in $PM_{2.5}$. The ISA used a multidisciplinary assessment of the evidence, in part to reach conclusions about causality, assigning effects to one of five categories. In identifying epidemiology studies of most relevance to evaluating the current and alternative levels of the $PM_{2.5}$ standards, the Policy Assessment (PA, EPA 2022b) focused on studies with effects that were judged by the ISA to be Causal or Likely Causal. As in past reviews, EPA limited studies of interest to those conducted in North America.

> "In our assessment of the evidence judged to be most relevant to decisions on the elements of the primary $PM_{2.5}$ standards, we place greater weight on U.S. and Canadian studies. This is because findings of U.S. and Canadian studies are more directly applicable for quantitative considerations in this reconsideration, as studies conducted in other countries reflect different populations, exposure characteristics, and air pollution mixtures."[19]

In reviewing EPA's assessment of these most relevant studies in the proposal, it was necessary to go back to the PA and ISA for greater clarity and balance provided in Tables and Figures that appear there. We also referred to the recommendations CASAC made to EPA, which are not all addressed in the proposal, as well as comments made by EPN and other public commenters during the course of this review.

We found several important flaws in the proposal's assessment that need to be corrected before promulgation. A major fault stems from EPA's reliance on the problematic and flawed "design value framework" discussed above. The design value approach placed improper importance on a study's design value in evaluating the level of the standard and led to the proposal suggesting several important classes of studies be given less weight because of "uncertainties" in estimating the studies' design values.

Classes of epidemiology studies downplayed in part for design value uncertainties, as well as other issues, include studies using hybrid modeling, studies conducted in Canada, studies that report results of restricted analysis that consider only levels below the annual standard, studies that report 25th percentiles, and accountability studies. In addition, the proposal ignored several otherwise highly relevant results from several studies, including some that were praised for using alternative methods to account for confounding.

A. ***EPA misused the implication of uncertainties in estimating Design Values for key Epidemiology Studies.***

The proposal attempted to rewrite the history of the role played by the design value of important studies as used by the Administrator in choosing the levels for $PM_{2.5}$ standards in 2012. That approach, summarized above, proposed a range for the annual standard (12 to 13 $\mu g/m^3$) and ultimately selected 12 $\mu g/m^3$, a level that was below the lowest mean (or composite) level in the key studies, in some cases as low as the 25th percentile.[20] The current proposal has stated:

> **"Consistent with the approach taken in 2012, in assessing how the overall mean (or median) $PM_{2.5}$ concentrations reported in key epidemiologic studies can inform**

[19] EPA 2022b at 3-77.
[20] 77 FR at 38932.

> **conclusions on the annual primary $PM_{2.5}$ standard**, the PA notes that the relationship between mean $PM_{2.5}$ concentrations and the area design value continues to be an important consideration in evaluating the adequacy of the current or potential alternative annual $PM_{2.5}$ standard levels in this reconsideration." (emphasis added) [21]

This is correct to the extent the 2012 Review did away with average or composite methods for determining an area's design value and compliance with the standard. However, the 2012 proposal was clear - the main use of information on area design values was to ensure the annual standard continued to be generally controlling as compared to the daily standard. For example:

> "In addition to considering the epidemiological evidence, the Administrator also has taken into account air quality information based on county-level 24-hour and annual design values to understand the implications of retaining the 24-hour standard level at 35 $\mu g/m^3$ in conjunction with an annual standard level within the proposed range of 12 to 13 $\mu g/m^3$. She has considered whether this suite of standards would meet a public health policy goal which includes setting the annual standard to be the "generally controlling" standard in conjunction with setting the 24-hour standard to provide supplemental protection to the extent that additional protection is warranted." [22]

The emphasis on the use of design values in understanding the balance of protection by annual and daily standards noted above was stated in various places.[23] Design values were also of interest in aspects of the focused roll back approach used in the risk assessment. [24]

Difficulty in estimating a design value was <u>not</u> used to suggest a study was less certain or less important in determining the level of the standard. Instead, the assessment of the key statistics for studies that supported the level of the annual standard was clearly illustrated in Figure 4 of the 2012 final rule. Figure 4 provided the study mean concentrations, whether it was a long-term cohort study or the average of an annual average of a study of daily effects, whether the 25^{th} and 10^{th} percentiles where available, and whether the effects observed in the study were classified as causal or likely causal. A design value for each study was not shown because it was <u>not</u> central to selecting the level of the standard.[25]

The level of the standard would, when promulgated, of course be compared to the design value for an area to determine compliance. But the design values of the studies played no role in picking the level of the standard. A level below the mean of the studies was the central metric EPA focused on in setting the level of the standard, not the design value of the studies, although they did consider the 25^{th} percentile where available. EPA properly determined that everyone in an area, including those exposed to the highest levels in an area, needed to be protected from the risks associated with exposures identified by the mean levels of the studies. The final level of 12 $\mu g/m^3$ was below the mean of all U.S. and Canadian exposure studies for causal

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[21] 88 FR at 5596.
[22] 77 FR 38890, 38943 (June 29, 2012).
[23] E.g., 77 FR at 38938.
[24] 77 FR at 38913. The term "design value" appears 17 times in the 2012 proposal for the primary $PM_{2.5}$ standards. By contrast, it is found over 110 times in the current proposal. A number of these refer to adding to the uncertainties for various classes of studies.
[25] 78 FR at 3135. Figure 4 is reproduced in the Appendix to these comments.

endpoints and near or below the 25th percentile for two of them.[26] The design value of the studies played no role in evaluating 12 μg/m^3 versus a higher or lower annual level.[27]

If the current EPA proposal followed the approach for standard setting used in the 2012 decision, the proposal would not arbitrarily suggest that a difficulty in estimating the design value for a particular study adds to the uncertainty in using it to set the annual level. An annual standard level set below the mean level in such a study or as low as the 25th percentile would in fact become the revised standard and would have to be met at all monitors in an area, most importantly at the design value monitor.

B. ***Treatment of studies using hybrid modeling.***

Most key epidemiology studies in the 2012 review used $PM_{2.5}$ monitors located in urban/suburban areas to assess exposure. More recently, most new key studies have used a hybrid-modeling approach that estimates exposures for cohorts that live farther away from monitors than in earlier studies. EPA's PA presented a useful assessment of the benefits and uncertainties of addressing the most recent approach that supplements monitoring with satellite, modeling and neural networks, and/or land use and other variables. In their review of the draft PA review and analysis, CASAC wrote:

> "The CASAC agrees with the statement (page 2-61) that "Hybrid $PM_{2.5}$ modeling methods have improved the ability to estimate $PM_{2.5}$ exposure for populations throughout the conterminous U.S. compared with the earlier approaches based on monitoring data alone. Excellent performance in cross-validation tests suggests that hybrid methods are reliable for estimating $PM_{2.5}$ exposure in many applications." Additionally, hybrid models do a better job of characterizing the exposures of rural residents, which are not as well represented by monitors. Thus, they better represent the diversity of exposures experienced and therefore, the CASAC suggests adding this point."[28]

The final PA did not make the recommended edit, but continued with the original text summarizing key limitations and uncertainties, including the importance of hybrid modeling surfaces using population weighting, without which the means and design values can be too low. The PA reached the following conclusion about the U.S. hybrid modeling studies that use this approach:

> "The majority of these studies estimate mean $PM_{2.5}$ exposure by averaging up from the grid cell spatial resolution used in the modeling approach to the spatial resolution of health study data (e.g., ZIP code or census tract). This incorporates an aspect of population weighting in

[26] Ibid.

[27] As discussed above, EPA did consider design values of areas (not studies) in other ways, primarily to determine the level of a daily standard. The design value of areas informed this issue as it related to the important issue of the extent to which the annual standard was controlling in areas across the country.

[28] Sheppard, EA. (2022a). Letter from Elizabeth A. (Lianne) Sheppard, Chair, Clean Air Scientific Advisory Committee, to Administrator Michael S. Regan. Re: CASAC Review of the EPA's *Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft - October 2021)*. March 18, 2022. EPA-CASAC-22-002. Office of the Administrator, Science Advisory Board U.S. EPA HQ, Washington DC. Available at: https://casac.epa.gov/ords/sab/f?p=113:0:8242276817767:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1094, p.5 of consensus responses.

> the calculation of the mean. Based on our air quality analyses, we would expect these epidemiologic studies to report means similar to those from monitor-based studies."[29]

Unfortunately, the proposal expanded its concern of lack of design values to monitor-based as well as hybrid modeling studies:

> "Regardless of whether a study uses monitoring data or a hybrid modeling approach when estimating $PM_{2.5}$ exposures, one key limitation that persists is associated with the interpretation of the study-reported mean $PM_{2.5}$ concentrations and how they compare to design values, the metric that describe the air quality status of a given area relative to the NAAQS."[30]

While it is important to consider any uncertainties in the mean of the studies in choosing a level for the standard, for reasons noted above, it is not necessary or appropriate to use the design value derived from a study in the way EPA proposed to use it in deciding on a level.

C. ***Downplaying the relevance of Canadian studies.***

As noted above, while examining all the scientific information in reviewing the PM NAAQS, when identifying key epidemiology studies EPA focused mainly on studies conducted in the U.S. and Canada.[31] Nevertheless, based on the PA, the proposal backed away from this long-standing policy before presenting the results of Canadian studies.

> "However, and as noted above, the PA also recognizes that while information from Canadian studies can be useful in assessing the adequacy of the annual standard, there are still important differences between the exposure environments in the U.S. and Canada and interpreting the data (e.g., mean concentrations) from the Canadian studies in the context of a U.S.-based standard may present challenges in directly and quantitatively informing questions regarding the adequacy of the current or potential alternative the levels of the annual standard."[32]

The PA repeated this concern about Canada, highlighting differences that previously were used to exclude studies outside of North America.

> "In identifying key epidemiologic studies for consideration, the PA places the greatest emphasis on studies conducted in the U.S. and Canada, although recognizes a number of limitations associated with interpreting the results of Canadian studies compared to studies conducted in the U.S. **Generally, there are differences in the exposure environments and population characteristics between the U.S. and other countries, including Canada**, that can affect the study-reported mean $PM_{2.5}$ concentration and its comparability

[29] EPA 2022b at 3-17.
[30] 88 FR at 5604.
[31] As noted above, the PA states: "This is because findings of U.S. and Canadian studies are more directly applicable for quantitative considerations in this reconsideration, as studies conducted in other countries reflect different populations, exposure characteristics, and air pollution mixtures." EPA 2022b at 3-77.
[32] 88 FR at 5598.

> with the annual standard level. **A number of other differences, including sources and pollutant mixtures, concentration gradients, and population densities, can make it challenging to interpret the mean $PM_{2.5}$ concentrations in Canadian studies in the context of a U.S.-based standard.** Specifically, it may be difficult to use such studies to directly and quantitatively inform questions regarding the adequacy of the current or potential alternative levels of the annual standard. Therefore, while the PA considers the mean $PM_{2.5}$ concentrations from U.S. and Canadian studies in reaching conclusions, it notes that **the U.S.-based epidemiologic studies are most informative for comparisons with the annual standard metric and for reaching conclusions on the current standards and for informing potential alternative levels of the standard."** (emphasis added) [33]

The proposal also emphasized EPA's concern about estimating design values from Canadian studies:

> "The PA also acknowledges that these types of challenges are also present in using information from Canadian studies to directly and quantitatively inform questions on the level of the annual standard given the difficulty of interpreting what the Canadian study means represent relative to U.S. design values."[34]

The full CASAC took exception to excluding Canadian studies, in particular based on the perceived difficulties cited in the PA in deriving design values for the U.S.

> "[T]here is concern with exclusion of Canadian studies because of not having design values in Canada to relate to area averages. The Canadian epidemiologic studies identify associations with area averages, and while there may be no design value in Canada, there are data that indicate what a U.S. design value would be if an area average like that found in the Canadian studies were to occur in the U.S."[35]

The CASAC majority was more specific in a bullet point citing specific Canadian epidemiology studies that suggest a standard of 10 $\mu g/m^3$ might not be protective:

> "Canadian studies, some of which showed such associations at concentrations below 10 $\mu g/m^3$ (Zhang, 2021) and 8 $\mu g/m^3$ (Christidis, 2019; Pappin, 2019; Pinault, 2017)."[36]

The proposal did not support its speculations about differences in pollution mixtures, sources, population characteristics, and exposure patterns with any specific evidence.

For decades, the substantial contribution of U.S. air pollution to Canada in the form of acid rain, particles, and ozone have been widely recognized. While the U.S. and Canada have made great progress, there should still be substantial intermixing of US and Canadian ozone and particle pollution in the 50 percent of Canada's population who live south of the 45.7th parallel, mostly in the corridor between Windsor (which is

[33] 88 FR at 5610-11.
[34] 88 FR at 5614.
[35] Sheppard 2022a, p.13 of consensus responses.
[36] Ibid, p.16 of consensus responses.

south of Detroit) to the other major urban areas of Ontario, and Quebec City.[37] Nearly 75 percent of Canadians live in urban areas.[38] They drive cars and use diesel-powered on- and off-road vehicles. Canadian stationary sources still include coal-fired power plants and industry such as steel mills, automobile production, and more. Moreover, Canada's monitoring methods and network design for $PM_{2.5}$ monitors are quite similar to those used in the U.S.[39] While it is still important to address specific features of the epidemiology studies for U.S. and Canadian studies, EPA's assertions about the relevance of Canadian studies to U.S. $PM_{2.5}$ standards are simply without merit.

Table 3-7 in the PA identified nine key Canadian studies that were based on monitors. Seven of these studies had reported means below 10 $\mu g/m^3$, and as the proposal noted,

> "For the majority of key Canadian epidemiologic studies that use monitor-based exposure, mean $PM_{2.5}$ concentrations generally ranged from 7.0 $\mu g/m^3$ to 9.0 $\mu g/m^3$."[40]

As discussed above as well as in CASAC comments, EPA provided no basis to change the role Canadian studies have been given in past reviews.[41] It remains the case that any uncertainties associated with estimating a design value for these are not relevant to their use in selecting a level for the standard.

Setting aside the improper reliance on considerations related to design values of studies, the proposal addressed aspects of the conduct and results of Canadian hybrid modeling results.

> "For the key Canadian epidemiologic studies that use hybrid model-predicted exposure, the mean $PM_{2.5}$ concentrations are generally lower than in U.S. model-based studies (U.S. EPA, 2022b, Figure 3-10), ranging from approximately 6.0 $\mu g/m^3$ to just below 10.0 $\mu g/m^3$ (U.S. EPA, 2022b, Figure 3-11). Most key Canadian epidemiologic studies that used hybrid modeling were completed at the nationwide scale, while four studies were completed at the regional geographic spatial scale. In addition, all the key Canadian epidemiologic studies apply aspects of population weighting, where all grid cells within a postal code are averaged, individuals are assigned exposure at the postal code resolution, and study mean $PM_{2.5}$ concentrations are based on the average of individual exposures."[42]

As noted above, the use of population weighting is important, and the PA and proposal correctly gave lower weight to U.S. studies that did not use it. The proposal raised a more substantive point based on the PA assessment of hybrid models:

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[37] Brilliant maps: 50% of Canadians Live South of The Red Line-available at https://brilliantmaps.com/half-canada/. Accessed March 2023.
[38] Statistics Canada 2022. Canada's large urban centres continue to grow and spread-available at https://www150.statcan.gc.ca/n1/daily-quotidien/220209/dq220209b-eng.htm. Accessed March 2023
[39] Canada's $PM_{2.5}$ monitoring network is similar in terms of monitors, locations, and an emphasis on high population areas. https://ccme.ca/en/res/ambientairmonitoringandqa-qcguidelines_ensecure.pdf
[40] 88 FR at 5602.
[41] As noted above, a multicity Canadian study (Burnett *et al*.,2004) was one of the two studies with means somewhat above 12 µg/m3 and featured in the 2012 decision that set the current annual standard.
[42] 88 FR at 5602.

> "However, the results of those analyses only reflect two surfaces and two types of approaches, so uncertainty remains in understanding the relationship between estimated modeled $PM_{2.5}$ concentrations and design values more broadly across hybrid modeling studies. Moreover, this analysis was completed using two hybrid modeling methods that estimate $PM_{2.5}$ concentrations in the U.S., thus an additional uncertainty includes understanding the relationship between modeled $PM_{2.5}$ concentrations and design values reported in Canada."[43]

The important issue here is not related to uncertainties about design values, but uncertainties in estimating mean levels. In particular, it raises the question of whether conclusions based on the analyses in the PA that included national and regional assessments in the U.S. would apply to Canada. One obvious observation is that a large percentage of Canadians live in urban areas near the U.S. border, so that the ranges and geographical features of population/source density in the southern portion of Canada should be similar to that in the nearest northern parts of the U.S.[44,45] One of the hybrid modeling approaches used in the PA assessment is Di *et al*., 2019, which was used in a number of U.S. studies. The other was based on the work of van Donkelaar (2019) and termed the VD2019 method. The lead author was involved in multiple Canadian hybrid modeling studies. Figure 2-37 in the PA illustrated model results from van Donkelaar *et al*., 2019 for the U.S. The study models $PM_{2.5}$ levels in the U.S. and Canada for 2001, 2006, 2011, and 2016 during which period, levels in eastern North America underwent major reductions. While EPA's analysis did not show predictions for Canada, van Donkelaar *et al*., 2019 do show trends in seasonal $PM_{2.5}$ levels for both sides of the border across this 16-year period. The figures presented did not reveal any obvious discontinuities near the U.S.-Canadian border, particularly in the most populated regions of the east noted above. The results showed Canadian and U.S. levels near the border dropped substantially by 2016.

That said, the PA summary concluded that in the U.S., the hybrid model predictions become less reliable with weaker performance at lower concentrations and at longer distances from monitors. The van Donkelaar *et al.* 2019 results for both countries suggest the same. These are uncertainties that apply to both sides of the border. Other than these, there is no evidence to suggest that the conclusions the PA reached about the use of U.S. hybrid model studies should not apply to Canadian studies. Factors such as concentrations and population-oriented approaches should be considered for both. The proposal was wrong to suggest Canadian studies should be given less consideration than U.S. studies *a priori*; for U.S. studies using appropriate methods, the PA,concluded, as noted above:

> "Based on our air quality analyses, we would expect these [hybrid modeling] epidemiologic studies to report means similar to those from monitor-based studies."[46]

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[43] EPA 2022b at 3-135.

[44] See e.g. EPA 2022b at Figure 2-36, which includes predictions for a number of border areas near Ontario that are north of parts of Canada. See also Government Health Impacts of Air Pollution in Canada: Estimates of morbidity and premature mortality outcomes – 2021 Report Figure 1 Three-year population-weighted average of daily $PM_{2.5}$ concentrations across Canadian census divisions – 2015–2017. Available at https://www.canada.ca/en/health-canada/services/publications/healthy-living/2021-health-effects-indoor-air-pollution.html

[45] One of the two methods that the PA used was developed by Van Donkeaar et al. 2019. The lead author played a role in contributing the Canadian studies using hybrid modeling.

[46] EPA 2022b at 3-17.

EPA, however, should also consider public comments from Joel Schwartz, who took issue with the PA analysis based on the Di *et al.* 2019 hybrid model. He wrote:

> "The statement that "Relatively weak performance in parts of the western U.S., possibly due to the sharp concentration gradients, complex terrain, low concentrations (and therefore signal-to-noise ratio), less dense monitoring, prevalence of wildfire, and challenges in satellite retrievals and CTM modeling (Di et al., 2016; Wang et al., 24 2018b; Hu et al., 2017; Kelly et al., 2019a)." again ignores the later model of Di 2019, used in many discussed studies. Di 2019 reports a cross validated (CV) R2 of 0.80 daily and 0.85 annually for the Pacific region. That is not much weaker than national, and certainly an excellent fit. The PA's omission of more recent PM models overestimates uncertainty.
>
> Di 2019 does not report weaker predictive ability at lower concentrations. It reports a) that the relationship between predicted and monitored values remains linear from 0 to 60 $\mu g/m^3$ and that the uncertainty in the relationship was smallest between 4 and 15 $\mu g/m^3$. This is shown in the figure below from that paper, showing the spline fit and 95% CI. Clearly the uncertainty is low between 5 and 10." Joel Schwartz 2019.[47]

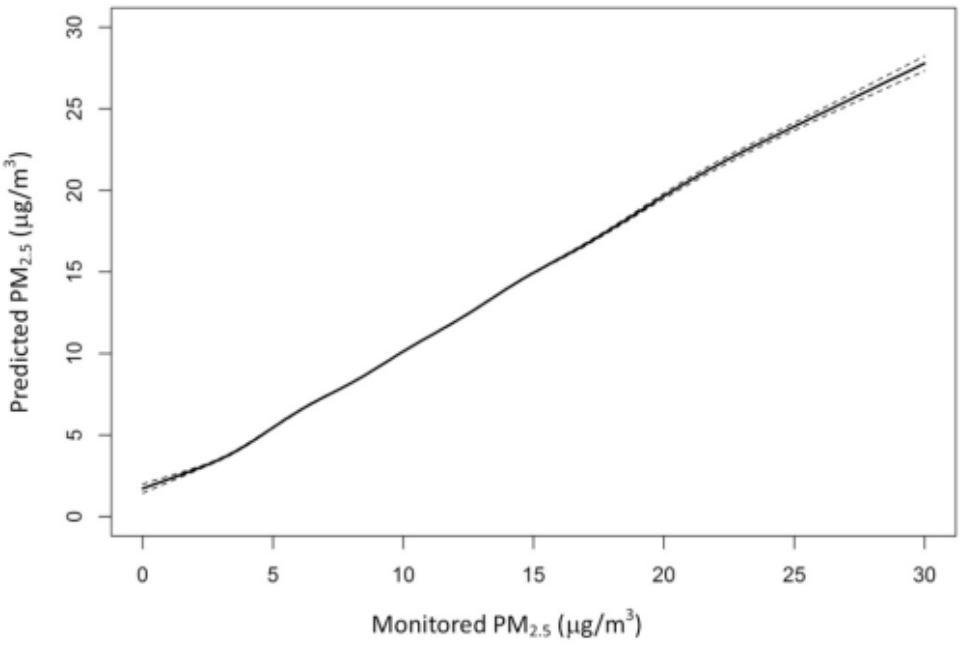

Fig. 4. Relationship between monitored and predicted $PM_{2.5}$ at annual level. We regressed annual averaged $PM_{2.5}$ predictions from the ensemble model against annual averaged monitored $PM_{2.5}$ in a generalized additive model, with spline on the monitored $PM_{2.5}$. Dashed lines represent 95% confidence interval.

Figure 1, from Di *et al*. 2019**.**

[47] Comments on EPA's Policy Assessment for $PM_{2.5}$, Joel Schwartz Professor of Environmental Health Harvard TH Chan School of Public Health $PM_{2.5}$ Submitted to SAB Staff Office. Public Meeting of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Panel 11/17/2021 to 12/02/2021.

EPA should consider these results in assessing more recent studies that use the Di *et al.* 2019 hybrid model.

D. ***Downplaying restricted level study results.***

Table 3-10 in the PA included five long-term epidemiology studies that provided an analysis excluding individuals exposed to levels above 12 $\mu g/m^3$ during the time they were followed. All found significant effects at these restricted levels. Only two of these five (Di *et al.* 2017b and Dominici *et al.* 2019) reported the means for the restricted analysis.

Once again, the proposal took issue with studies using restricted analyses for questionable reasons:

> "[T]hese studies also have inherent uncertainties and limitations, including uncertainty in how studies exclude concentrations (e.g., are they excluded at the modeled grid cell level, the ZIP code level) and in how concentrations in studies that restrict air quality data relate to design values for the annual and 24-hour standards."[48]

Based on EPA's own misunderstandings, the proposal actually suggested that the lack of means for three studies is a good thing.

> However, it is important to note that, **even if the other studies had reported the mean $PM_{2.5}$ concentrations for the restricted analysis, these means would not necessarily have been useful in the context of the decision framework as was used in past reviews** (above in section II.B.3.b.), given uncertainties associated with identifying the relationship between a calculated mean concentration that excludes specific daily or annual average concentrations above a certain threshold and the design value used to determine compliance with a standard (either the annual or 24-hour standard). Moreover, the PA emphasizes there is uncertainty in how studies exclude concentrations (e.g., at what spatial resolution are concentrations being excluded), which would make any comparisons of mean concentrations in restricted analyses difficult to compare to design values." (emphasis added)[49]

As above, given the departure this proposal has made from "the decision framework as was used in past reviews," EPA should dismiss its concerns with the uncertainties related to finding study design values. The issue of how researchers excluded concentrations is cleared up in the studies themselves. In the case of long-term studies at issue here, the studies simply examined their database that linked subjects to long term concentration above 12 $\mu g/m^3$, deleted them from the analysis, and reran the analysis. We can at least agree with the PA and proposal's conclusion that:

> "[I]t would not be unreasonable to presume that the mean $PM_{2.5}$ concentrations in the restricted analyses are less than the study-reported mean $PM_{2.5}$ concentrations in the main analyses."[50]

[48] 88 FR at 5603.
[49] 88 FR at 5613.
[50] Ibid.

We do, however, take strong issue with the fact that the proposal neglected to report results from two additional restricted modeling studies that are cited in the PA - Wu *et al.* 2020 and Yazdi *et al.* 2021. Both studies were included in Table 3-11 in the PA highlighting recent studies that provided alternative methods for confounder control.[51]

Significantly, both of these studies used the improved hybrid model of Di *et al* 2019 noted above. One of the two, Wu *et al.* 2020, appeared in Table 3-10 that featured restricted analyses. It reported a mean of 8.4 $\mu g/m^3$ for those Medicare subjects who were not exposed to levels above 12 $\mu g/m^3$. This makes its omission in the proposal's discussion of the restricted analysis results for this study extremely difficult to understand. Equally troubling is that the CASAC majority highlighted both Wu and other restricted studies as providing support for standards at lower levels below 10 $\mu g/m^3$.[52] Yazdi *et al.* is entirely based on a restricted analysis, and reports a mean of 8.2 $\mu g/m^3$ and a 25^{th} percentile of 6.9 $\mu g/m^3$. Unfortunately, the PA did not follow CASAC's suggestion to include Yazdi *et al.* 2021 in Table 3-10 and the proposal mentions neither in the context of restricted results.

Ironically, both are among the strongest examples of recent advances in air pollution epidemiology using multiple innovative approaches to address confounding as well as an improved hybrid model. They provide strong evidence to wholly reject a standard above 9 $\mu g/m^3$, and as the CASAC majority suggested, serious consideration of a standard of 8 $\mu g/m^3$.

E. ***Downgrading three accountability studies in a footnote.***

Recent PAs have stressed the importance of studies that examine changes in mortality or other health effects that occur as the result of decreases in air pollution concentrations. Table 3-12 lists 12 epidemiology studies examining health impacts of long-term reduction in ambient $PM_{2.5}$ concentrations. They provide strong support for concluding that the kinds of effects observed in other epidemiology studies are causal. The proposal highlighted three recent studies that stood out:

> "More specifically, of the accountability studies that account for changes in $PM_{2.5}$ concentrations due to a policy or the implementation of an intervention to assess whether there was evidence of changes in associations with mortality or cardiovascular effects due to changes in annual $PM_{2.5}$ concentrations, Corrigan et al. (2018), Henneman et al. (2019b) and Sanders et al. (2020a) present analyses with starting concentrations (or concentrations prior to the policy or intervention) below 12.0 $\mu g/m^3$."[53]

The proposal provided a useful summary of the key findings of each of the three, including noting the initial $PM_{2.5}$ concentrations and in the case of Henneman *et al.*, the findings included the initial mean (10 $\mu g/m^3$) before reductions as well as the mean after reductions (7.2 $\mu g/m^3$).[54] However, in a further discussion of the use of these studies in Section D.3 Conclusions on the Primary Standard the proposal adds the following footnote:

[51] EPA 2022b at 3-35.
[52] Sheppard, 2022a, p.16 of consensus responses.
[53] 88 FR at 5604.
[54] Ibid.

> "We note that the studies by Corrigan et al. (2018) and Sanders et al. (2020a) report monitor-based average $PM_{2.5}$ concentrations, and the study by [sic] reports model-based average $PM_{2.5}$ concentrations, and that these studies do not report design values."[55]

This is an indirect way to suggest the studies may be important, but may have added uncertainties that make the results less useful for selecting the level of an annual standard. As noted elsewhere, the design value of a study is not needed for this purpose, other than in the multi-study context of ensuring the annual standard remains controlling.

More appropriately, the Administrator did suggest these studies carry weight in the decision of whether the current standard should be strengthened.

> "In further assessing the adequacy of the current annual standard, the Administrator also evaluates what the accountability studies may indicate with respect to potential for improvements in public health with improvements in air quality. In so doing, he takes note of three accountability studies (Sanders et al., 2020b; Corrigan et al., 2018; and Henneman et al., 2019a) newly available in this reconsideration with starting concentrations at or below 12.0 $\mu g/m^3$ that indicate positive and significant associations with mortality and morbidity and reductions in ambient $PM_{2.5}$ (described above in section II.B.3.b and in Table 3-12 of the PA) and notes that these studies suggest public health improvements may occur at concentrations below 12 $\mu g/m^3$."[56]

This is an appropriate conclusion as far as it goes. Yet, when addressing these studies in the context of proposing a level between 9 and 10 $\mu g/m^3$, he repeatedly left out part of the key aspects of these studies:

> "The Administrator notes that a revised annual standard level of 9.0-10.0 $\mu g/m^3$ would be at or below the lowest starting concentration of these accountability studies (i.e., 10.0 $\mu g/m^3$)."[57]

and

> "The Administrator notes a standard level of 9.0-10.0 $\mu g/m^3$, would also be at or below the lowest starting concentration of the newest available accountability studies (i.e., 10.0-11.1 $\mu g/m^3$)."[58]

Neither the Administrator's statement nor the proposal section quoted earlier provided the $PM_{2.5}$ levels following the reductions examined in these studies. If the Administrator only considered the starting point, he is missing the most important aspect of the effort – that reductions that begin below 10 to 11 $\mu g/m^3$ continue well below the starting level. This issue is clearest for Henneman *et al.*, where the average level starts at 10 $\mu g/m^3$ and the reductions lowered the average to 7.2 $\mu g/m^3$. The study found health benefits from reducing $PM_{2.5}$ from 10 $\mu g/m^3$ by about 3 $\mu g/m^3$. The starting level for subjects in attainment areas in Corrigan was 11.1 $\mu g/m^3$, which was lowered to 10.2 $\mu g/m^3$. For Sanders, the attainment areas start at 11 $\mu g/m^3$ and are reduced to 9.3 $\mu g/m^3$.

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[55] 88 FR note 93 at 5613.
[56] 88 FR at 5620.
[57] 88 FR at 5627.
[58] 88 FR at 5628.

At least two of these studies directly call a standard level of 10 $\mu g/m^3$ into question, as it's highly unlikely the benefits observed were solely the result of a small reduction of less than 1 $\mu g/m^3$. It is unreasonable and unfounded to believe that a standard of 9 to 10 $\mu g/m^3$ being **at or below** the starting concentration protects public health with any margin of safety, without even mentioning or evaluating the lower levels involved. In fact, the levels associated with improvements suggest the margin of safety is negative.

F. ***The proposal's summary of CASAC's comments (Section D.1.) ignores a number of specific CASAC comments on the PA and evidence supporting annual standard levels.***

This part of the proposal appropriately summarized the CASAC comments on the overall quality and utility of the PA. There is no doubt EPA staff produced a substantial update of their 2020 PA that addressed the key scientific information in both the 2019 and 2022 update of the ISA. In addition to addressing the implications of new material, the PA also updated the risk assessment and improved treatment of a number of areas, from the implication of improved approaches for dealing with confounders to new analysis of environmental justice and sensitive populations in the risk assessment. We note that both the ISA supplement and the PA did add several additional recent studies that were recommended by public commenters and CASAC. Yet it is appropriate to note that the CASAC letter made it clear that some of their provisional conclusions were contingent on EPA making additional changes to the PA in response to their recommendations:

> "The discussion of epidemiologic studies is clearly organized, well written, and accurately describes the body of available epidemiologic literature (**with some exceptions of omitted publications noted**). The technical approach evaluating the relationship between the mean $PM_{2.5}$ concentrations reported in the epidemiologic studies and annual design values is clearly presented. However, the CASAC has concerns about the use of only mean concentrations for the purpose of informing the adequacy of the primary $PM_{2.5}$ standards and recommends a discussion of its limitations as well as the likely effect that using other concentrations from the study exposure distributions would have on the results and conclusions of the Draft PA." (emphasis added) [59]
>
> "The CASAC appreciates the opportunity to provide advice on the Draft PA and looks forward to the agency's response." [60]

The PA summary of CASAC Advice was similar to the general overview in the proposal.[61] It appears to err, however, in suggesting that the comments regarding omitted publications and the focus on mean values noted above reflected only the majority members; the quote on page 2 is clearly from the consensus portion of the letter.

While, as noted above, the PA did cite some relevant additional studies, the CASAC majority requested additional weight be given to a number of specific studies organized by approach. The first group included the four studies that used restricted air quality exposures cited above. Again, the proposal did not cite the

[59] Sheppard, 2022a, p.2 of consensus letter.
[60] Sheppard, 2022a, p.4 of consensus letter.
[61] EPA 2022b at 3-168.

two most important of these (Wu *et al.* 2020 and Yazdi *et al.* 2021) in the discussion of this category of studies.

The second group recommended by the CASAC majority included

> "Epidemiologic studies in the United States showing such associations at concentrations below 10 μg/m^3 (Ward-Caviness 2020) and below 8 μg/m^3 (Wei, 2020; Wang, 2020)."[62]

Ward-Caviness *et al.* 2020 is an EPA study summarized in the ISA supplement and noted in the PA, but not included in any tables. It assessed mortality in North Carolina and reported a median concentration of 10.1 μg/m^3, but the concentration/response curve suggests significant risk below 9.5 μg/m^3 (see **Figure 2**).

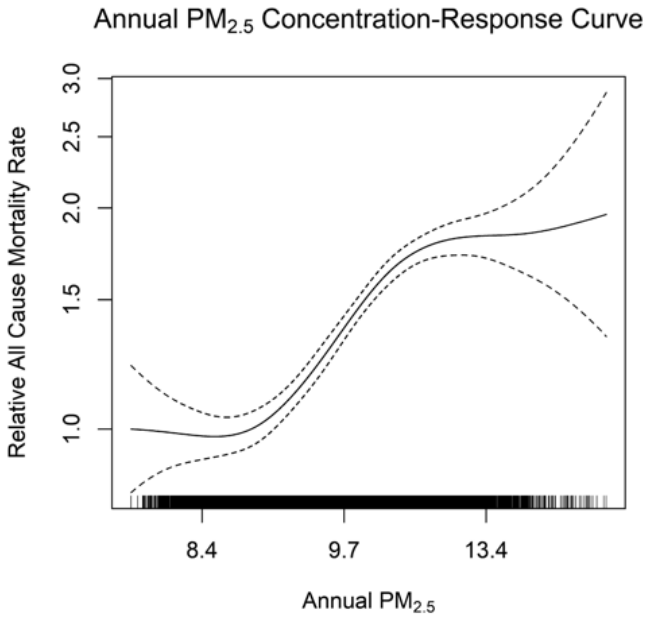

Figure 2, taken from Ward-Caviness *et al*. 2020.

Wei *et al.* 2020 was cited in the ISA supplement, but despite CASAC's recommendation it was not included in the PA or the proposal. It includes an assessment of both long- and short-term mortality in Medicare recipients in Massachusetts. The annual average was 9 μg/m^3. Wang *et al.* 2020 was included in the PA and is a national Medicare cohort study of mortality reporting effects at a mean concentration of 10.3 μg/m^3. Yet despite how close the average is to 10 μg/m^3, it was not cited in the proposal. The results of all three of these neglected in the proposed decision clearly raise questions about any margin of safety at 10 μg/m^3 and for the first two suggest effects at or near 9 μg/m^3.

The third group recommended by CASAC were well covered-in the PA:

> "Canadian studies, some of which showed such associations at concentrations below 10 μg/m^3 (Zhang, 2021) and 8 μg/m^3 (Christidis, 2019; Pappin, 2019; Pinault, 2017)."

[62] Sheppard, 2022a, p.16 of consensus responses.

All but one of these studies was included in PA Table 3-9 of Canadian model-based exposure studies. Pappin *et al.* 2019 did not meet the PA criteria for evaluating model performance.[63]

The final study CASAC recommended was:

> "A meta-analysis of 53 studies, 14 of which were conducted with mean concentrations below 10 $\mu g/m^3$, showing such associations down to 5 $\mu g/m^3$ (Vodonos, 2018)."[64]

This omission from the past and current ISA supplement and the PA is difficult to understand. This important study published in 2018 was a major meta-analysis of multiple epidemiology studies. This is a major approach to combining results of multiple epidemiology studies, in this case to examine the nature of the concentration-response curves for $PM_{2.5}$. It should have been considered in the 2019 ISA and 2020 PA and decision. EPN and study coauthor Joel Schwartz recommended its inclusion to EPA and the previous CASAC in 2019. Both repeated this recommendation to EPA in 2021, and in this case, CASAC did as well. Yet it did not appear in the ISA, ISA supplement, PA or proposal.

The main analysis includes 53 studies around the world, including 39 from North America. As CASAC noted, the most relevant results are from a second meta-analysis of a subset of 14 studies with concentrations below 10 $\mu g/m^3$. Twelve of the 14 studies with means below 10 $\mu g/m^3$ were conducted in North America. The authors reported "we had ample power to demonstrate effects below the WHO standard," which at that time was 10 $\mu g/m^3$. These results add significant evidence to question proposing a standard as high as 10 $\mu g/m^3$. Given CASAC's recommendations, EPA has no excuse for not considering this relevant study in the final decision.

IV. **An Approach for a More Holistic Consideration of the Key Epidemiology Studies in Selecting the Level of the Annual Fine Particle Standard.**

The sheer amount of material presented in the proposal on evidence of health effects from $PM_{2.5}$ makes it challenging to evaluate, including the repetition in many cases of information in various sections of the Executive summary, Section II B's Overview of the Health Effects Evidence, Section II D's presentation of the evidence and risk-based considerations in the Policy Assessment, Section III and the use of the evidence in developing the rationale for the proposed decision. Each of these sections dealt with key studies that EPA classified by factors such as the nature of effects, how exposure is monitored (monitor or hybrid model), country of origin, restricted analysis, accountability results, annual and/or daily effects, and more. Our comments on these sections to this point have focused on concerns about aspects of EPA's assessments of the evidence, particularly in regard to issues of uncertainties and conclusions drawn by EPA, especially with respect to how they affect the weight that should be given to the various categories of evidence.

EPA's sequential text-based presentation of the study classes makes it harder to evaluate the weight of the evidence as a whole. In this regard, the PA took a useful approach by showing graphical presentations of results of key studies for various categories, organized by concentrations. The proposal only presented two of these PA figures: Figure 1 for monitor-based means and 10^{th} and 25^{th} percentiles,[65] and Figure 2, which

[63] Sheppard, 2022a, p.16 of consensus responses; EPA 2022b at B-3 note 4.
[64] Sheppard, 2022a, p.16 of consensus responses.
[65] 88 FR at 5600.

presents the same information for U.S. hybrid-model means.[66] It is easy to see the difference in levels from the earlier to the more recent studies, where levels were influenced by more recent reductions and cover larger areas.[67] Both figures specified short-and long-term studies grouped by two mortality and morbidity endpoints.

These two figures, however, have various problems. One problem is neither figure shows results from restricted analysis or accountability studies, nor are graphs provided for Canadian studies using monitors or hybrid-models. While the text provided some of this information in the proposal discussion, it is harder to visualize the comparative impacts. In addition, Figure 2 omitted some important studies and study results discussed in Section III; for example, the results from two key restricted analyses were not presented in the proposal (Wu *et al.* 2020; Yazdi *et al.* 2021). Moreover, none of the four restricted analyses in the high-quality Dominici, Di, Wu, and Yazdi studies appeared in Figure 1, yet all four should have a profound effect on the decision.

In the 2012 Review, EPA staff addressed the need to depict the results of multiple key epidemiology studies by developing a graphic that included all identified key studies in a single figure that appears in the PA and 2012 proposal, which is noted several times in Section III above. **Figure 3** is a comparable figure that focuses on a group of key studies and results that is somewhat larger than what the proposal has highlighted. It focuses on studies EPA identified as key in PA Tables 3-7, 3-8, and 3-9, but including only those with annual means or 25th percentiles at or below 12 $\mu g/m^3$. It excludes all hybrid modeling studies that did not provide population weighting that were included in PA Table 3-8. The figure also adds two studies (Ward-Caviness *et al.* 2020 and Wei *et al.* 2020) based on CASAC recommendations as well as the fact both used the most recent hybrid modeling approach of Di *et al.* 2019.[68] It also adds the two studies reporting means from restricted analyses from PA Table 3-10, plus the two studies EPA omitted in the proposal that appear in PA Table 3-11. It also includes one of the three key new accountability studies (Henneman *et al.* 2019b) from PA Table 3-12.

Figure 3 includes three clusters of studies, each ordered by declining annual concentration as in the proposal's Figure 1:

1. Long-term studies including U.S. and Canadian studies that were based on monitors and U.S. studies based on hybrid modeling.
2. Canadian based hybrid modeling studies (all long-term)
3. Short-term exposure studies including U.S. and Canadian studies that were based on monitors and U.S. studies based on hybrid modeling.

Table 1 below supplements **Figure 3** by providing the numerical levels shown in the figure, as well as some additional details about the key studies.

[66] 88 FR at 5601.
[67] An issue for Figure 1 is that 19 of the 26 studies were above the level of the current annual standard, making them less useful for the current decision. In most cases, this is related to the age of the study. As noted in the accountability studies cited above, $PM_{2.5}$ levels have dropped considerably from those in many of these studies.
[68] Wei *et al*. 2020 was cited in the ISA supplement, but not in the PA.

Figure 3 -Translating Epidemiological Evidence from Key Studies into Annual $PM_{2.5}$ Standards

Long term Studies
Dominici et al 2019 US Medicare model-based
Di et al. 2017b US Medicare model based
Wang et al, 2017 7 SE states Medicare model-based
Zeger et al 2008 668 US counties Medicare monitor based
Wang et al 2020 US Medicare model based
Schwartz et al 2021 US Medicare model-based
Ward-Caveness et al 2020 N. Carolina model-based.
Henneman et al 2019b E. US States -Accountability range
Eum etal 2018 – Central U.S. monitor-based
Wu et al, 2020 US Medicare model-based
Wei et al. 2020 Mass Medicare model-based
Crouse et al 2020 11 Canadian cities - monitor-based
Yazdi et al. 2021 U.S. Medicare model-based

Canadian Model based Long term
Shin et al. 2019 ONPHEC Ontario
Bau et al. 2019 ONPHEC Ontario
Erickson et al. 2020 Canada wide Non-Immigrants vs Imig
Chen et al. 2020 ONPHEC Ontario
Erickson et al. 2019 Canada wide CCHS - CanChec
Zhang et al 2021 OHS Ontario Health Study
Crouse et al 2020 Canada wide CanChec - 8-year result
Pinault et al. 2017 Canada wide CCHS
Pinault et al. 2018 Canada wide mCHHS/CanChec
Pinault et al. 2016 Canada wide CanChec
Christidis et al 2019 Canada wide mCHHS

Short-term Exposure Studies (ordered by concentration)
Klemm and Mason 2003 Harvard six cities monitor-based.
Di et al. 2017a Model US national model-based
Wyatt et al 2020c 530 US Counties model-based
Liu et al 2019 25 Canadian cities monitor-based
Lavigne et al. 2018 24 Canadian cities monitor-based
Szyszkowicz 2009 7 Canadian. cities monitor-based
Steib et al. 2009 7 Canadian cities monitor-based
Weichenthal et al, 2016, 15 Ontario cities monitor-based

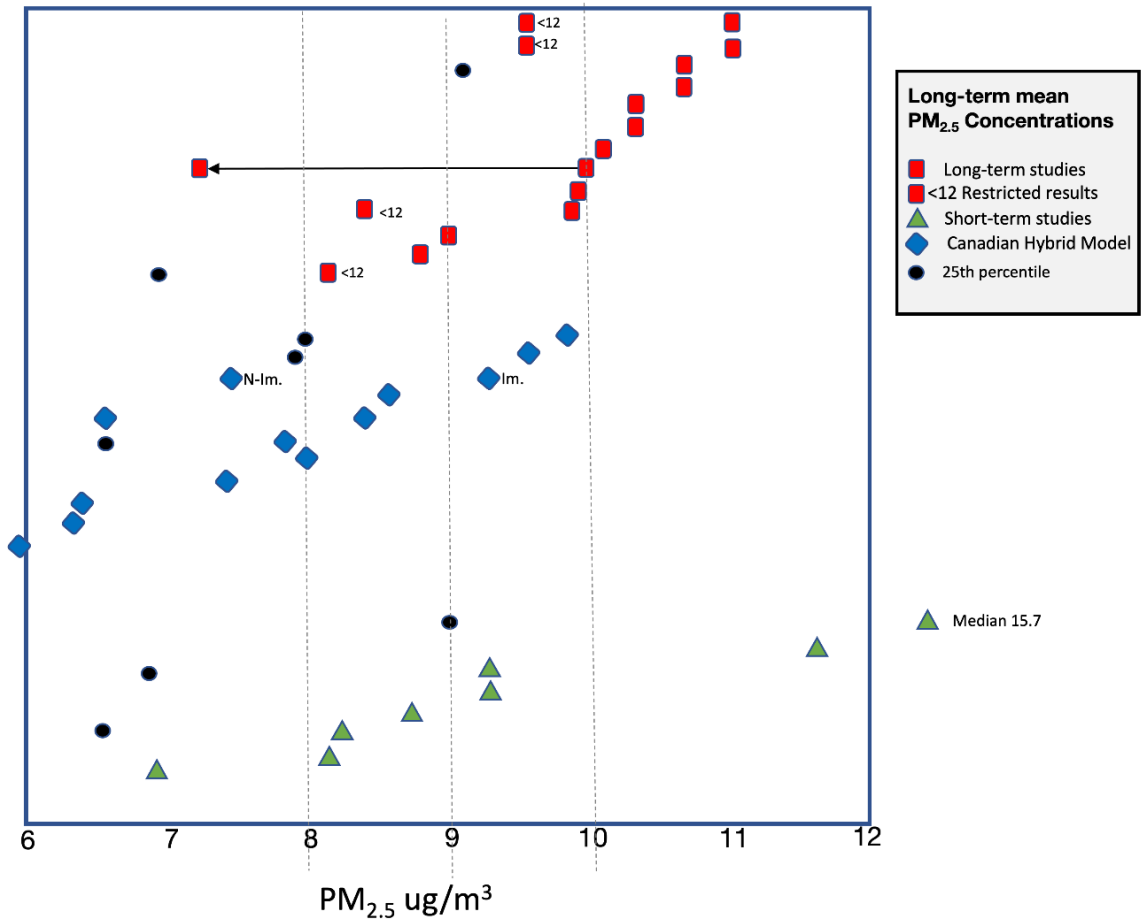

Table 1 - Concentrations from key studies included in Figure 3.

Long-Term Studies	**Mean $PM_{2.5}$ ($\mu g/m^3$)**
Dominici *et al.* 2019, U.S. Medicare, model-based*	11.0 <12, 9.6
Di *et al.* 2017b, U.S. Medicare, model-based	11.0 <12, 9.6
Wang *et al.* 2017, Seven SE states Medicare, model-based	10.7 median 25th percentile, 9.1
Zeger *et al.* 2008, 668 U.S. counties Medicare, monitor-based	10.7 central region
Wang *et al.* 2020 U.S. Medicare, model-based	10.3
Schwartz *et al.* 2021 U.S. Medicare, model-based*	10.3
Ward-Caveness *et al.* 2020 North Carolina, model-based*	10.1 median
Henneman *et al.* 2019b, Eastern U.S. - Accountability range	10 down to 7.2
Eum *et al.* 2018, Central U.S., monitor-based	9.9
Wu *et al.* 2020, U.S. Medicare, model-based*	9.8 v<12, 8.4
Wei *et al.* 2020, Massachusetts Medicare, model-based*	9.0
Crouse *et al.* 2020, 11 Canadian cities, monitor-based	8.7
Yazdi *et al.* 2021, U.S. Medicare, model-based	8.2 25th percentile, 6.9
Canadian Model-Based Long-Term Studies	
Shin *et al.* 2019, ONPHEC	9.8 25th percentile, 8
Bau *et al.* 2019, ONPHEC	9.6 25th percentile, 7.9
Erickson *et al.* 2020, CanCHEC (Canada-wide) Immigrants	9.3 levels range from 9.1 to 9.7
Non-Immigrants	7.5
Chen *et al.* 2020, ONPHEC	8.6
Erickson *et al.* 2019, CanCHEC (Canada-wide)	8.4
CCHS	6.7
Zhang *et al.* 2021, Ontario Health Study	7.8 25th percentile, 6.7
Crouse *et al.* 2020, CanCHEC (Canada-wide) 8-year result	8.0
1- and 6-year results	7.2 / 7.4
Pinault *et al.* 2017, CCHS	7.4
Pinault *et al.* 2018, CanCHEC (Canada-wide)	7.4
mCHHS	6.4
Pinault *et al.* 2016, CanCHEC (Canada-wide)	6.3
Christidis *et al.* 2019, mCHHS	5.9 25th percentile, 4.3
Short-Term Exposure Studies (Ordered by Concentration)	
Klemm and Mason 2003, Harvard six cities, monitor-based	15.7 median 25th percentile, 9.0
Di *et al.* 2017a, U.S. national, model-based	11.6 25th percentile, 6.7
Wyatt *et al.* 2020c, 530 U.S. counties, model-based	9.3
Liu *et al.* 2019, 25 Canadian cities, monitor-based	9.3
Lavigne *et al.* 2018, 24 Canadian cities, monitor-based	8.8
Szyszkowicz 2009, Seven Canadian cities, monitor-based	8.3 25th percentile, 6.5
Steib *et al.* 2009, Seven Canadian cities, monitor-based	8.2 25th percentile, 6.8
Weichenthal *et al.* 2016, 15 Ontario cities, monitor-based	6.9

**U.S. Studies using Di et al. 2019 hybrid-model*
CanCHEC - Canadian Census Health and Environment Cohorts; ONPHEC - Ontario Population Health and Environment Cohort; CCHS - Canadian Community Health Survey; mCHHS - mortality cohort of CCHS

While the key studies in **Figure 3** do not all carry the same weight, it is important to consider them together, taking into account their levels and alternative approaches that are relevant in deciding on the level of an annual standard. The three clusters and study-specific summaries provide information relevant to evaluating aspects of different study groupings.

Looking only at U.S. studies, as EPA did in Figures 1 and 2 of the proposal, four U.S. studies have means within 0.3 $\mu g/m^3$ of 10 $\mu g/m^3$and seven have levels below 10 $\mu g/m^3$, with three reporting health effects at

levels at or below 9 μg/m^3. Of the four U.S. studies reporting 25th percentiles, two are near 9 μg/m^3 and two are well below. Taken together, **Figure 3** makes it clear that the Administrator's rationale for proposing a range of 9 to 10 μg/m^3 is not supported by the key studies with means below the current standard of 12 μg/m^3, including those identified in the PA and the additional study results noted above that should have been considered by EPA.

This more complete treatment of the available U.S. studies presents a substantially different picture from that stated in the proposal:

> "For the key U.S. monitor-based epidemiologic studies, the study reported mean concentrations range from 9.9–16.5 μg/m^3 and for the U.S. hybrid modeling based key epidemiologic studies, the mean concentrations range from 9.3– 12.2 μg/m^3." [69]

One alternative grouping would focus only on the kinds of studies that were considered in the 2012 review, U.S. and Canadian studies that relied on monitoring. In that grouping, with means below 12 μg/m^3, there is one U.S. study with a mean of 10.7 μg/m^3 and seven studies with means below 10 μg/m^3, five of which have means below 9 μg/m^3. Values for 25th percentiles range from 6.5 to 9 μg/m^3.

To be clear, the mean levels reported in these studies represent concentrations associated with mortality and/or other serious health effects in sensitive populations. EPA should not consider setting a standard level to meet a study mean – the means should be a starting point for proposing standards that should be set below the means, as the Administrator did in the 2012 decision and what the current CASAC majority recommended.

As discussed in Section III, the PA identified uncertainties for Canadian hybrid-modeling studies, particularly those with lower concentrations. The grouping in **Figure 3** suggests several of the Canada-wide studies do tend to report lower means than other monitored or model-based studies focused on Ontario. As noted above, the PA employed the Di *et al.* 2019 model in their assessment of hybrid model performance.[70] The PA was not able to provide an assessment of the relative performance of hybrid models used in various Canadian hybrid studies, particularly relatively low PM concentrations. A focus on studies conducted in more urbanized Ontario, as well as the immigrant studies of Erickson 2020[71], shows higher levels. All five are below 10 μg/m^3, and two are below 9 μg/m^3. Given the potential uncertainties presented in the PA, it would be premature to suggest the results in some of the Canada-wide studies would support consideration of a standard level below 8 μg/m^3, the lower bound of the range recommended by the CASAC majority.

In assessing these key studies, it is not appropriate to suggest that the target for developing a standard level should be based solely on the reported mean levels in studies - where EPA argues we have the strongest evidence. As the Administrator made clear in her review of the 2012 standard, the level of the annual standard should be based on a concentration that provides a margin of safety, which calls for setting the level below the means. The CASAC comments also took note of this issue in recommending EPA consider alternatives such as the 25th percentile, which in fact the Administrator considered in the 2012 decision.

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[69] 88 FR at 2656. Note also that older studies with reported means above 12 μg/m^3 are not particularly useful for selecting a level for a standard at or below 10 μg/m^3.

[70] As illustrated in **Figure 1** reproduced in Section III-C, the Di *et al*. 2019 model estimates appear to be reliable down to relatively low levels.

[71] As noted in the study, immigrants tended to live in more urbanized areas, as opposed to native-born Canadians.

Moreover, we know from Di *et al.* 2019 and from studies that provide concentration-response curves that data suggesting adverse effects are not necessarily always more certain at the mean. (See Section III-C above). While the proposal noted the CASAC recommendation and suggested a possible consideration of the 25th percentile, proposing a level as high as 10 $\mu g/m^3$ made it clear that EPA ignored the proper interpretation of study means.

As Section II explains, the limited set of results the Administrator focused on in justifying a range of 9 to 10 $\mu g/m^3$ would not support a level of 10 $\mu g/m^3$. EPA's rationale claimed that such a level would result in general, area-wide exposures to levels at or below 10 $\mu g/m^3$. Setting aside the actual data in **Figure 3**, a standard set at 10 $\mu g/m^3$ would give no weight to at least three studies with means of 9.3 to 9.9 $\mu g/m^3$. A standard set at 10 $\mu g/m^3$ would allow the most exposed at-risk groups, those who live and work at or near the design value, as well as others, to be exposed to levels at or above those found to produce increased mortality and other significant health effects.

The PA notes the following with respect to the at-risk populations most likely to live in areas of high $PM_{2.5}$ concentrations:

> "There is strong evidence demonstrating that Black and Hispanic populations, in particular, have higher $PM_{2.5}$ exposures than non-Hispanic White populations (U.S. EPA, 2019, Figure 12-2; U.S. EPA, 2022, Figure 3-38). Black populations or individuals that live in predominantly Black neighborhoods experience higher $PM_{2.5}$ exposures, in comparison to non-Hispanic White populations. There is also consistent evidence across multiple studies that demonstrate increased risk of $PM_{2.5}$ -related health effects, with the strongest evidence for health risk disparities for mortality (U.S. EPA, 2019, section 12.5.4). There is also evidence of health risk disparities for both Hispanic and non-Hispanic Black populations compared to non-Hispanic White populations for cause-specific mortality and incident hypertension (U.S. EPA, 2022, section 3.3.3.2)." [72]

The PA risk assessment included an At-Risk analysis, which assumed all areas just met the current standard of 12 $\mu g/m^3$ and estimated the risk reduction for alternative standards below 12 $\mu g/m^3$. It concluded:

> "Figure 3-22 shows that under the hypothetical air quality scenarios, disparities exist between Black and White populations with regards to both $PM_{2.5}$ exposures and $PM_{2.5}$ -attributable mortality risk rates under the current PM NAAQS. Figure 3-23 shows that in absolute terms, the Black population is predicted to experience larger reductions in both $PM_{2.5}$ exposures and $PM_{2.5}$ -attributable mortality risk rates as the standard is lowered. Table 3-19 and Table 3-20 show that minority populations are estimated to also experience larger reductions in $PM_{2.5}$ exposures and $PM_{2.5}$ -attributable mortality risk in relative/proportional terms. When considering the lowest alternative annual standard evaluated, an alternative annual standard of 8 μg/m3, disparities in exposure are virtually eliminated, whereas disparities in mortality risk remain, due to the concentration-response relationship identified from Di et al. (2017b)." [73]

[72] EPA 2022b at 3-55.
[73] EPA 2022b at 3-162.

Although some CASAC members noted that the specific risk estimates are inflated by the initial assumptions, the direction of more equitable benefits for minorities is clear. EPA also included an environmental justice assessment in the draft Regulatory Impact Analysis (RIA) that projected risks would exist in the future based on an analysis which does not increase levels as in the PA approach. It concluded:

> "Specifically, Hispanics, Asians, Blacks, and those less educated (no high school) have higher national annual exposures, on average and across the distributions, than both the overall reference population or other populations (e.g., non-Hispanic, White, and more educated)."[74]

In this analysis, all groups showed improved results with each lower level, with the relative results by race varying with region.[75]

It bears repeating that the proposed range was largely based on a design value approach that focused on using the design values of studies to project when alternative levels of a standard would keep area-wide concentrations at or below the means of certain studies. As discussed in Section II and above, this would fail to protect those at-risk people exposed to levels higher than average, area-wide concentrations, the people exposed to the higher levels measured by an area's design monitor. The approach resulted in overplaying the uncertainties, especially related to estimating design values and also omitted some important studies and results. The combined flaws in the framework or approach used to select a level of the standard and the selection of science to use in this framework make this proposal both a step backwards in protecting public health in general and one that continues higher, harmful exposures for multiple at-risk minority groups.

We hope EPA, which has taken a number of actions toward improving environmental justice, will correct both the wrong-headed approach and consider the full range of key U.S. and Canadian studies identified in **Figure 3** when selecting a level for the annual standard. Even excluding some or all Canadian hybrid modeling studies provides numerous U.S. and Canadian studies that fully refute the Administrator's proposal of a range from 9 to 10 $\mu g/m^3$. In particular the finding not to propose a standard below 9 $\mu g/m^3$ because:

> "the uncertainties as to the public health risks and benefits associated with such a standard [are] too great at this time."[76]

The information and analysis we summarize in these comments make this simply an untenable conclusion. In fact, even excluding all Canadian model-based studies, we have 10 U.S. and Canadian studies with results as low as 9 $\mu g/m^3$ and below. A few of these report 25th percentiles even lower.

The compelling nature of the full scientific criteria, the recommendations of the majority of CASAC, and the requirements of Section 109 lead us to strongly recommend that EPA reject a standard above 9.0 $\mu g/m^3$. The evidence of adverse effects at and below 10.0 $\mu g/m^3$ is very strong and does not support a finding that at-risk people exposed to levels of 10.0 $\mu g/m^3$ are protected with an adequate margin of safety. Even a standard of 9.0 $\mu g/m^3$ is very hard to justify as providing an adequate margin of safety, given the range of studies showing serious adverse effects just above and below 9.0 $\mu g/m^3$. Applying a proper framework to

[74] RIA at ES-21.
[75] "… reductions among Black populations tend to be proportionally larger than among the reference population in California, the west, and the northeast, especially under the proposed alternative standard level of 9/35 μg/m3 and the more stringent alternative standard level of 8/35 μg/m3" RIA at ES-21.
[76] 88 FR at 5629.

the large body of evidence before EPA, like the framework applied in the 2012 Review, means the Administrator should seriously consider selecting a standard of 8.0 $\mu g/m^3$, a level within the range recommended by CASAC.

V. **The 24-Hour Standard.**

EPN agrees with the CASAC majority that the combined results of several epidemiology studies and controlled human studies suggest consideration of a daily standard of 25 to 35 $\mu g/m^3$. Again, we believe EPA has ignored relevant information that would support this result.

EPA's PA summarized the Agency's long-held approach to the role of annual and daily standards:

> "[O]ur focus in evaluating the current primary standards is on the protection provided by the combination of the annual and 24-hour standards against the distribution of both short- and long-term $PM_{2.5}$ exposures."[77]

After a review of the evidence and risk assessment, the PA concluded not to revise the daily standard.

> "When the information summarized above is considered in the context of the 24-hour standard, we reach the conclusion that, in conjunction with a lower annual standard level intended to increase protection against average short- and long-term $PM_{2.5}$ exposures across the U.S., the evidence does not support the need for additional protection against short-term exposures to peak $PM_{2.5}$ concentrations."[78]

The CASAC majority strongly disagreed with this conclusion:

> "Regarding the 24-hour $PM_{2.5}$ standard, the majority of CASAC members find that the available evidence calls into question the adequacy of the current 24-hour standard. … all CASAC members conclude that the Draft PA does not provide sufficient information to adequately consider alternative form and level combinations. Thus, the discussion that follows first addresses the level conditional on the current form…
>
> Regarding the level of the 24-hour $PM_{2.5}$ standard, conditional on retaining the current form, the majority of CASAC members favor lowering the 24-hour standard. These members are convinced that there is substantial epidemiologic evidence from both morbidity and mortality studies that the current standard is not adequately protective. This includes three US air pollution studies with analyses restricted to 24-hour concentrations below 25 $\mu g/m^3$ (Table 3-10). The members also note that the controlled human exposure studies are not the best evidence to use for justifying retaining the 24-hour standard without revision. These are important because they provide causality and study an array of endpoints that provide biological plausibility to the epidemiology studies by identifying pathways altered by $PM_{2.5}$ exposure that can lead to adverse cardiovascular effects. However, these studies preferentially recruit less susceptible individuals and have a typical exposure duration much shorter than

[77] EPA 2022b at 3-199 to 3-200.
[78] EPA 2022b at 3-222.

> 24 hours, **so the evidence of effects from controlled human exposure studies with exposures close to the current standard support epidemiological evidence for lowering the standard.** Overall, these members place greater weight on the scientific evidence than on the values estimated by the risk assessment. They are concerned that the risk assessment may not adequately capture areas with wintertime stagnation and residential wood-burning where the annual standard is less likely to be protective. They also are less confident that the annual standard could adequately protect against health effects of short-term exposures. These members suggest that the EPA revise the level as part of the current review, and that a range of 25-30 $\mu g/m^3$ for the 24-hour $PM_{2.5}$ standard would be adequately protective." (emphasis added)[79]

The PA took issue with the CASAC majority regarding the implications of the three key epidemiology studies that restricted daily levels to below the current level of 35 $\mu g/m^3$, stating:

> "The body of epidemiologic evidence provides limited support for judging adequacy of the level of the 24-hour standard. As discussed in detail above (section 3.3.3.2.1), epidemiologic studies provide the strongest support for reported health effect associations for the part of the air quality distribution corresponding to the bulk of the underlying data (i.e., estimated exposures and/or health events), often around the overall mean concentrations evaluated rather than near the upper end of the distribution. Additionally, the magnitudes of the associations in restricted analyses are similar to or larger than the magnitudes of the associations based on the full cohorts (Table 3-10), suggesting that, at a minimum, short-term exposures to peak $PM_{2.5}$ concentrations are not disproportionately responsible for reported health effect associations." [80]

Based on EPA's assessment, the Administrator has concluded the restricted analyses support causality, but they do not:

> "help to inform questions on the adequacy of the current 24-hour standard given that the 24-hour standard focuses on reducing "peak" exposures (with its 98th percentile form). In further evaluating these studies, the Administrator notes that the fact that there are positive and significant associations in these analyses does not mean that one can conclude that there would be short-term effects occurring in areas that meet a 24-hour standard at these levels." [81]

EPN's review of the draft PA in 2021 focused on how it did not adequately consider the implications from recent controlled human results bolded in the CASAC comment above. CASAC is referring to two studies[82]

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[79] Sheppard 2022a, p. 17 of consensus letter.
[80] EPA 2022b at 3-221.
[81] 88 FR at 5621.
[82] Wyatt LH, Devlin RB, Rappold AG, Case MW and Diaz-Sanchez D. Low levels of fine particulate matter increase vascular damage and reduce pulmonary function in young healthy adults. *Particle and Fibre Toxicology,* 2020, 17:50; https://doi.org/10.1186/s12989-020-00389-5
Hemmingsen JG, Rissler J, Lykkesfeldt J, Sallsten G, Kristiansen J, Møller P and Loft. S. Controlled exposure to particulate matter from urban street air is associated with decreased vasodilation and heart rate variability in overweight and older adults. *Particle and Fibre Toxicology,* 2015a, 12:6. DOI 10.1186/s12989-015-0081-9

included in Table 3-4 of the draft PA, one using concentrated Chapel Hill, North Carolina, particle pollution (Wyatt *et al.* 2020), and the other using ambient levels from traffic pollution in Copenhagen (Hemmingsen et al 2015a,b). See **Table 2**.

Hemmingsen et al., 2015a, Hemmingsen et al., 2015b	Healthy, overweight older adults	24 µg/m^3 (unfiltered) vs 3.0 µg/m^3 (filtered) Copenhagen PM; 5 h	Impaired vascular function and altered heart rate variability; no significant changes in blood pressure or markers of inflammation or oxidative stress
Wyatt et al., 2020a *	Healthy young adults (18-35)	37.8 µg/m^3 CAP vs 2.1 µg/m^3 (filtered); 4h	Increased blood inflammatory markers; Inconsistent changes in HRV

Table 2, excerpt from Table 3-4 of the EPA draft Policy Assessment.

The proposal focused more on 'inconsistencies' in these studies[83] than on the fact both found effects related to cardiac function at levels at or well below the level of the current daily standard. The PA suggested that periodic exercise in the 4-hour Wyatt *et al.* study would have produced exposure doses similar to those that occur in the 2-hour studies that find effects at higher levels. If this is the case, we could speculate perhaps still longer exposures (e.g., 24 hours) would also produce similar doses at still lower levels. It is certainly the case that even susceptible individuals, including people who live and work near sources that produce peak concentrations, may have some levels of activity during the course of a day.[84]

However, EPN, believes a major limitation in the PA is the failure to give sufficient weight to the numerous panel studies that have associated $PM_{2.5}$ exposure with changes in clinical end points. These studies are able to study at-risk populations exposed to levels of $PM_{2.5}$ well below the current 24-hour standard, can assess effects from 1-5 days of exposure, and measure the same end points that are measured in controlled human exposure studies. We believe these short-term panel studies conducted in outdoor environments are supported by controlled human exposure studies and together find consistent subclinical effects that are risk factors for adverse cardiovascular events. In some cases panel studies can even link exposure with adverse cardiopulmonary events. For example, a recent panel study (Zhang *et al.* 2021) concluded that:

> "[o]ur study suggests that acute $PM_{2.5}$ exposure may elevate indicators of myocardial tissue damage. This finding substantiates the association of air pollution exposure with adverse cardiovascular events." [85]

Despite our comments, this study was not added to the ISA supplement and can only be given conditional consideration. Nor did the PA consider the implications of a number of other panel studies of fine particles and heart-related responses that are cited in the 2020 ISA and earlier ISAs. We cite a number of examples of

Hemmingsen JG, Jantzen K, Møller P and Loft. S No oxidative stress or DNA damage in peripheral blood mononuclear cells after exposure to particles from urban street air in overweight elderly. *Mutagenesis*, 2015b, 30, 635–642. doi:10.1093/mutage/gev027

[83] E.g., 88 FR at 5593.

[84] Note that the 8-hour studies that include exercise are a major basis for the ozone standard.

[85] Oral Comments of Dan Costa, Sc.D., Former National Program Director, Air, Climate, and Energy Research Program, EPA Office of Research and Development, Before the Clean Air Science Advisory Committee on Particulate Matter Panel November 17, 2021 https://www.environmentalprotectionnetwork.org/wp-content/uploads/2021/11/D.-Costa-Oral-Comments-PM-ISA-11-17-2021-.pdf

relevant panel studies, but there are many more EPA should consider in a more comprehensive review of the scientific literature.[86]

Taken only as affirmation of plausible causality misses the impact these combined studies reveal on daily and hourly exposure via effects on inflammatory and cardiopulmonary variables in elderly and at-risk people at or below the daily NAAQS. Taken together with the controlled human exposure studies noted above, they show coherent cardiac and inflammatory markers, lending credence to the results of larger short-term epidemiology studies in the Supplement, which find more serious responses when restricted to levels below the 24-hour $PM_{2.5}$ standard. Several of these larger studies show mortality and morbidity via downstream cardiac and inflammatory events.

While we agree these studies would not justify a shorter averaging time, they certainly suggest the need for a more thorough consideration of the evidence that might support a more protective 24-hour standard, including that from the short-term epidemiology studies. We agree with the CASAC majority that **the evidence of effects from controlled human exposure studies with exposures close to the current standard support epidemiological evidence for lowering the daily standard to a level between 25 and 30 μg/m^3.**

[86] Zhang S, Breitner S, Cascio WE, Devlin RB, Neas LM, Ward-Caviness C, Diaz-Sanchez D, Kraus WE, Hauser ER, Schwartz J, Peters A, Schneider A. Association between short-term exposure to ambient fine particulate matter and myocardial injury in the CATHGEN cohort. *Environ Pollut*. 2021, 275:116663. doi: 10.1016/j.envpol.2021.116663. New study not included in the ISA.
Mirowsky JE, Carraway MS, Dhingra R, Tong H, Neas L, Diaz-Sanchez D, Cascio WE, Case M, Crooks JL, Hauser ER, Dowdy ZE, Kraus WE, Devlin RB**.** Exposures to low-levels of fine particulate matter are associated with acute changes in heart rate variability, cardiac repolarization, and circulating blood lipids in coronary artery disease patients. *Environ Res*. 2022 Nov;214(Pt 1):113768. doi: 10.1016/j.envres.2022.113768. Epub 2022 Jun 30. PMID: 35780850. This EPA study is too recent to be included in the ISA or PA.
Croft DP, Cameron SJ, Morrell CN, Lowenstein CJ, Ling F, Zareba W, Hopke PK, Utell MJ, Thurston SW, Thevenet-Morrison K, Evans KA, Chalupa D, Rich DQ. Associations between ambient wood smoke and other particulate pollutants and biomarkers of systemic inflammation, coagulation and thrombosis in cardiac patients. *Environ Res*. 2017 April; 154: 352–361. doi:10.1016/j.envres.2017.01.027.
Huttunen K, Siponen T, Salonen I, Yli-Tuomi T, Aurela M, Dufva H, Hillamo R, Linkola E, Pekkanen J, Pennanen A, Peters A, Salonen RO, Schneider A, Tiittanen P, Hirvonen MR, Lanki T. Low-level exposure to ambient particulate matter is associated with systemic inflammation in ischemic heart disease patients. *Environ Res*. 2012 Jul;116:44-51. doi: 10.1016/j.envres.2012.04.004. Epub 2012 Apr 26. PMID: 22541720.
Liao D, Shaffer ML, Rodriguez-Colon S, He F, Li X, Wolbrette DL, Yanosky J, and Cascio WE.
Acute Adverse Effects of Fine Particulate Air Pollution on Ventricular Repolarization. *Environ Health Perspect.* 118:1010–1015 (2010). doi:10.1289/ehp.0901648.
Liu L, Ruddy T, Dalipaj M, Poon R, Szyszkowicz M, You H, Dales RE, Wheeler AJ. Effects of indoor, outdoor, and personal exposure to particulate air pollution on cardiovascular physiology and systemic mediators in seniors. *J Occup Environ Med*. 2009 Sep;51(9):1088-98. doi: 10.1097/JOM.0b013e3181b35144. PMID: 19701101.
Schneider A, NeasL, Herbst MC, Case M, Williams JW, CascioW, Hinderliter A, Holguin F, Buse JB, Dungan K, Styner M, Peters A. and Devlin RB2 Endothelial Dysfunction: Associations with Exposure to Ambient Fine Particles in Diabetic Individuals *Environ Health Perspect* 116:1666–1674 (2008). doi:10.1289/ehp.11666 available via http://dx.doi.org/
Peters A, Dockery DW, Muller JE, and Mittleman MA. Increased Particulate Air Pollution and the Triggering of Myocardial Infarction. *Circulation*. 2001;103:2810–2815. https://doi.org/10.1161/01.CIR.103.23.2810

VI. **Benefits Analysis of Alternative Standards in EPA's Regulatory Impacts Analysis.**

In selecting annual and 24-hour standards, the Administrator should consider certain results in the risk assessment of alternative standards that appear in the Regulatory Impacts Analysis (RIA). The analysis projected reductions in mortality and a number of categories of morbidity, giving a sense of the relative health benefits of four alternative $PM_{2.5}$ standard levels. Focusing on the mortality risks, it is clear a tighter annual standard would prolong the lives of thousands of Americans each year. Yet the benefits of an annual standard of 8.0 $\mu g/m^3$ are markedly larger than for the other options. A level of 8.0 $\mu g/m^3$ would result in more than twice the benefits than a level of 9.0 $\mu g/m^3$ and over 4 times larger than 10.0 $\mu g/m^3$. Similar disparities appear in the morbidity effects. The results also suggest hundreds of lives prolonged for a daily standard of 30 $\mu g/m^3$.[87,88]

VII. **Conclusion.**

Based on the above, EPN recommends:

Annual Standard - The Administrator clearly should reject a level of 10.0 $\mu g/m^3$. The evidence also shows that a standard of 9.0 $\mu g/m^3$ is difficult to justify. The Administrator should seriously consider selecting a standard of 8.0 $\mu g/m^3$, a level within the range recommended by CASAC.

24-Hour Standard - EPN does not agree that EPA should retain the current level of the 24-hour standard. Instead, EPA should consider revising the 24-hour standard to a level between 25 and 30 $\mu g/m^3$.

These comments were prepared by John Bachmann and John Hannon, with assistance from Dan Costa and John Vandenberg, on behalf of EPN.

[87] Table ES-6 from the RIA is reproduced in the Appendix.

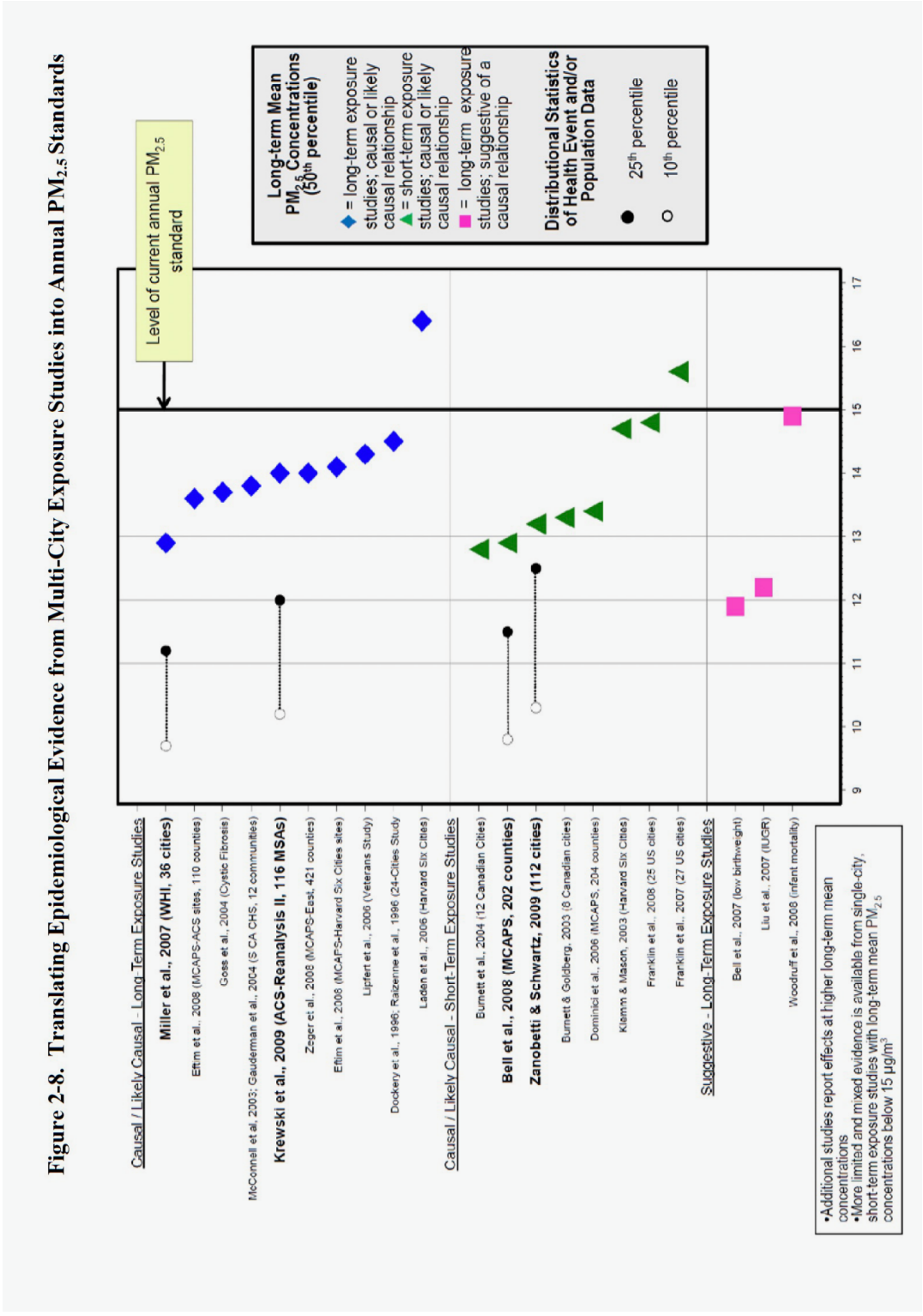
[88] In its proposal, EPA said the information and analyses presented in the RIA are for informational purposes only, and the proposed decisions on the NAAQS are not based on consideration of them. EPA's position is based on the determination in *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001) that EPA may not consider the costs of implementing the NAAQS in making decisions on the appropriate NAAQS. 88 FR 5558, 5563 (January 27, 2023).

EPN's use of the RIA's air quality analysis and related projected health impacts, and information on the RIA's environmental justice assessment, is fully consistent with this limitation on EPA's authority. EPN refers solely to a limited part of the RIA, the analysis that models the air quality levels of various NAAQS standards and evaluates the health impacts projected for such air quality levels and the exposure information in the environmental justice assessment. This limited use is totally separate and distinct from any consideration of costs of the NAAQS or comparison of such costs to benefits.

EPN is not commenting on the RIA – EPN's comments concern EPA's proposed decision and its underlying rationale, including EPA's reliance on the similar air quality analysis performed in the Risk Assessment. While the air quality analysis in the RIA is similar to the analysis in the PA, it differs in important ways, including methodological differences that CASAC has commented on to EPA. EPN's discussion of this information in the RIA and its implications can and should be carefully considered by EPA.

APPENDIX

1. Original Figure at 2-8, 2011 Draft Policy Assessment (2012 Review). See 78 FR at 3135.



2. Table ES-6 from the RIA.

Table ES-6 Estimated Avoided PM-Related Premature Mortalities and Illnesses of the Control Strategies for the Alternative Primary $PM_{2.5}$ Standard Levels for 2032 (95% Confidence Interval)

Avoided Mortality[a]	10/35 μg/m³	10/30 μg/m³	9/35 μg/m³	8/35 μg/m³
Pope III et al., 2019 (adult mortality ages 18-99 years)	1,700 (1,200 to 2,100)	1,900 (1,400 to 2,400)	4,200 (3,000 to 5,300)	9,200 (6,600 to 12,000)
Wu et al., 2020 (adult mortality ages 65-99 years)	810 (710 to 900)	920 (810 to 1,000)	2,000 (1,800 to 2,200)	4,400 (3,900 to 4,900)
Woodruff et al., 2008 (infant mortality)	1.6 (-0.99 to 4.0)	1.8 (-1.1 to 4.6)	4.7 (-3.0 to 12)	11 (-6.9 to 28)
Avoided Morbidity	**10/35 μg/m³**	**10/30 μg/m³**	**9/35 μg/m³**	**8/35 μg/m³**
Hospital admissions—cardiovascular (age > 18)	140 (100 to 170)	150 (110 to 190)	310 (230 to 400)	660 (480 to 840)
Hospital admissions—respiratory	93 (31 to 150)	100 (35 to 170)	210 (74 to 350)	460 (160 to 740)
ED visits--cardiovascular	260 (-100 to 610)	290 (-110 to 670)	630 (-240 to 1,500)	1,400 (-530 to 3,200)
ED visits—respiratory	490 (95 to 1,000)	530 (100 to 1,100)	1,200 (240 to 2,600)	2,700 (540 to 5,700)
Acute Myocardial Infarction	29 (5.9 to 17)	32 (19 to 45)	67 (39 to 94)	143 (83 to 200)
Cardiac arrest	15 (-5.9 to 33)	16 (-6.6 to 37)	34 (-14 to 76)	72 (-29 to 160)
Hospital admissions--Alzheimer's Disease	360 (270 to 440)	390 (300 to 480)	850 (640 to 1,000)	1,900 (1,500 to 2,400)
Hospital admissions--Parkinson's Disease	48 (25 to 70)	54 (28 to 79)	120 (63 to 180)	270 (140 to 390)
Stroke	55 (14 to 94)	61 (16 to 110)	130 (33 to 220)	270 (71 to 470)
Lung cancer	65 (20 to 110)	73 (22 to 120)	150 (46 to 250)	320 (99 to 530)
Hay Fever/Rhinitis	15,000 (3,500 to 25,000)	16,000 (4,000 to 28,000)	35,000 (8,500 to 60,000)	75,000 (18,000 to 130,000)
Asthma Onset	2,200 (2,100 to 2,300)	2,500 (2,400 to 2,600)	5,400 (5,100 to 5,600)	11,000 (11,000 to 12,000)
Asthma symptoms – Albuterol use	310,000 (-150,000 to 750,000)	350,000 (-170,000 to 850,000)	740,000 (-360,000 to 1,800,000)	1,600,000 (-780,000 to 3,900,000)
Lost work days	110,000 (97,000 to 130,000)	130,000 (110,000 to 150,000)	270,000 (230,000 to 310,000)	580,000 (490,000 to 660,000)
Minor restricted-activity days	680,000 (550,000 to 800,000)	750,000 (610,000 to 890,000)	1,600,000 (1,300,000 to 1,900,000)	3,400,000 (2,700,000 to 4,000,000)

Note: Values rounded to two significant figures.

[a] Reported here are two alternative estimates of the number of premature deaths among adults due to long-term exposure to $PM_{2.5}$. These values should not be added to one another.