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Introduction

We submit the following comments on behalf of Physicians for Social Responsibility (PSR), a national, non-profit 501-c-3 scientific and educational organization. PSR represents over 28,000 physicians, nurses, health care professionals medical students and concerned citizens in 23 chapters throughout the United States and holds a four-star 92% Charity Navigator rating.[1] PSR and its members are devoted to the prevention of nuclear war, to slowing, stopping, and reversing global warming and to the promotion of better health through environmental protection. PSR's Environment and Health program focuses on many aspects of the interrelationships between the environment and health. We place a special a emphasis on the health and development of children and other vulnerable populations. It is in this context that we submit our comments on the proposed changes in the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) particularly PM with an aerodynamic diameter of 2.5 microns or less, commonly referred to as $PM_{2.5}$. (Note: henceforth we use $PM_{2.5}$ to refer to the aerodynamic diameter of these particles with the knowledge that the definition of aerodynamic diameter is complex and determined by multiple factors.)

Summary of PSR's Position

PSR holds that the EPA's proposed primary annual mean standard of between 9.0 and 10.0 $\mu g/m^3$, averaged over three years, is too high to protect health. On the basis of studies in the peer-reviewed literature, we believe that the standard should be no more than 5.0 $\mu g/m^3$. This is the standard put forth by the World Health Organization (WHO) in 2021 in their report, which states "The data obtained support a long-term AQG [air quality guideline] level of no more than 5.0 $\mu g/m^3$, based on the association between long-term $PM_{2.5}$ and all non-accidental mortality."[2] Most of the studies reviewed by the WHO failed to establish a no adverse effect level (NOAEL). Since the publication of the WHO guideline, Weichenthal et al. reported a supralineal concentration-response relationship between outdoor $PM_{2.5}$ concentrations and mortality at levels below 5 $\mu g/m^3$. [3] In addition, other data show that $PM_{2.5}$ concentrations in previously redlined parts of American cities and near schools in New York City are higher than in other parts of these cities.[4,5] Lowering the NAAQ for $PM_{2.5}$ would be an environmentally just step in the right direction to address this problem.

Comments

General Comments

PSR supports, in principle, the United States Environmental Protection Agency's (EPA or the Agency) overdue plan to lower the primary annual National Ambient Air Quality Standard (NAAQ) for $PM_{2.5}$. The primary, or health-related, standard was last updated in 2013 when it was set at 12 $\mu g/m^3$ (FR f 78 no 10 January 15, 2013). The standard was retained without revision in 2020. Since that date, additional research published in peer-reviewed scientific journals and reputable agencies has shown clearly that the standard must be lowered.

(The literature we cite to support our position is not exhaustive but selected for relevance.)

Air pollution is one of the world's most important risk factors for the production of disease.[6] Atmospheric $PM_{2.5}$ is a leading threat in that realm. The author of a 2023 commentary published in PNAS wrote that "Ambient air pollution is the most important environmental risk factor globally due to its well-established burden of respiratory and cardiovascular diseases."[7] The World Health Organization (WHO) is in agreement and has published a new exposure standard.[2] Since the Agency's most recent examination of the link between $PM_{2.5}$ exposure and human disease, the evidence to support the association between $PM_{2.5}$ and human diseases has grown stronger.[2, 8-10] In addition, new data support the inclusion of more diseases with clear-cut links to PM exposure. We believe that it is critically important for the EPA to lower the NAAQ for $PM_{2.5}$ to no more than 5.0 $\mu g/m^3$ to protect the health of Americans.

The Agency has proposed lowering the standard to between 9.0 and 10.0 $\mu g/m^3$.[9] The Clean Air Scientific Advisory Committee (CASAC) also concluded that the standard should be lowered but finds that "lowering [the standard] to between 8.0 and 10.0 $\mu g/m^3$ would be appropriate."[10] If a new standard lies within either the EPA range or the CASAC range, we conclude that the Agency will have failed in its mission "to protect human health and the environment" and to do so with an adequate margin of safety so that vulnerable populations are protected appropriately. The standard should be set to no more than 5.0 $\mu g/m^3$.

Support for PSR's Position
In 2021 the WHO's evidence-based analysis led to a reset of the standard for $PM_{2.5}$ at 5 $\mu g/m^3$.[2] The WHO rationale relied heavily on a 2020 comprehensive review of the literature and meta-analysis.[8] These authors reviewed over 3,000 recent abstracts and identified 107 for additional attention. They focused on all-cause mortality and death due to cardiovascular disease including stroke, respiratory diseases and lung cancer. They found that the combined risk ratio (RR) for $PM_{2.5}$ and naturally-caused disease mortality was 1.08 with a 95% confidence interval (CI) between 1.06 and 1.09. The meta-analysis of studies of $PM_{2.5}$ at progressively lower mean levels (< 25, 20, 15, 12 and 10 $\mu g/m^3$) yielded RRs that were similar to or higher than the overall RR. This supported the hypothesis that there is a linear relationship between diseases studied and the atmospheric concentration of $PM_{2.5}$. The analysis also suggested that the concentration-response curve may become steeper below 10 $\mu g/m^3$, i.e. there may be a more potent effect of $PM_{2.5}$ below this concentration. We will address that possibility later in our comments.

In general, the meta-analyses performed for the WHO yielded RRs for specific diseases that were higher than for the all-cause mortality.[8] Examples include the following RRs and CIs: diseases of the circulatory system RR = 1.11 (1.09, 1.14); ischemic heart disease 1.16 (1.10, 1.21); stroke1.11 (1.04, 1.18); respiratory diseases 1.11 (1.03, 1.18); and lung cancer 1.12 (1.07, 1.16).

To supplement these data, we cite the following studies that link $PM_{2.5}$ to two diseases that exact a terrible toll on Americans; type II diabetes mellitus and senile dementia of the Alzheimer type and related neurodegenerative diseases. A large number of Americans are diabetic. A Centers for Disease Control and Prevention 2020 report estimates that 34.2 million Americans have diabetes or over 10% of the population.[11] An additional 7.8 million are believed to have undiagnosed and therefore untreated diabetes.

Every day 20 million citizens of Mexico City are exposed to PM concentrations that exceed national and international standards, making it a fertile ground for the studies of PM-linked diseases.[12] In that population, a 10 $\mu g/m^3$ increase in $PM_{2.5}$ led to an astonishing odds ratio that

describes the risk for contracting diabetes of 3.09 (95% CIs were 1.17, 8.15). Another group of investigators evaluated the global burden of diabetes attributable to $PM_{2.5}$.[13] They reported an age-standardized mortality rate for type II diabetes attributable to $PM_{2.5}$ of 2.47 (95% CI, 1.71, 3.24).

An accumulating literature hypothesizes that there are links between the atmospheric concentration of $PM_{2.5}$ and pathogenesis of dementia, particularly Alzheimer's disease. Two large recent peer-reviewed studies have shown that this hypothesis is virtually certain to be true. Data for the first of these studies was drawn from over 63 million Americans in the Medicare population. In that cohort there were one million patients with Parkinson's disease and 3.4 million patients with Alzheimer's disease and related dementias who required an initial admission to a hospital. In that cohort the authors found evidence that the annual atmospheric concentration of $PM_{2.5}$ was significantly associated with the hazard for an initial hospitalization for either Parkinson's disease or Alzheimer's disease and related dementias. The second study we cite is a systematic review and meta-analysis of publications up through August, 2021.[14] Twenty studies were included in their systematic review and 17 in the associated meta-analysis. Over 91 million individuals were included in this study population of whom 5.5 million had been diagnosed with dementia. The authors report that the risk for dementia increased by three percent for an increment of 1 $\mu g/m^3$ in the atmospheric concentration of $PM_{2.5}$.

The composition of PM makes a difference. In an analysis of patients included in the Medicare Chronic Conditions Warehouse data base and two independently-sourced high-resolution concentrations of $PM_{2.5}$ the authors reaffirmed the link between $PM_{2.5}$ Alzheimer's disease and all-cause dementia.[15] In addition, the investigators found that these associations remained significant for $PM_{2.5}$ constituents including black carbon, organic matter, sulfate ions and ammonium ions. Traffic and fossil fuel combustion were thought to be responsible for the origin of these $PM_{2.5}$ constituents and the associations with dementing illnesses. An editorial accompanied the second study.[7] The editorialist wrote that PM gains access to the brain via the olfactory tract and less directly via the bloodstream serving multiple organs including the lungs, the gastrointestinal tract and others. In the brain, PM triggers inflammation and oxidative stress which are thought to lead to neural injury and dementia.[16] The black carbon component appears to be particularly dangerous with a ten-fold higher effect per unit concentration than the mixed PM fraction containing all components. The author concludes the editorial by writing that "air pollution mitigation strategies need to be a part of regional and national agendas." We agree.

Finally, it seems increasingly probable that the dose-response curve describing the relationship between the atmospheric concentration of $PM_{2.5}$ and the production of disease may be at its steepest at concentrations below 5 $\mu g/m^3$. Investigators have found that the health benefits associated with lowering atmospheric $PM_{2.5}$ concentrations to the new WHO standard of 5 $\mu g/m^3$ will be greater than calculated previously.[3] The WHO report itself reaches a related conclusion, stating that "The data obtained support a long-term AQG [air quality guideline] level of no more than 5 $\mu g/m^3$ based on the association between long-term $PM_{2.5}$ and non-accident mortality."[2] This raises an important question. Is there a concentration of $PM_{2.5}$ that considered to be safe? The answer may well be no and continued reductions below an annual standard of 5 $\mu g/m^3$ must be considered in the future as more data are published.

Vulnerable Populations
PSR is committed to the protection of vulnerable populations. These include individuals who live

in previously-redlined areas of cities and children of school age. Redlining in cities was a federally-initiated discriminatory mortgage appraisal process initiated by the Homeowners Owner's Loan Corporation (HOLC) during the New Deal. The HOLC "residential security maps" were designed to protect lending institutions that were called upon to issue emergency home loans after the Great Depression.[17] Previously redlined areas continue to identify urban areas that disproportionately include people of color as well as socially and economically disadvantaged individuals and those with other markers of inequality.[18] These boundaries have been used in numerous epidemiological studies. Children are vulnerable because this is the time during which critical developmental process occur and because of their behavioral characteristics.[16]

A 2020 study revealed that atmospheric $PM_{2.5}$ concentrations are in a monotonic risk relationship with HOLC grades (redlined = highest financial risk, greenlined = lowest financial risk) with redlined areas being the most polluted and the highest financial risk parts of cities.[5] The HOLC grade proved to be a better pollution disparity predictor than race or ethnicity. In a complementary study of 1431 California census tracts, the percentage of individuals living in poverty and the concentration of diesel exhaust particles both increased as the HOLC assignment moved toward redlining.[19] Not surprisingly, the relative risk for an emergency room visit for the treatment of asthma followed suit.

The exposure of children to air pollution was addressed in a 2020 study.[4] These researchers retrieved the black carbon fraction of PM and total $PM_{2.5}$ concentrations over a 10 year period from monitoring sites around New York City Schools. Although the investigators found evidence for a steady decrease in the concentration of these pollutants, there were smaller reductions around schools in previously redlined neighborhoods.

Summary
While PSR applauds the EPA for reconsidering the primary national ambient air quality standard, we do not believe that the Agency's proposed standard or that of the CASAC will appropriately protect the health of all Americans with an adequate margin of safety. On the basis of the literature, we are particularly concerned with the health of children, the elderly, individuals with chronic illnesses, the poor, people of color and those who are economically disadvantaged. Our analysis of the literature leads us to conclude that a standard of no more than 5.0 $\mu g/m^3$ is appropriate and that continued vigilance is warranted as the data evolve.

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