SOUNDING BOARD

The Need for a Tighter Particulate-Matter Air-Quality Standard

Independent Particulate Matter Review Panel

The Environmental Protection Agency (EPA) proposes to retain the current National Ambient Air Quality Standards (NAAQS) for fine particulate matter (particles with a diameter of ≤2.5 μm [$PM_{2.5}$]) — that is, levels not exceeding an annual average of 12 μg per cubic meter and a 24-hour average of 35 μg per cubic meter.[1] The current NAAQS were set in 2012 on the basis of a scientific review that was largely completed in 2010.[2] At that time, available epidemiologic evidence, supported by toxicologic evidence and a risk assessment conducted by EPA staff, indicated that annual exposure to $PM_{2.5}$ caused premature death at ambient concentrations as low as 11 μg per cubic meter. However, on the basis of more recent evidence, as described below, exposure to ambient $PM_{2.5}$ at the levels of the current standards is estimated by the EPA to be responsible for tens of thousands of premature deaths in the United States each year.[3]

The Clean Air Act requires air-quality standards that are "requisite to protect the public health" with an "adequate margin of safety." Such standards "shall accurately reflect the latest scientific knowledge" regarding "the kind and extent of all identifiable effects on public health." According to requirements of the Clean Air Act, the EPA administrator "shall appoint an independent scientific review committee," known as the Clean Air Scientific Advisory Committee, to periodically "review" the standards.

We were members of the EPA Clean Air Scientific Advisory Committee Particulate Matter (PM) Review Panel that was formed in 2015. By law, the Clean Air Scientific Advisory Committee, which we augmented, has seven members, including at least one physician. However, seven members are not enough to provide breadth, depth, and diversity of expertise, experience, and perspective in the multiple scientific disciplines necessary for these reviews. That is why, for four decades, the Clean Air Scientific Advisory Committee has been augmented with panels of additional experts for the periodic review of each regulated air pollutant. It has been common to have multiple experts in epidemiology, toxicology, and controlled human exposure studies on these panels, as well as experts in the measurement and modeling of air pollution, exposure and risk assessment, uncertainty analysis, and other areas.

In 2016, we advised the EPA administrator about the Integrated Review Plan for subsequent science and policy assessments. Our PM Review Panel was dismissed by press release on October 10, 2018, just before the draft science assessment was released. Shortly thereafter, we formed the nongovernmental Independent Particulate Matter Review Panel. Our volunteer panel continued to review the science and develop advice for the EPA administrator and the public. We reconvened, with support from the Union of Concerned Scientists and former EPA staff. During a 2-day meeting of our nongovernmental panel, conducted under the ground rules for an official EPA federal advisory committee, we deliberated on the strengths and limitations of available scientific evidence.[4]

In the past two decades, over multiple review cycles, the EPA has used evidence- and risk-based approaches to assess the NAAQS. The evidence-based approach takes into account empirical research on the health hazard posed by an air pollutant, as well as the ambient concentrations at which adverse effects are observed, and is based on a thoughtful and comprehensive synthesis of epidemiologic studies, controlled human exposure studies, and toxicologic studies in animals.[3,4] The risk-based approach uses concentration–response relationships inferred from key epidemiologic studies to estimate the population risk under current and potential alternative standards. Given uncertainties, the risk-based ap-

proach used by EPA staff provides useful qualitative insights regarding the magnitude of the risk and risk reduction. Our panel gave more weight to the evidence-based approach, with the risk-based approach providing supporting information.

We delivered our findings in a report submitted to the administrator and the EPA docket on October 22, 2019.[4] We concluded that the current $PM_{2.5}$ standards are insufficient to protect public health, on the basis of a review of the scientific evidence from epidemiologic studies, toxicologic studies in animals, and controlled human exposure studies; this evidence is consistent within each discipline and coherent among the multiple disciplines in supporting a causal, biologically plausible relationship between ambient concentrations well below the current $PM_{2.5}$ standards and adverse health effects, including premature death.[3] The epidemiologic evidence is consistent across studies with diverse designs, populations, pollutant mixtures, locations, and statistical approaches. For example, new epidemiologic studies consider large populations and report effects below the current annual standard, either by restricting the cohort analyzed to persons living in areas with lower levels of ambient exposure or because the average cohort exposures are well below the annual standard.[5-7] The populations in these studies are more than an order of magnitude larger than those in studies available for previous reviews, which has been made possible by scientific developments in quantification of spatial variability in ambient concentrations with the use of new modeling tools. We found no evidence for an ambient concentration threshold for health effects at the lowest observed levels, either for annual or for 24-hour exposure periods.

Populations with preexisting health conditions (e.g., cardiovascular disease, respiratory disease, diabetes, and obesity) or increased exposures (e.g., disadvantaged populations) represent a substantial portion of the U.S. population. These populations are at increased risk for harm from particulate air pollution, owing to their location near emission sources or to demographic or clinical characteristics (e.g., age or disease status) that increase their susceptibility.

The results of the evidence-based review clearly call into question the adequacy of the existing standards. Furthermore, the risk assessment conducted by the EPA shows that, in a sample of people 30 years of age or older living in 47 urban study areas, a large number of premature deaths are attributable to $PM_{2.5}$ exposure under the current standard.[3] The estimated all-cause mortality from long-term exposure to $PM_{2.5}$, calculated on the basis of the 2015 air quality adjusted to just meet the existing standards, ranges from 13,500 to 52,100 deaths annually. The actual air quality in the selected study areas is typically somewhat above the current standards and is adjusted downward, with the use of air-quality models, to enable quantification of what the risk would be if the current standards were met. In addition, the estimated all-cause mortality from short-term exposure to $PM_{2.5}$ ranges from 1200 to 3870 deaths annually. For locations in which ambient $PM_{2.5}$ concentrations would meet the annual standard but not the daily standard, the EPA estimates relative risk reductions of 21 to 27% by changing the standard from 12 μg per cubic meter to 9 μg per cubic meter. Although there is uncertainty around the estimates, the risk assessment supports the conclusions based on the scientific evidence that at the levels of the current fine-particle standards, the risk of premature death is unacceptably high.

The EPA risk assessment focused on all-cause mortality, mortality due to ischemic heart disease, and mortality due to lung cancer. Exposure to current levels of $PM_{2.5}$ is also causally linked to numerous other adverse health outcomes, including long- and short-term cardiovascular events, respiratory illnesses, death from cancers other than lung cancer, and nervous system diseases (e.g., cognitive decrements and dementia). Additional health concerns, such as adverse pregnancy and birth outcomes, are associated with particulate air pollution, although the evidence of causality is weaker.

We unequivocally and unanimously concluded that the current $PM_{2.5}$ standards do not adequately protect public health. An annual standard between 10 μg per cubic meter and 8 μg per cubic meter would protect the general public and at-risk groups. However, even at the lower end of the range, risk is not reduced to zero. The margin of safety increases as the level of the standard is lowered within this range. The choice of standard within this range is a policy judgment reserved for the EPA administrator. In the interest of environmental justice, we advised the administrator that disparities in health risk borne

by minority communities need to be taken into consideration in choosing a margin of safety.

In contrast to the recommendation of the EPA staff that the 24-hour $PM_{2.5}$ standard also be retained, the current 24-hour standard does not provide an adequate level of public health protection in locations for which the 24-hour standard, and not the annual standard, would be violated. On the basis of the scientific evidence, and with the acknowledgment that there is a continuum of adverse effects that decrease as the level of the standard decreases, the panel recommends that the 24-hour standard be set between 30 μg per cubic meter and 25 μg per cubic meter.

Between 2017 and 2018, all Clean Air Scientific Advisory Committee members were replaced. The seven-member committee newly appointed by the EPA largely reached a different conclusion than we did.[8] The lone physician–scientist on the committee found that the weight of evidence, including recent epidemiologic studies, reasonably calls into question the adequacy of the current long-term standard. However, the committee chair, an industry consultant, and some other members of the committee concluded that there is no evidence that calls into question the adequacy of the current standards. Nonetheless, the committee noted the "exceptional nature" of the current review, including the dismissal of our panel, the accelerated timeline, and the production of a policy assessment before the science assessment was completed. Although some committee members acknowledged our report, the Clean Air Scientific Advisory Committee largely disregarded the advice from our panel.

There is no doubt that on promulgating a final rule, the EPA will be sued. Federal courts have in the past given considerable deference to the Clean Air Scientific Advisory Committee regarding its scientific advice. Will the courts defer to a committee that has been arbitrarily and capriciously deprived of a particulate matter–specific expert panel? Or will the courts look elsewhere, such as to public comments from experts and input from the dismissed panel?

The dismissal of our review panel is just one of numerous recent ad hoc changes to scientific review of the NAAQS since 2017 that undermine the quality, credibility, and integrity of the review process and its outcome. Other changes include imposing nonscientific criteria for appointing the Clean Air Scientific Advisory Committee members related to geographic diversity and affiliation with governments, replacing the entire membership of the chartered committee over a period of 1 year, banning nongovernmental recipients of EPA scientific research grants from committee membership while allowing membership for persons affiliated with regulated industries, ignoring statutory requirements for the need for a thorough and accurate scientific review of the NAAQS in setting a review schedule, disregarding key elements of the committee-approved Integrated Review Plan, reducing the number of drafts of a document for committee review irrespective of whether substantial revision of scientific content is needed, commingling science and policy issues, and creating an ad hoc "pool" of consultants that fails to address the deficiencies caused by dismissing the Clean Air Scientific Advisory Committee PM Review Panel. The courts are already grappling with the ban on academic recipients of research grants.

Although our panel did not specifically assess other current EPA initiatives, there are at least two that are closely related to $PM_{2.5}$. One is the so-called Transparency in Regulatory Science proposed rule and supplement. This rule could exclude from regulatory consideration studies for which data are not publicly available, irrespective of their scientific rigor.[9] Such an exclusion could apply to studies based on data from human participants, including epidemiologic studies such as the seminal Harvard Six Cities and American Cancer Society studies, which were important in previous NAAQS reviews. The other initiative is a change to the EPA benefit–cost assessment to exclude "cobenefits." As an example, the Mercury and Air Toxics Standard for power plants reduces mercury emissions but has the cobenefit of also reducing $PM_{2.5}$ emissions.[10] For this and other rules, $PM_{2.5}$ cobenefits can be much larger than the direct benefits of reducing the pollutant specifically targeted by the rule. The multiple EPA initiatives aimed at undermining the appropriate role of scientific and economic assessment of adverse effects from $PM_{2.5}$ directly threaten health.

The 60-day public comment period for the proposed rule, which ends on June 29, 2020, is the last remaining opportunity for experts and stakeholders to provide input on a flawed rulemaking that ignores science and that will lead to avoidable premature deaths.

October 2019 meetings of the Independent Particulate Matter Review Panel were hosted by the Union of Concerned Scientists (UCS). Some panelists received travel reimbursement from UCS. Panelists did not accept honoraria or other compensation. This article reflects exclusively the deliberations of the panel.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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This article was published on June 10, 2020, at NEJM.org.

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DOI: 10.1056/NEJMsb2011009