

NOT YET SCHEDULED FOR ORAL ARGUMENT

Nos. 24-1050, 24-1051, 24-1052, 24-1073, 24-1091

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

COMMONWEALTH OF KENTUCKY, et al.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

Petitions for Review of Action of the U.S. Environmental Protection Agency

BRIEF FOR U.S. ENVIRONMENTAL PROTECTION AGENCY

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES**A. Parties and Amici**

All parties, intervenors, and amici appearing [before the district court and] in this Court are listed in the Briefs for Petitioners.

B. Rulings Under Review

References to the ruling at issue appear in the Briefs for Petitioners.

C. Related Cases

Aside from these consolidated petitions, there are no other related cases within the meaning of Circuit Rule 28(a)(1).

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GLOSSARY

CASAC	Clean Air Scientific Advisory Committee
EPA	Environmental Protection Agency
NAAQS	National Ambient Air Quality Standards
PM _{2.5}	Fine particulate matter

INTRODUCTION

The Clean Air Act directs the U.S. Environmental Protection Agency to establish national ambient air quality standards, or “NAAQS,” that are “requisite to protect the public health” with an “adequate margin of safety.” 42 U.S.C.

§ 7409(b)(1). In 2021, EPA launched a proceeding to review and potentially revise the then-applicable standards for fine particulate matter, or “PM_{2.5},” because of concerns that the current standards did not meet that mandate.

The EPA Administrator ultimately determined that the prior primary annual PM_{2.5} standard was not adequate to protect public health. His decision to revise that standard is consistent with the advice of the independent Clean Air Scientific Advisory Committee and supported by overwhelming scientific evidence, which EPA weighed using the same methodological and policy approaches that this Court has endorsed on at least three occasions. *Nat’l Ass’n of Mfrs. v. EPA*, 750 F.3d 921, 924 (D.C. Cir. 2014); *Am. Farm Bureau Fed’n v. EPA*, 559 F.3d 512, 526–27 (D.C. Cir. 2009); *Am. Trucking Ass’ns, Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002) (“*ATA III*”).

Industry and State Petitioners do not seriously contest the scientific support for EPA’s decision. Instead, their petitions for review contend that EPA lacked statutory authority to revise the NAAQS in the manner it did, and that EPA needed

to consider factors like implementation cost and feasibility in determining whether to revise the standards.

Petitioners' attack on EPA's authority to revise the NAAQS disregards the statutory text, which permits EPA to "review and revise [air quality] criteria or promulgate new standards earlier or more frequently" than otherwise required. 42 U.S.C. § 7409(d)(1). And Petitioners' attack on EPA's refusal to consider cost and related factors when revising the particulate matter standards disregards settled Supreme Court and D.C. Circuit precedent. *See, e.g., Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457 (2001); *Murray Energy Corp. v. EPA*, 936 F.3d 597 (D.C. Cir. 2019).

These and Petitioners' other arguments are meritless. The Court should deny the petitions for review.

STATEMENT OF JURISDICTION

This Court has jurisdiction under 42 U.S.C. § 7607(b)(1).

STATEMENT OF THE ISSUES

1. Whether the EPA Administrator lawfully exercised his 42 U.S.C. § 7409(d)(1) authority to "review and revise or promulgate new standards earlier or more frequently" than the "thorough review" and revision of air quality criteria and standards that EPA must complete at five-year intervals.

2. Whether the EPA Administrator appropriately declined to consider costs and other non-public health factors in identifying a PM_{2.5} standard “requisite to protect the public health,” 42 U.S.C. § 7409(b)(1), in line with *American Trucking*, 531 U.S. at 471, and *Murray Energy*, 936 F.3d at 621–22.

a. Whether, as the Supreme Court concluded in *American Trucking*, 531 U.S. at 474–76, Section 7409’s mandate that the Administrator set national ambient air quality standards based solely on public health considerations is lawful and “fits comfortably within the scope of discretion permitted by” nondelegation doctrine precedent, *id.* at 476.

b. Whether the Administrator appropriately declined to consider “attainability” in identifying a PM_{2.5} standard “requisite to protect the public health,” 42 U.S.C. § 7409(b)(1), in line with *Murray Energy*, 936 F.3d at 621, and *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1181 (D.C. Cir. 1981).

3. Whether the Administrator, applying the same analytical approach previously approved by this Court, adequately explained his reasonable decision that the prior standards for PM_{2.5} were inadequate to protect public health with an adequate margin of safety and to lower the level of the revised primary annual standard to 9 µg/m³.

4. Whether, as explained in and supported by the administrative record,

the Final Rule was based on public health, not other purportedly unlawful considerations.

PERTINENT STATUTES AND REGULATIONS

All pertinent statutes and regulations not cited in Petitioners' addenda are set forth in the Addendum following this brief.

STATEMENT OF THE CASE

A. Statutory and regulatory background

The Clean Air Act, 42 U.S.C. §§ 7401–7671q, establishes a comprehensive program to protect and enhance the Nation's air quality through a system of shared federal and state responsibility. *Id.* § 7401(b)(1). Central to this program are the national ambient air quality standards, or “NAAQS,” which EPA sets to limit the concentration of certain air pollutants in the “ambient” (outside) air to protect against the pollutants' effects on public health and welfare. *Id.* §§ 7408–09. EPA has established NAAQS for six common air pollutants, including particulate matter. 40 C.F.R. pt. 50.

The NAAQS must be promulgated according to the rulemaking procedures established at 42 U.S.C. § 7607(d), *see id.* § 7607(d)(1)(A), and the procedural and substantive requirements of Section 7409. EPA first develops “air quality criteria,” a compilation of the “latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare” that may result from a

pollutant's presence in the ambient air. *Id.* § 7408(a)(2). The criteria are not themselves guidelines or standards, but the scientific bases for the standards. *See* 42 U.S.C. § 7409(b); *Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1136–37 (D.C. Cir. 1980).

To ensure that NAAQS keep pace with scientific advances, EPA must regularly review and, if appropriate, revise the criteria and NAAQS. At five-year intervals, EPA must “complete a thorough review” of the air quality criteria under Section 7408 “and the national ambient air quality standards” promulgated under Section 7409, “and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 7408 of this title” (the air quality criteria) “and subsection (b) of this section.” 42 U.S.C. § 7409(d)(1); *see also id.* § 7408(c) (EPA must “from time to time review, and, as appropriate, modify, and reissue” the air quality criteria). Separately, EPA may “review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph.” *Id.* § 7409(d)(1).

To assist in this process, EPA must appoint an independent scientific review committee, the Clean Air Scientific Advisory Committee (“CASAC”), to review and recommend revisions to existing criteria and NAAQS. *Id.* § 7409(d)(2)(A)–(B). Although EPA is not bound by CASAC’s recommendations, if EPA’s revisions to NAAQS differ significantly from those recommendations, EPA must

explain the reasons for that departure. 42 U.S.C. § 7607(d)(3), (d)(6); *see Mississippi v. EPA*, 744 F.3d 1334, 1355 (D.C. Cir. 2014).

Based on the criteria and considering CASAC's advice, EPA then promulgates NAAQS, which establish a nationwide benchmark whose attainment will protect public health and welfare. 42 U.S.C. § 7409(b).

There are two types of NAAQS. "Primary" NAAQS are air quality standards "which in the judgment of the Administrator . . . are requisite to protect the public health." *Id.* § 7409(b)(1). By contrast, "secondary" NAAQS are standards requisite to protect "public welfare." *Id.* § 7409(b)(2). This case concerns EPA's revision of the primary NAAQS for PM_{2.5}.

EPA must set primary NAAQS based solely on public health considerations, without reference to the cost or feasibility of achieving the standards. *Am. Trucking Ass'ns*, 531 U.S. at 471. The "public health" includes not only the health of average individuals, but also that of sensitive populations (such as children or older adults) or at-risk populations (such as those living in areas with the worst air quality) who may be particularly vulnerable to air pollution. *Am. Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998). And in setting primary NAAQS, EPA must allow an "adequate margin of safety," 42 U.S.C. § 7409(b)(1), so that the standard will "protect against effects which have not yet been uncovered by

research and effects whose medical significance is a matter of disagreement.” *Lead Indus. Ass’n*, 647 F.2d at 1154.

Each NAAQS has four basic elements: (1) the “indicator,” the pollutant to be measured—here, fine particulate matter, or PM_{2.5};² (2) the “level,” the concentration of the indicator pollutant used to determine whether the standard is achieved; (3) the “form,” the way that compliance with the level will be determined (for example, the level will not be exceeded more than one time every year); and (4) the “averaging time,” the period over which pollution is measured. *Am. Farm Bureau Fed’n*, 559 F.3d at 516.

Once EPA promulgates a new or revised NAAQS, EPA and states must act to attain and maintain that standard. EPA is required to designate all areas of the country as “attainment,” “nonattainment,” or “unclassifiable” with respect to each NAAQS. 42 U.S.C. § 7407(d). EPA bases these designations on data collected from air quality monitors situated throughout the country, along with other factors and forms of analysis. *Id.* § 7619. States may request that EPA exclude monitoring data directly influenced by “exceptional events”—natural events that are not reasonably controllable or preventable, like wildfires and high-wind dust events, or

² The PM_{2.5} standard applies to particulate matter with a diameter less than or equal to 2.5 micrometers. There is a separate standard for PM₁₀ that applies to particulate matter with a diameter less than or equal to 10 micrometers.

that are caused by human activity unlikely to recur at a particular location. *Id.*

§ 7619(b); 40 C.F.R. § 50.14(a)(1)(i), (b)(4), (b)(5), (c)(3)(iv).

States must develop state implementation plans to “implement[], maintain[], and enforce[]” the NAAQS within their jurisdictions. 42 U.S.C. § 7410(a)(1). After adopting an implementation plan, a state submits the plan to EPA for review. *Id.* § 7410(c).

B. Factual background

1. Health risks from particulate matter pollution

Particulate matter comprises a mixture of solid and liquid droplets in the ambient air. 89 Fed. Reg. 16202, 16213 (Mar. 6, 2024). Humans can be exposed to particulate matter resulting either from direct emissions (from, for example, smokestacks, wildfires, or construction sites) or complex atmospheric reactions of chemicals emitted by sources such as power plants and cars. *Id.*

The health effects of particulate matter exposure depend, in part, on the particle’s size. *Id.* at 16212–13. Smaller particles like PM_{2.5} are generally more harmful to human health than larger particles—once inhaled, fine particles can reach the lungs, where some can enter the blood and affect other organs. 2019 Science Assessment § 4.3, JA_ __. Particulate matter exposure “is associated with increased mortality (premature death) rates and morbidity (illness) effects such as

cardiovascular disease and decreased lung function.” *Am. Farm Bureau Fed’n*, 559 F.3d at 515; 2019 Science Assessment at ES-12–ES-17, JA __.

To determine health risks from exposure to particulate matter in ambient air, EPA reviews a wide range of scientific evidence, including animal toxicological studies, controlled human exposure studies, and epidemiologic studies. 2019 Science Assessment at P-11–P-14, JA __. From that evidence, EPA identifies the types of health effects associated with particulate matter exposure by assessing the consistency of observed patterns of health effects across the scientific literature. *Id.* That evidence informs EPA’s assessment of the relationship between long-term (months to years) or short-term (hours to weeks) particulate matter exposure and adverse health effects. *Id.* at P-14–P-17, JA __.

EPA assesses the relationship between particulate matter exposure and health effects by considering strengths, limitations, and uncertainties in the scientific evidence, to make one of five “causality determinations,” ranging from “causal” to “not likely to be causal.” *Id.* at P-12–P-13 (Table P-2) JA __. A “causal” relationship is one where the scientific evidence is robust enough to conclude that exposure to a particular pollutant has been shown to result in health effects. *Id.* A “likely to be causal” relationship is one where the scientific evidence is sufficient to conclude that a causal relationship between pollutant exposure and health effects is likely to exist, but uncertainties remain in the evidence overall. In

assessing whether the NAAQS are sufficient to protect public health, EPA generally places the greatest weight on health effects for which the available scientific evidence is strongest, specifically those categories with evidence supporting either a conclusion that particulate matter has a “causal” or “likely to be causal” relationship. 2022 Policy Assessment at 3-16, JA_.

Epidemiologic studies—observational studies that examine the association between health effects and particulate matter concentrations—are an important line of evidence for EPA’s assessment. 2019 Science Assessment at P-15, JA_. To study associations between particulate matter exposure and health effects, epidemiologic studies use various approaches to estimate particulate matter exposure. Traditionally, these studies relied on ground-based air quality monitors to provide information on local particulate matter concentrations. 89 Fed. Reg. at 16217. Those monitors are generally sited in areas expected to have the highest particulate matter concentrations. 2022 Policy Assessment at 2-18, JA_.

More recently, scientists have started using hybrid models, which combine ground-based monitored data with air quality-modeled estimates and satellite information to estimate particulate matter exposure. Hybrid model-based studies increase the geographic area over which scientists can estimate particulate matter concentrations and thus estimate exposures for populations often excluded from monitor-based studies. 89 Fed. Reg. at 16240.

Using either method, epidemiologic studies identify associations between exposure to certain concentrations of particulate matter and health effects and report the mean or median particulate matter concentration over the study duration. *See* 2022 Policy Assessment at 3-2, JA_.

2. Past particulate matter NAAQS reviews

Over the years, EPA has promulgated or revised particulate matter NAAQS as new studies reflecting the latest science became available. *See* 89 Fed. Reg. at 16207–09.

In 1971, EPA adopted standards based on “total suspended particulate” (that is, particles of any size in the air). 36 Fed. Reg. 8186 (Apr. 30, 1971). In 1984, EPA proposed to set a PM₁₀ standard. 49 Fed. Reg. 10408 (Mar. 20, 1984). After proposal, EPA determined that newly published studies could impact the level of the new PM₁₀ standard. 51 Fed. Reg. 11058 (Apr. 1, 1986). EPA reopened the PM₁₀ air quality criteria, issued separate “targeted” addenda to the criteria, evaluating only “the relevant new studies and discussing their potential implications for standard-setting.” *Id.* at 11058. Based on the criteria, including the addenda, EPA ultimately finalized a more stringent PM₁₀ standard. 52 Fed. Reg. 24634 (July 1, 1987).

In 1997, EPA adopted new standards based on even smaller particles—PM_{2.5}. 62 Fed. Reg. 38652 (July 18, 1997). EPA revised those standards in 2006

and 2012 to reflect new scientific evidence about public health risks. 71 Fed. Reg. 61144 (Oct. 17, 2006); 78 Fed. Reg. 3086 (Jan. 15, 2013).

EPA currently sets two primary standards for PM_{2.5}: a 24-hour standard and an annual standard. *See* 89 Fed. Reg. at 16203, 16207. EPA also sets a primary 24-hour standard for PM₁₀.

Whenever EPA reviews and revises the particulate matter NAAQS, it first reviews the particulate matter air quality criteria. The product of that review is an Integrated Science Assessment, which synthesizes relevant health and welfare information and serves as the scientific basis for EPA's NAAQS review. *See* 2019 Science Assessment at P-9, JA_. EPA also publishes a Policy Assessment, which evaluates the adequacy of applicable standards, considering the Integrated Science Assessment and other information on exposures and risks likely to be experienced by people in their daily lives. *See* 2022 Policy Assessment at 1-2, JA_. These documents are reviewed by CASAC, which makes recommendations as to any revisions based on that review. *Id.* at 1-2–1-3, JA_–_. Taking the criteria, EPA's Assessments, CASAC's recommendations, and public comment into account, the Administrator determines whether a new particulate matter standard is required to protect public health or welfare. *Id.*

3. EPA's 2020 review of the particulate matter NAAQS

EPA initiated a review of the particulate matter criteria and NAAQS in 2014. This review resulted in EPA's 2020 action retaining all particulate matter standards ("2020 Decision"), based on EPA's 2019 Science Assessment, 2020 Policy Assessment, CASAC's advice, and public comments. *See* 89 Fed. Reg. at 16209.

EPA's 2019 Science Assessment assessed thousands of studies examining particulate matter's impact on human health. The epidemiologic studies EPA evaluated reported serious health effects at even lower long-term particulate matter concentrations than previous reviews. *See* 89 Fed. Reg. at 16204. As Figure 1 (below) shows, EPA explained that the scientific evidence supported a "causal" relationship between both short- and long-term PM_{2.5} exposure and cardiovascular effects and mortality, and a "likely to be causal" relationship between (1) short-term and long-term PM_{2.5} exposure and respiratory effects, and (2) long-term PM_{2.5} exposure and nervous system effects and cancer. *See* 89 Fed. Reg. at 16220.

Figure 1 (from 2022 Policy Assessment at 3-20, JA__)

Health Outcome	Size Fraction	Exposure Duration	2009 ISA	2019 ISA
Mortality	PM _{2.5}	Long-term	Causal	Causal
		Short-term		
Cardiovascular effects	PM _{2.5}	Long-term	Causal	Causal
		Short-term		
	UFP	Short-term	Suggestive of, but not sufficient to infer	Suggestive of, but not sufficient to infer
Respiratory effects	PM _{2.5}	Long-term	Likely to be causal	Likely to be causal
		Short-term		
	UFP	Short-term	Suggestive of, but not sufficient to infer	Suggestive of, but not sufficient to infer
Cancer	PM _{2.5}	Long-term	Suggestive of, but not sufficient to infer	Likely to be causal
Nervous System effects	PM _{2.5}	Long-term	---	Likely to be causal
		Short-term	Inadequate	Suggestive of, but not sufficient to infer
	UFP	Long-term	---	Suggestive of, but not sufficient to infer
		Short-term	Inadequate	Suggestive of, but not sufficient to infer
Metabolic effects	PM _{2.5}	Long-term	---	Suggestive of, but not sufficient to infer
		Short-term	---	Suggestive of, but not sufficient to infer
Reproduction and Fertility	PM _{2.5}	Long-, Short-term	Suggestive of, but not sufficient to infer	Suggestive of, but not sufficient to infer
Pregnancy and Birth Outcomes				

Table 3-1 lists the health outcomes for which the 2019 ISA concludes the evidence supports either a causal, a likely to be causal, or a suggestive relationship. For other health outcomes, the 2019 ISA concludes the evidence is inadequate to infer a causal relationship (U.S. EPA, 2019, Table 1-4).

The 2009 ISA (U.S. EPA, 2009) made causality determinations for the broad category of “Reproductive and Developmental Effects.” Causality determinations for 2009 represent this broad category and not specifically for “Male and Female Reproduction and Fertility” and “Pregnancy and Birth Outcomes”.

For reproductive and developmental effects, the 2019 ISA’s causality determinations reflect the combined evidence for both short- and long-term exposures (U.S. EPA, 2019, Chapter 9).

EPA also authored a 2020 Policy Assessment, informed by the 2019 Science Assessment, CASAC's advice, and public comment. In that Assessment, EPA concluded that the available scientific evidence calls "into question the adequacy of the public health protection afforded by the combination of the current annual and 24-hour primary PM_{2.5} standards." 2020 Policy Assessment at 3-106, JA_. The 2020 Policy Assessment added that retaining the 12 µg/m³ primary annual PM_{2.5} standard "would place little weight on the broad body of epidemiologic evidence" that showed "statistically significant health effect associations" from particulate matter exposure at concentrations below that standard. *Id.*

CASAC reviewed EPA's draft Science and Policy Assessments. CASAC did not reach consensus on whether to retain the primary annual PM_{2.5} standard: some CASAC members concluded that the annual standard was not adequate to protect public health and thus should be lowered, while others thought the existing annual standard was adequate. *See* 89 Fed. Reg. at 16252; 2019 CASAC Review at 1, JA_.

Those members who concluded that the 12 µg/m³ standard was not adequate noted that recent studies supported associations between health effects and PM_{2.5} exposure at concentrations below 12 µg/m³. 2019 CASAC Review at 1, JA_. They concluded that it was "highly unlikely that the extensive body of evidence . . .

could be fully explained by confounding or by other non-causal explanations.” *Id.* at 8, JA_ ; 89 Fed. Reg. at 16252.

By contrast, those members who concluded that the 12 $\mu\text{g}/\text{m}^3$ standard was adequate emphasized uncertainties in the epidemiologic studies. Those included the potential for confounding factors (that is, the potential that the health effects described in the science can be explained by factors other than particulate matter). 2019 CASAC Review at 8, JA_. Those members thought that additional “accountability studies”—studies examining whether a policy reducing $\text{PM}_{2.5}$ concentrations leads to reductions in $\text{PM}_{2.5}$ -associated health outcomes,³ 89 Fed. Reg. at 16264—were needed to alleviate that uncertainty. 2019 CASAC Review at 10, JA_ ; 89 Fed. Reg. at 16252.

EPA finalized the decision to retain all particulate matter standards in December 2020. 85 Fed. Reg. 82684, 82714 (Dec. 18, 2020). The 2020 Decision cited uncertainty about whether lowering standards would meaningfully improve public health. *Id.* at 82717. It also found that the epidemiologic studies showing health effects from exposure to lower mean $\text{PM}_{2.5}$ concentrations could not justify a revised standard, in part because existing accountability studies generally did not include areas with ambient air conditions meeting the 12 $\mu\text{g}/\text{m}^3$ standard. *Id.*

³ For example, an accountability study could look at whether health effects nearby manual tollbooths on the Interstate 95 corridor decreased when those tollbooths were replaced with automatic EZPass, decreasing congestion.

The 2020 Decision diverged from the settled EPA approach of setting the primary annual PM_{2.5} standard. Rather than looking at all key epidemiologic studies and setting the standard slightly below the lowest mean PM_{2.5} concentration where health effects are observed,⁴ EPA averaged the mean PM_{2.5} concentrations from the monitor-based studies, excluding the more recent hybrid model-based studies. That analysis resulted in a “mean of means” of 13.5 µg/m³ (above the standard). *See id.* at 82717–18.

The 2020 Rule was challenged by several states and environmental groups in this Court. *See California v. EPA*, No. 21-1014 (D.C. Cir.).⁵

C. Agency proceedings

Following the Presidential transition in January 2021, EPA announced that it was reviewing the 2020 Decision to determine whether reconsideration was appropriate. After thorough consideration, EPA determined it would reconsider the 2020 Decision. *See* 89 Fed. Reg. at 16210 & n.18. EPA concluded that

⁴ That approach has been repeatedly upheld by this Court. *Nat’l Ass’n of Mfrs.*, 750 F.3d at 924; *Am. Farm Bureau Fed’n*, 559 F.3d at 526–27; *ATA III*, 283 F.3d at 372.

⁵ Those cases were placed in abeyance to allow EPA to consider whether to reconsider the 2020 Decision and have remained in abeyance during this reconsideration action. *California v. EPA*, No. 21-1014, Doc. Nos. 1885786, 1900745, 1916444. Most recently, the Court extended the abeyance and ordered the parties to file motions to govern future proceedings within 30 days of the Court’s disposition of this case. *Id.* Doc. No. 2057116.

reconsideration was appropriate because the scientific evidence in the 2019 Science Assessment, assessed in the 2020 Policy Assessment, suggested that the existing standards may not adequately protect public health. *Id.* at 16210.

1. 2022 Science and Policy Assessments

EPA next considered whether to reopen and update the Science and Policy Assessments to ensure that its reconsideration would be based on the latest scientific knowledge. EPA was aware of certain studies published since the literature cutoff date for the 2019 Science Assessment addressing issues likely to be relevant to its reconsideration of the particulate matter standards. *Id.* at 16211. Not wanting to ignore these important developments—and given its statutory duty to ensure that the air quality criteria on which standards are based “reflect the latest scientific knowledge useful in indicating the kind and extent” of public health effects, 42 U.S.C. § 7408(a)(2)—EPA announced that it would develop a supplemental science assessment and a new policy assessment. 89 Fed. Reg. at 16211.⁶

EPA’s 2022 Supplemental Science Assessment (“2022 Supplement”) provides a targeted assessment of new studies that focused on key scientific topics. 2022 Supplement § 1.2.2, JA_–_–; 89 Fed. Reg. at 16260. The recent studies

⁶ *See also infra* p. 80 (describing past NAAQS reviews where EPA reopened air quality criteria based on newly published relevant studies).

supported and extended the 2019 Science Assessment's conclusions, also showing that PM_{2.5} exposure is associated with cardiovascular effects and mortality. 89 Fed. Reg. at 16230–31. Many new studies reported health effects at exposure to long-term mean concentrations of PM_{2.5} well below the 12 µg/m³ annual standard. *See* 2022 Policy Assessment at 3-92–3-107 (Table 3-6–3-9), JA__.

The 2022 Supplement also included studies that addressed gaps identified in the 2020 Decision. For instance, several new epidemiologic studies used alternative methods for confounder control that strengthened confidence in the observed associations between PM_{2.5} exposure and health effects. *See* 89 Fed. Reg. at 16278. The 2022 Supplement also evaluated accountability studies analyzing areas with ambient air conditions starting at 12 µg/m³ and found public health improvements from reducing PM_{2.5} concentrations below 12 µg/m³. *See* 89 Fed. Reg. at 16276; *see also* 2022 Policy Assessment at 3-129–3-133 & Table 3-12, JA__.

EPA also published a new Policy Assessment in May 2022, which considered the scientific studies included in the 2019 Science Assessment and the 2022 Supplement. The 2022 Policy Assessment estimated health risks based on a range of air quality conditions and air quality analyses, recognizing that the 12 µg/m³ standard could allow a substantial number of PM_{2.5}-associated deaths. 2022 Policy Assessment at 3-136–3-167, JA__. As in the 2020 Policy

Assessment, the 2022 Policy Assessment concluded that the evidence “call[s] into question the adequacy of the public health protection afforded by” the current PM_{2.5} standards. *Id.* at 3-207, JA_.

2. CASAC’s review and recommendations

As in 2019, EPA provided drafts of the 2022 Supplement and 2022 Policy Assessment to CASAC for review, and to the public for comment. 89 Fed. Reg. at 16211, 16252–53. Though most of CASAC’s membership was new since 2019, two members remained the same. One of those members had previously concluded, based EPA’s draft Assessments in the 2020 review, that the annual PM_{2.5} standard should be retained. *See* 89 Fed. Reg. at 16257 n.93. Unlike in 2019, the CASAC members unanimously agreed with EPA that the 12 µg/m³ annual PM_{2.5} standard was not adequate to protect public health and that the standard should be lowered. *Id.* at 16253; 2022 CASAC Review at 2, JA_. CASAC did not agree on the level the standard should be set at: a majority believed that a standard between 8-10 µg/m³ was most appropriate, whereas a minority believed a standard between 10-11 µg/m³ would be adequate. 2022 CASAC Review at 16, JA_.

3. The Administrator’s conclusions

Based on the air quality criteria and considering CASAC’s advice, the Administrator determined that the existing PM_{2.5} standard was not “‘requisite’ to

protect the public health with an adequate margin of safety.” 89 Fed. Reg. at 16273–86.

The Administrator noted that studies evaluated in the 2019 Science Assessment and 2022 Supplement show statistically significant associations between health effects and PM_{2.5} concentrations well below 12 µg/m³. *Id.* at 16274. Unlike in 2020, the Final Rule placed weight on epidemiologic studies that used both ground-based monitoring *and* hybrid-based modeling approaches, explaining that hybrid-based modeling studies demonstrated advancements in available science in recent years. *Id.* at 16275. The Administrator also placed less weight on uncertainties, explaining that newer studies collectively reduced some of these uncertainties. *Id.* at 16275–76. The Administrator further explained the statutory requirement that NAAQS provide an “adequate margin of safety,” 42 U.S.C. § 7409(b)(1), is meant to “address uncertainties associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards that research has not yet identified,” 89 Fed. Reg. at 16273.

The Administrator also considered the 2022 Policy Assessment’s quantitative assessment of estimated exposure and health risks, or “risk assessment.” *Id.* at 16275. Though recognizing that risk assessments have inherent limitations, the Administrator explained that the risk assessment estimated a

substantial number of deaths could result from the 12 $\mu\text{g}/\text{m}^3$ annual $\text{PM}_{2.5}$ standard and found that the “general magnitude of the risk estimates provide support for significant health impacts, particularly for lower alternative annual standard levels.” *Id.*

The Administrator also considered CASAC’s advice. The Administrator noted that, with the benefit of the more recent scientific evidence in the 2022 Supplement as well as the 2019 Science Assessment, a unanimous CASAC agreed that the annual $\text{PM}_{2.5}$ standard should be lowered to adequately protect public health. *Id.* at 16275.

Upon concluding that the annual $\text{PM}_{2.5}$ standard was not adequate to protect public health, the Administrator decided that revising the annual $\text{PM}_{2.5}$ standard to 9 $\mu\text{g}/\text{m}^3$ would provide the requisite public health protection. *Id.* at 16285. In determining the appropriate standard, the Administrator relied on the same approach that had been used in setting the annual $\text{PM}_{2.5}$ standard in 1997, 2006, and 2012: he looked at all key U.S.-based epidemiologic studies and set the standard slightly below the lowest mean $\text{PM}_{2.5}$ concentration where health effects were observed (9.3 $\mu\text{g}/\text{m}^3$). *Id.* at 16275, 16279. The Administrator judged that significantly discounting epidemiologic studies or relying on the prior “mean of the means” approach would not protect public health with an adequate margin of safety. *Id.* at 16260.

The Administrator considered setting the standard lower (at 8 $\mu\text{g}/\text{m}^3$) or higher (at 10 $\mu\text{g}/\text{m}^3$) and rejected both approaches, concluding that a standard of 9 $\mu\text{g}/\text{m}^3$ was “neither more nor less stringent than necessary . . . to protect public health with an adequate margin of safety.” *Id.* at 16285.

D. Petitions for review

EPA finalized the Administrator’s determination on March 6, 2024. 89 Fed. Reg. 16202. Five groups of Petitioners—states and industry groups—filed petitions seeking this Court’s review of the Final Rule. *See* Case Nos. 24-1050, 24-1051, 24-1052, 24-1073, 24-1091.

SUMMARY OF ARGUMENT

1. The Clean Air Act expressly confers authority on EPA to review and revise air quality criteria and standards at any time. *See* 42 U.S.C. § 7409(d)(1); *see also id.* § 7408(c). EPA properly exercised that authority when it reconsidered the 2020 Decision and ultimately revised the $\text{PM}_{2.5}$ annual standard from 12 $\mu\text{g}/\text{m}^3$ to 9 $\mu\text{g}/\text{m}^3$. Industry Petitioners are wrong that EPA cannot exercise that authority without first conducting a “thorough review” of all aspects of the particulate matter air quality criteria. Section 7409(d)(1)’s first sentence requires EPA to complete that review, and revise air quality criteria and standards as appropriate, at five-year intervals. But that section’s second sentence allows EPA to “review and revise criteria and promulgate new standards earlier or more frequently than required”

under the first sentence. The statutory text, context, and history are clear that this permissive authority is not conditioned on completing another “thorough review.”

2. EPA properly revised the particulate matter standards relying *only* on considerations consistent with Section 7409(b)(1)’s health-based standard, to the exclusion of cost and cost-related considerations. That approach is mandated by this Court’s and Supreme Court precedent, which establishes that the Clean Air Act “unambiguously bars cost considerations from the NAAQS-setting process.” *Am. Trucking Ass’ns*, 531 U.S. at 471. Petitioners’ attempt to shoehorn cost considerations into the decision whether to revise standards in the first place contradicts the statute’s plain text and is practically unworkable within courts’ well-established interpretation of EPA’s task. State Petitioners’ argument that barring cost considerations renders Section 7409 an unconstitutional delegation of legislative power has likewise been considered and rejected by the Supreme Court and this Court—and would be wrong regardless.

3. On the merits, the EPA Administrator rationally exercised his judgment in determining to revise the annual PM_{2.5} standards from 12 µg/m³ to 9 µg/m³. In doing so, the Administrator looked to all key epidemiologic studies reporting health effects and set the standard slightly below the lowest study mean—an approach consistent with that taken in previous particulate matter NAAQS reviews and upheld by this Court three times. *See Nat’l Ass’n of Mfrs.*,

750 F.3d at 924; *Am. Farm Bureau Fed'n*, 559 F.3d at 526–27; *ATA III*, 283 F.3d at 372. That determination was based on robust scientific evidence, accorded with CASAC's recommendations, and is due deference.

The Court should reject Petitioners' attack on this rational approach. The Administrator thoroughly explained why EPA set the primary annual PM_{2.5} standard at 9 µg/m³, considering and reasonably rejecting calls to set the standard at both a more and less stringent limit. Additionally, the Administrator reasonably considered EPA's risk assessment, which confirmed that that level was necessary to protect populations most at risk from particulate matter exposure. *See Am. Petroleum Inst. v. EPA*, 684 F.3d 1342, 1352 (D.C. Cir. 2012); *Nat'l Ass'n of Mfrs.*, 750 F.3d at 925. Finally, the Administrator thoroughly explained his assessment of uncertainties, an assessment that is aligned with the Clean Air Act, which recognizes that uncertainties are inherent in scientific studies but still requires the Administrator to use his judgment to set a safe standard. *See* 42 U.S.C. § 7409(b).

4. Finally, State Petitioners are wrong that EPA was motivated by or relied on irrelevant factors in revising the particulate matter standards. Nothing in the record supports State Petitioners' baseless accusation that EPA ignored that statutory mandate in favor of separate climate change, environmental justice, or political considerations. Rather, EPA has consistently explained the public health

reasons for initiating reconsideration and for the revision promulgated in the Final Rule. State Petitioners identify no basis for overcoming the presumption of regularity and disregarding the Agency's explanation, and substantively cannot show that public health evidence in the record does not support EPA's action. There are also no grounds to apply heightened "skepticism," States' Br. 24, to EPA's action. And the record shows that EPA acknowledged that it was changing course from the 2020 Decision and adequately considered potential reliance interests in doing so.

The Court should deny the petitions for review.

STANDARD OF REVIEW

Review of the Final Rule is governed by 42 U.S.C. § 7607(d)(9)(A), which provides that the Court may reverse an action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Under this "narrow" standard, the Court is "not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). "To withstand review, an agency must have examined all relevant facts and data, and articulated a rational explanation for its decision, including a reasonable connection between the facts and the ultimate outcome." *Murray Energy*, 936 F.3d at 608.

In applying that standard, the Court “cannot look at EPA’s decision as would a scientist, but instead must exercise our ‘narrowly defined duty of holding agencies to certain minimal standards of rationality.’” *Id.* (quoting *Mississippi*, 744 F.3d at 1342). Accordingly, the Court must “defer to the EPA’s scientific judgment while examining the record to ensure the Agency has considered the relevant factors and reasonably explained how it reached its conclusions.” *Am. Farm Bureau Fed’n*, 559 F.3d at 520; *see also Ctr. for Biological Diversity v. EPA*, 749 F.3d 1079, 1087–88 (D.C. Cir. 2014) (“We will give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise.” (cleaned up)).

An agency’s statutory interpretation, made in pursuance of official duty and based on special experience, is a “‘body of experience and informed judgment to which courts and litigants could properly resort for guidance,’ even on legal questions.” *Loper Bright Enter. v. Raimondo*, 144 S. Ct. 2244, 2259 (2024) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 139–40 (1944)) (cleaned up)).

ARGUMENT

I. EPA lawfully revised the annual PM_{2.5} standard per Section 7409(d)(1).

This case at bottom asks whether EPA may review and revise its air quality standards sooner than five years after its last review. Congress spoke directly to that question in the second sentence of Section 7409(d)(1): EPA “may review and

revise” air quality criteria or promulgate new air quality standards “earlier or more frequently than” the five-year interval otherwise required. That, as EPA stated in its Response to Comments, “is precisely what the Administrator [did] here.” RTC at 121, JA__.

Everyone agrees that the Clean Air Act confers authority to revise the standard at issue. The parties disagree about whether EPA may do so by “reconsidering” a prior NAAQS decision, and whether EPA can revise criteria and standards “earlier or more frequently” under Section 7409(d)(1)’s second sentence without also conducting another “thorough review” that Section 7409(d)(1)’s first sentence requires EPA to complete every five years. But, as discussed further in Part I.B, the text does not support Petitioners’ attempt to import the requirements of the first sentence’s *mandatory* authority into the second sentence’s separate, *permissive* authority.

A. The Clean Air Act expressly gives EPA authority to reconsider and revise air quality standards.

Revision and reconsideration of rules, after notice and comment, is part of the basic architecture of administrative law. *See, e.g.,* 5 U.S.C. § 553(e). Thus, when a statute authorizes an agency to decide a matter, that authority is implicitly “accompanied by the power to reconsider” that decision. *Nat. Res. Def. Council v. Regan*, 67 F.4th 397, 401 (D.C. Cir. 2023); *accord Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 86 (D.C. Cir. 2014) (explaining that “the power to

reconsider is inherent in the power to decide” (internal quotation omitted)). To be sure, Congress “can limit an agency’s discretion to reverse itself.” *See, e.g., New Jersey v. EPA*, 517 F.3d 574, 583 (D.C. Cir. 2008). But where Congress has not barred reconsideration either expressly or implicitly, such as by providing a “mechanism capable of rectifying mistaken actions,” *Am. Methyl Corp. v. EPA*, 749 F.2d 826, 835 (D.C. Cir. 1984), an agency need not identify explicit reconsideration authority to revisit and revise a prior decision.

That basic principle would itself provide sufficient authority for EPA to revise the PM_{2.5} air quality standard as it did here. But here EPA has more: the Clean Air Act expressly confers authority to revisit and revise prior standards. Separate from EPA’s mandatory obligation to review and revise standards and criteria at five-year intervals, the second sentence of Section 7409(d)(1) states EPA may (1) “review and revise criteria” *or* (2) “promulgate new standards earlier or more frequently” than otherwise required. 42 U.S.C. § 7409(d)(1). It was that authority that EPA relied on to revise the PM_{2.5} standard in the Final Rule. *See* RTC at 121–22, JA __.

EPA exercised that authority consistent with Section 7409. EPA announced in June 2021 that it would reconsider the 2020 Decision because the available scientific and technical evidence indicated that the 12 µg/m³ standard retained in 2020 “may not be adequate to protect public health”—that is, the standard may not

meet the substantive requirements of Section 7409(b)(1). *See* 88 Fed. Reg. 5558, 5560 (Jan. 27, 2023). EPA’s reconsideration met both the substantive standards and procedural requirements for revising air quality standards.

1. EPA lawfully reopened and revised the 2020 air quality criteria to include pertinent new studies.

NAAQS must be based on “the latest scientific knowledge.” 42 U.S.C. §§ 7408(a)(2), 7409(b). Thus, to inform its decision whether to revise the particulate matter standards, EPA looked to the air quality criteria as embodied in the 2019 Science Assessment and the 2020 Policy Assessment. EPA noted, however, that additional studies had been published since the cutoff date for the 2019 Science Assessment “that could either inform the adequacy of the current PM NAAQS or address key scientific topics that have evolved since the 2020 PM NAAQS review was completed.” 2022 Supplement at 1-2, JA__.

Given that, EPA revised the air quality criteria, in targeted fashion, to incorporate new scientific information on issues “of greatest relevance to the reconsideration of the PM NAAQS.” *Id.* That information included epidemiologic studies on health effects for which the 2019 Science Assessment concluded a “causal” relationship exists with particulate matter exposure—that is, those effects that drive the actual standard. That information also included epidemiologic studies that used alternative methods for confounder control and new accountability analyses, both of which could narrow the gap of uncertainties discussed in the

2020 Decision. *Id.* The air quality criteria revision is embodied in the 2022 Supplement, which was peer reviewed by the CASAC.

As Industry Petitioners note (at 24), in reviewing and revising the air quality criteria and standards in the Final Rule, EPA did not purport to complete the “thorough review” of all aspects of the air quality criteria for particulate matter contemplated in the first sentence of Section 7409(d)(1). *See* RTC at 121, JA ___. That is not to say that EPA’s review was not “thorough” in the usual sense of the word. As detailed in Part III, *infra*, EPA’s supplemental review, together with its consideration of the 2020 “thorough review” materials, brings together a complete picture of the latest scientific knowledge most useful to the primary PM_{2.5} standards. Rather, EPA did not complete the “thorough review” in the technical sense, because its comprehensive evaluation of scientific information *supplementing* the 2019 Science Assessment did not address the full suite of issues that comprise the air quality criteria for particulate matter under Section 7408.

And it need not have. Section 7409(d)(1)’s two sentences provide distinct authorities serving complementary purposes. At five-year intervals, EPA *must* complete a comprehensive (or “thorough”) review of the air quality criteria, 42 U.S.C. § 7409(d)(1), covering the waterfront of scientific developments relevant to that pollutant, pollutant exposures, and health and welfare effects. Those include, per Section 7408(a)(2), “(A) those variable factors . . . which of themselves or in

combination with other factors may alter the effects on public health or welfare of the pollutant,” “(B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare,” and “(C) any known or anticipated adverse effects on welfare.” 42 U.S.C. § 7408(a)(2); *see* RTC at 121–22, JA __; *see, e.g.*, 2019 Science Assessment at P-14–P-17, JA __ (scope of 2019 assessment).

Not every element of the air quality criteria will be relevant to the ultimate primary standards. For instance, scientific developments on health effects associated with exposure to coarse particulate matter, PM₁₀, are unlikely to affect EPA’s ultimate assessment of primary standards for PM_{2.5}. Additionally, not every one of the “identifiable effects on public health” from exposure to PM_{2.5} is ultimately going to move the needle on what standard is requisite to protect public health. 42 U.S.C. § 7408(a)(2). EPA has identified scientific evidence that is “suggestive of, but not sufficient to infer” a causal relationship between some health effects and particulate matter—such as reproductive and metabolic effects, *see* 2019 Science Assessment, fig. 1-1, JA __, *supra* at p.14—which it has (and must) review in the air quality criteria documents as part of its thorough review. But because that body of evidence is not robust enough for EPA to find a “causal” or “likely to be causal” relationship between those health effects and fine particulate matter exposure, it does not inform the level of the PM_{2.5} standard. *See*

2022 Supplement at 1-5, JA__ (“[T]his Supplement critically evaluates and provides key study-specific information for only those recent studies deemed to be of greatest significance for impending regulatory decisions regarding the PM NAAQS in the context of the body of evidence and scientific conclusions presented in the 2019 [Science Assessment].”).

In authorizing EPA to review and revise the criteria more frequently, without a comprehensive review, Congress thus allowed the Agency to address new, impactful studies as they arise, even on discrete elements of the air quality criteria. And here, EPA revised the criteria to account for epidemiologic studies post-dating the cutoff date for the 2019 Science Assessment that bore on questions directly relevant to the primary PM_{2.5} standards.

2. EPA lawfully revised the PM_{2.5} standard, in accordance with the air quality criteria.

With revised air quality criteria in hand, the Administrator then considered whether the existing standards were sufficient to protect public health. As directed by Sections 7409(a)(1), 7409(b)(1), and 7607(d), EPA published a proposal and solicited public comment. *See, e.g.*, 88 Fed. Reg. at 5562. EPA proposed to find that the existing standards were not requisite to protect public health and, consistent with 42 U.S.C. § 7409(a)(1)(B), sought comment on revising the annual PM_{2.5} standard to somewhere in a range of 9–10 µg/m³. After considering comments, the Administrator concluded that an annual PM_{2.5} standard of 9 µg/m³

would be “requisite to protect the public health” with an “adequate margin of safety,” 42 U.S.C. § 7409(b)(1). EPA accordingly promulgated the Final Rule revising the standard.

In short, as authorized by Section 7409(d)(1), EPA “reviewed and revised” the criteria and standards at a time earlier than the five-year interval otherwise “required.” As instructed by Section 7409(b)(2), EPA revised the annual PM_{2.5} standard “in the same manner as promulgated,” which, per Section 7409(a)(1), meant that it “publish[ed] proposed regulations” and, “after a reasonable time for interested persons to submit written comments thereon,” promulgated the revised standard. EPA’s action also followed Section 7607(d)(3)’s rulemaking procedures that apply to actions including “the promulgation or revision of any national ambient air quality standard under section 7409[.]” The Final Rule thus accorded both with EPA’s substantive authority to revise standards and the procedural requirements for doing so.

B. EPA need not complete a “thorough review” when revising standards in between five-year reviews.

Industry Petitioners advance two lines of attack on EPA’s exercise of the authority described above that converge on one (mistaken) proposition. Industry Petitioners contend that EPA may only exercise the permissive authority to review or revise standards at any time conferred by Section 7409(d)(1)’s second sentence if the Agency first completes a task addressed only in Section 7409(d)(1)’s first

sentence: that is, the mandatory duty every five years to complete a “thorough review” of the air quality criteria. Industry Petitioners argue that the first sentence “sets forth a specific process” to be followed in any criteria or standards revision. Industry Br. 24. Industry Petitioners also argue that EPA cannot “bypass” the purported “thorough review” requirement because that requirement constitutes a “mechanism capable of rectifying” inadequate air quality standards and thus implicitly bars reconsideration through another process. *Id.* at 25.

Those arguments rest on two interpretive errors.

First, the thorough review referred to in Section 7409(d)(1)’s first sentence is not a “mechanism” or “process” defining *how* EPA is to revise air quality standards. Rather, the first sentence describes only *what* EPA must do every five years: (1) EPA “shall complete a thorough review of the criteria published under section 7408 of this title;” and then (2) EPA “shall make such revisions in such criteria and standards”; and (3) “promulgate such new standards as may be appropriate in accordance with section 7408 of this title and subsection (b) of this section.” 42 U.S.C. § 7409(d)(1). It is a prototypical “nondiscretionary duty” provision requiring specific actions by a date certain. *See, e.g., Am. Lung Ass’n v. Reilly*, 962 F.2d 258, 263 (1992) (first sentence of Section 7409(d)(1) establishes a “bright-line rule for agency action” which is enforceable as a nondiscretionary duty).

The *process* for revising standards, by contrast, is found in Section 7409(b)(1), which instructs EPA to revise standards “in the same manner as promulgated.” Section 7607(d)(3), which establishes rulemaking procedures that apply to revising the NAAQS, and Section 7409(a)(1), in turn, define the manner of promulgating those standards: EPA is to provide “a reasonable time for interested persons to submit written comments” on proposed standards and then promulgate those standards “by regulation” following those comments. 42 U.S.C. § 7409(a)(1)(B). And, ultimately, EPA is to set standards requisite to protect public health, with an adequate margin of safety, “based on” the air quality criteria developed consistent with Section 7408.

That is what EPA did here. *See supra* Part I.A; *see also* RTC at 120, JA__.

For the same reason, Petitioners’ appeal to *New Jersey v. EPA*, 517 F.3d 574, and *American Methyl Corp. v. EPA*, 749 F.2d 826 (D.C. Cir. 1984), is inapt. Those cases conclude that an agency cannot “nullif[y] textually applicable provisions meant to limit EPA’s discretion” to reverse or change a prior action. *New Jersey*, 517 F.3d at 583; *see also Nat. Res. Def. Counsel*, 67 F.4th at 401. For instance, in *New Jersey*, EPA had determined, pursuant to 42 U.S.C. § 7412(n)(1)(A), that it was “appropriate and necessary” to regulate mercury from certain coal- and gas-fired electric generating units. It then listed those units as sources of hazardous air pollutants under 42 U.S.C. § 7412(c). *See New Jersey*,

517 F.3d at 579. EPA later reconsidered and removed those electric generating units from that list, arguing that it had the authority to do so “any time that it makes a negative appropriate and necessary finding.” *Id.* at 580. This Court explained that although, in the usual course, an agency has discretion to “change its position and reverse a decision,” Congress had limited that discretion in 42 U.S.C. § 7412(c)(9) by providing an express mechanism for de-listing sources with specific requirements that EPA’s reconsideration had avoided. *Id.* at 582–83.

The Court applied the same reasoning in *American Methyl Corp.*, 749 F.2d at 835. There, EPA had reversed on reconsideration a decision granting a waiver allowing a methanol/gasoline blend fuel to enter commerce under Section 211(f)(1) of the Clean Air Act, 42 U.S.C. § 7545(f) (1982). *Id.* at 828. The Court concluded that EPA could not revoke that waiver by reconsideration because the statute provided a “mechanism capable of rectifying mistaken actions”—specifically, Section 211(c) of the Act, 42 U.S.C. § 7547(c), which imposed “substantive and procedural requirements [EPA] must satisfy before controlling or prohibiting a fuel or fuel additive.” *Am. Methyl Corp.*, 749 F.2d at 830, 835–36.

Here, the statutory text does not limit EPA’s discretion to revise air quality standards; it invites and even obligates EPA to do so when those standards do not meet the public health and welfare standards in 42 U.S.C. § 7409(b). Nothing about the obligation to “complete a thorough review” of the air quality criteria at

five-year intervals limits EPA's independent authority to "revise criteria or promulgate new standards earlier or more frequently." 42 U.S.C. § 7409(d)(1).

And EPA followed both the substantive and procedural requirements for revising the standard under its Section 7409(d)(1) authority to promulgate new standards "earlier or more frequently" than otherwise required. *See supra* Part I.A.

Second, Industry Petitioners err by reading the second sentence's reference to the *timing* component of the first sentence as incorporating the entire first sentence. *See* Industry Br. 26–27. That unnatural reading ignores that the second sentence of Section 7409(d)(1) has two parts. It first states *what* the Administrator may do: he may "review and revise criteria or promulgate new standards[.]" 42 U.S.C. § 7409(d)(1). It then states *when* the Administrator may do it: "earlier or more frequently than required under this paragraph." *Id.* The only question that the first sentence of Section 7409(d)(1) is called upon to answer, then, is how "frequently" a review and revision must otherwise be conducted.

Still, Industry Petitioners contend that the timing reference "incorporates the process in the first sentence," which is "summariz[ed]" in the second sentence as "review and revise criteria or promulgate new standards." Industry Br. 26–27. That *sortie* falls before well-established canons of construction. Foremost is that "when Congress includes particular language in one section of a statute but omits it in another—let alone in the very next provision," courts "presume that Congress

intended a difference in meaning.” *Loughrin v. United States*, 573 U.S. 351, 358 (2014) (cleaned up); *see also Ysleta Del Sur Pueblo v. Texas*, 596 U.S. 685, 698 (2022) (explaining the “usual presumption that differences in language . . . convey differences in meaning” (internal quotation omitted)). Unlike the first sentence of Section 7409(d)(1), the second sentence refers *only* to discretionary authority to “review and revise criteria or promulgate new standards.” 42 U.S.C. § 7409(d)(1). To imply a requirement to first “complete a thorough review” violates the classic maxim that *expressio unius est exclusio alterius* (“the expression of one thing is the exclusion of the other”).

The Supreme Court has cautioned against precisely the sort of interpretive move that Industry Petitioners make here. “We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.” *Jama v. Immigration & Customs Enf’t*, 543 U.S. 335, 341 (2005). The omission of a “thorough review” requirement from the sentence conferring distinct, discretionary authority shuts the door on Petitioners’ argument.

The difference in text, and therefore meaning, serves an important purpose in Section 7409(d)(1). As noted in Part I.A.1, the requirement to complete a thorough review at five-year intervals means that EPA regularly and thoroughly

canvasses the scientific literature to ensure the air quality criteria reflect the latest “scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare[.]” 42 U.S.C. § 7408(a)(2). But the *permissive* authority in Section 7409(d)(1) allows EPA to more nimbly react to changes in discrete aspects of the air quality criteria that may warrant revising the standards as needed to protect public health. *See, e.g.*, 89 Fed. Reg. at 16211 (explaining EPA’s decision to “focus on studies that were most likely to inform decisions on the appropriate standard,” not areas “judged unlikely to have new information that would be useful for the Administrator’s decision making”).

The legislative history relating to the NAAQS confirms that interpretation. As originally enacted in 1970, Section 7409 did not require periodic review and revision, but simply permitted EPA to revise standards “in the same manner as promulgated.” Pub. L. No. 91-604, 84 Stat. 1676, 1680 (Dec. 31, 1970). The statute separately provided, as it does to this day, that the Administrator must “from time to time” review and revise the air quality criteria. *Id.* at 1679. Congress amended Section 7409 to add what is now subsection (d) in 1977. Pub. L. No. 95-95, 91 Stat. 685, 691 (Aug. 7, 1977). The House Conference Report explained that the new provisions require a review of the standards every five years, and that “[t]he Administrator is authorized to conduct review of existing ambient standards more frequently than every 5 years and is expected to revise standards *whenever*

available information justifies a revision.” H.R. Conf. Rep. No. 95-564 at 124 (1977) (emphasis added). That understanding of Section 7409(d)(1) matches EPA’s.

Industry Petitioners’ interpretation is also undermined by the conjunctive/disjunctive canon, which dictates that the word “or” connotes a disjunctive list. Scalia & Garner, *Reading Law: The Interpretation of Legal Texts* 116 (2012). Thus, when the second sentence of Section 7409(d)(1) states that the Administrator “may review and revise criteria *or* promulgate new standards,” the “or” signifies that the Administrator can revise air quality standards without reviewing or revising the air quality criteria. *See* RTC at 122, JA_. It would be odd to conclude—as Industry Petitioners appear to—that, although EPA may revise air quality standards without reviewing air quality criteria at all, it must nonetheless “complete a thorough review of the criteria” before doing so.

Even so, Industry Petitioners insist that the plain reading of the text would produce an absurd result because, they contend, absent a requirement to complete a “thorough review” of the air quality criteria, EPA could revise those criteria or promulgate new standards “*without any limitations or requirements whatsoever.*” Industry Br. 27 (emphasis in original).

Not so. Whether or not preceded by a “thorough review,” any decision whether to revise or retain the NAAQS must comply with the procedural and

substantive requirements of the Clean Air Act. Standards must be based on the air quality criteria and be requisite to protect public health with an adequate margin of safety. 42 U.S.C. § 7409(b)(1); RTC at 120, JA_. They must be revised in the same manner as promulgated, following notice and comment rulemaking procedures. 42 U.S.C. §§ 7409(a)(1)(B), 7607(d); RTC at 120 n.19, JA_. They must ultimately reflect the Administrator’s reasoned judgment, supported by the administrative record. *See generally State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 51–52. And they are subject to judicial review. 42 U.S.C. § 7607(d)(9)(A).

And to be clear, although Industry Petitioners suggest (at 27) that EPA’s construction would allow it to “ignore” the product of a thorough review in a later revision, they do not actually contend that EPA “ignored” the last review here. It did not. The reconsideration and ultimate revision of the annual PM_{2.5} standard was “based on the thorough review of the air quality criteria completed in 2020”—embodied in the 2019 Science Assessment and 2020 Policy Assessment—“as supplemented by the additional studies, information, and analyses” in the 2022 Supplement and the 2022 Policy Assessment. *See* 89 Fed. Reg. at 16223 (explaining that “[w]hile the 2019 [Science Assessment] provides the broad scientific foundation for this reconsideration, additional literature has become available . . . that expands the body of evidence related to mortality and cardiovascular effects” from PM_{2.5} exposure); *id.* at 16256 (explaining that the

2019 Science Assessment and the 2022 Supplement “together provide a strong scientific foundation for concluding that the current primary PM_{2.5} standards are not adequate”); *see also* RTC at 121, JA_.

The supplemental review supporting the Final Rule thus adds to the 2020 “thorough review”; it does not replace or ignore it. Indeed, because the supplemental review did not cover the waterfront of all aspects of the air quality criteria for particulate matter, EPA acknowledged that that assessment “does not itself satisfy the EPA’s obligation to periodically complete a thorough review of the air quality criteria” and thus that “a ‘thorough review’ of the air quality criteria for PM, along with any revisions to the criteria and NAAQS that may be appropriate, should still be completed within five years of the most recent complete review, which concluded in 2020.” RTC at 121, JA_.

Nor do Industry Petitioners contend that in *not* completing a “thorough review” of the air quality criteria, EPA elided some evidence that would have affected the Agency’s final result. That is, Industry Petitioners did not identify in comments, and do not identify here, any scientific evidence that EPA ignored that may have supported different standards. Industry Petitioners suggest EPA did not follow the proper “process,” but they do not explain how that changed EPA’s decision. Industry Br. 24, 33; *cf.* 42 U.S.C. § 7607(d)(8), (d)(9).

In the end, EPA’s decision to supplement the 2020 review was reasonable and consistent with its statutory direction to base standards on the “latest scientific information useful in indicating” public health effects, 42 U.S.C. § 7408(a)(2). It was also consistent with EPA’s well-established practice, “when the EPA believes new science is sufficiently important to be material to decision making on NAAQS,” to “reopen[] the air quality criteria to allow the CASAC and the public, as well as the Administrator, to fully consider the evidence.” RTC at 122, JA₁; *see, e.g.*, 51 Fed. Reg. at 11058 (explaining that addenda “focus[ed] on a limited set of scientific studies” and would not “reexamine all of the available health effects information or related issues that have already been adequately addressed in the criteria document and staff papers”). So, recognizing that additional significant studies became available after the 2019 Science Assessment’s cutoff date, EPA asked CASAC to review a supplemental assessment of “those studies most likely to be useful in judging whether the current standards are requisite.” *Id.*

In sum, EPA must ensure that the NAAQS are based on the latest science and are regularly updated to reflect that science to protect public health. *See* 42 U.S.C. §§ 7408(a)(2), 7408(c), 7409(b), 7409(d). The plain language of Section 7409(d)(1) grants EPA separate, discretionary authority to “review and revise air quality criteria or promulgate new standards” independent of the “thorough review.” That plain language “should be conclusive” under that “preeminent canon

of statutory interpretation [that] requires us to presume that the legislature says in a statute what it means and means in a statute what it says there.” *Eagle Pharm. Inc. v. Azar*, 952 F.3d 323, 330 (D.C. Cir. 2020) (cleaned up). The Court should reject Industry Petitioners’ invitation to rewrite the statute.

II. EPA appropriately declined to consider costs, attainability, and other impermissible factors.

Petitioners’ next arguments are ones that have been raised and rejected in prior decisions by this Court and the Supreme Court. Petitioners assert that the Final Rule is unlawful because EPA declined to consider cost and cost-related factors like “attainability.” *See* Industry Br. 36, 38; States’ Br. 39–41. Industry Petitioners also contend that EPA did not appropriately weigh “background” pollution levels in revising the PM_{2.5} standard. Industry Br. 41. And State Petitioners contend that if EPA is barred from considering factors like cost, then Section 7409 is an unlawful delegation of legislative power. States’ Br. 41–43.

Binding precedent forecloses each of those arguments. This Court held in *Lead Industries Association*, 647 F.2d at 1148, that “economic considerations play no part in the promulgation of ambient air quality standards” under Section 7409. It reiterated that rule in many later cases. *See Am. Lung Ass’n*, 134 F.3d at 389; *Nat. Res. Def. Council v. EPA*, 902 F.2d 962, 973 (D.C. Cir. 1990), *vacated in part on other grounds*, 921 F.2d 326 (D.C. Cir. 1991); *Am. Petroleum Inst.*, 665 F.2d at 1185.

The Supreme Court agreed in *American Trucking*, 531 U.S. at 465. The Court held that Section 7409(b), which describes what the NAAQS “shall be,” “unambiguously bars cost considerations from the NAAQS-setting process, and thus ends the matter for us as well as the EPA.” *Id.* at 471. The Court explained that the language of Section 7409(b) “is absolute.” *Id.* at 465 (internal quotation omitted). “Nowhere are the costs of achieving such a standard made part of that initial calculation.” *Id.*

The Supreme Court explicitly rejected the argument “that while the Administrator’s judgment about what is requisite to protect the public health must be ‘based on [the]’ criteria documents developed under [7408(a)(2)], *see* § [7409(b)(1)]” it need not be “necessarily *limited*” to considering health and welfare effects alone. *Id.* at 469. “Even if we were to concede those premises, we still would not conclude that one of the unenumerated factors that the agency can consider in developing and applying the criteria is cost of implementation.” *Id.* Implementation cost “is *both* so indirectly related to public health *and* so full of potential for canceling the conclusions drawn from direct health effects that it would surely have been expressly mentioned in [Sections 7408 and 7409] had Congress meant it to be considered.” *Id.* “Yet while those provisions describe in detail how the health effects of pollutants in the ambient air are to be calculated and given effect, *see* [§ 7408(a)(2)], they say not a word about costs.” *Id.*

The Supreme Court also rejected an argument, like Industry Petitioners' here, that the CASAC's mandate to "advise the Administrator of any adverse public health, welfare, social, economic or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards," 42 U.S.C. § 7409(d)(2)(C)(iv), implicitly permitted EPA to consider costs in setting NAAQS. "That is not so. These provisions enable the Administrator to assist the States in carrying out their statutory role as primary *implementers* of the NAAQS." *Am. Trucking Ass'ns*, 531 U.S. at 470. It "has no bearing upon whether cost considerations are to be taken into account in formulating the standards." *Id.* at 471; *see also Murray Energy*, 936 F.3d at 622 (noting that the argument based on Section 7409(d)(2)(C) was "raised and rejected in [*American Trucking*]").

In sum, EPA may not consider costs when promulgating or revising the NAAQS.

A. The same public-health factors apply to deciding to revise a NAAQS as to setting the standard.

Petitioners attempt to elude that settled precedent by deconstructing the act of revising standards into two steps: first, *whether* to revise the NAAQS; and second, *how* to revise the NAAQS. *See* Industry Br. 33. To Petitioners, prior cases address only what criteria EPA may consider at "step two," "setting" NAAQS. *See* Industry Br. 37. And while they might concede that precedent bars EPA from

considering cost in determining what standard is “requisite to protect the public health,” *but see* Industry Br. 34 n.14, they contend that a careful parsing of Section 7409(d)(1) indicates that “the standards of section [7409(b)] apply” only to “setting” the NAAQS at “step two.” Industry Br. 33–34.

That is slicing the baloney too thinly. Even if “promulgating new standards” can conceptually be broken into “whether” and “how” to revise steps, nothing in the statute’s text or structure indicates that EPA is to apply separate substantive standards to those steps. Quite the opposite: NAAQS are to be revised “in the same manner as promulgated.” 42 U.S.C. § 7409(b)(1). And so, as the statute requires, EPA here asked, “is the current standard requisite to protect public health?” *See* 89 Fed. Reg. at 16273. Concluding, based on the air quality criteria and the Administrator’s judgment, that it was not, EPA then asked, “*what standard would be requisite to protect public health*”? *See id.* at 16277.⁷ The result is a standard

⁷ Notably this is the same two-step process that two of the Industry Petitioners—the Chamber of Commerce and the National Association of Manufacturers—previously argued is *required* when EPA revises the NAAQS. *See* Brief of Pet’rs, *National Ass’n of Mfrs. v. EPA*, Case No. 13-1069 (D.C. Cir.) at 18–19 (Doc. 1452391) (“Thus, in a NAAQS review, EPA must first answer the question whether the NAAQS needs to be revised (i.e., whether the current NAAQS remains ‘requisite to protect the public health’ with ‘an adequate margin of safety’”). In that case, this Court rejected an argument that EPA failed to seek comment on whether to revise the NAAQS, explaining that “when EPA requested comments on *how* to revise the NAAQS, regulated entities could have responded by disputing the premise that revisions were required in the first place.” *Nat’l Ass’n of Mfrs.*, 750 F.3d at 924.

that tracks Section 7409(b)(1)'s definition of what primary NAAQS "shall be," and a process that satisfies Congress's intent to ensure that EPA is continually updating that standard to achieve better public health.

Petitioners employ an inscrutable (and flawed) order of operations to coax a different meaning out of Section 7409(d)(1). Recall that the first sentence of Section 7409(d)(1) says that the Administrator "shall make such revisions in [air quality] criteria and standards and promulgate such new standards as may be appropriate in accordance with section 7408 of this title and subsection (b) of this section." Industry Petitioners contend that "as may be appropriate" applies to *whether* to revise standards, and then "in accordance with section 7408 of this title and subsection (b) of this section" applies to *how* to revise them. *See* Industry Br. 34. Put differently, Petitioners would have EPA evaluate the implementation costs that may attend revising the NAAQS and decline to revise the NAAQS if the costs are too high, even if EPA knew the standards no longer provided the requisite protection of public health required under Section 7409(b).

As an initial matter, EPA here exercised the authority of the *second* sentence of Section 7409(d)(1), making Petitioners' deep dive into the "appropriate in accordance with" clause out of place. The Supreme Court and this Court have barred the consideration of costs by interpreting Section 7409(b), which sets forth

the substantive standards that apply to promulgating *or* revising NAAQS—including revision under the second sentence of Section 7409(d)(1).

In any event, nothing but Petitioners’ desire to import cost factors into the word “appropriate” excuses prying that word apart from “in accordance with” as they suggest. The two are part of a unitary phrase. There is no punctuation separating the two, nor any intervening words or phrases indicating that the words apply to separate steps. Moreover, separating “appropriate” from “in accordance with” strips that word of the context and meaning that Congress was attempting to give to it. What would make revising air quality standards “appropriate”? If doing so was “in accordance with . . . subsection (b) of this section,” 42 U.S.C. § 7409(d)(1)—that is, “based on” the air quality criteria and “requisite to protect public health with an adequate margin of safety,” *id.* § 7409(b)(1). That natural construction is consistent with the canon, *noscitur a sociis*—“a word is known by the company it keeps”—which cautions against “ascribing to one word a meaning so broad that it is inconsistent with its accompanying words thus giving unintended breadth to Acts of Congress.” *Yates v. United States*, 574 U.S. 528, 543 (2015).

In this text and context, then, the word “appropriate” in Section 7409(d)(1) is not an invitation for EPA to consider cost in setting NAAQS—or in deciding whether to revise a NAAQS. And so this Court has held. In *Murray Energy*, 936 F.3d at 621, this Court rejected the argument that, in the wake of *Michigan v. EPA*,

the term “appropriate” in Section 7409(d)(1) “must take into account the adverse socioeconomic and energy impacts”—the cost—of a revised NAAQS.

Recognizing that “at bottom this is the same argument rejected in [*American Trucking*],” the Court explained, “[w]e have already rejected the idea that ‘appropriate’ in section [7409(d)] requires consideration of economic costs.” *Id.* at 622.

So has the Supreme Court. In *Michigan v. EPA*, the Supreme Court acknowledged that “[t]here are undoubtedly settings in which the phrase ‘appropriate and necessary’ does not encompass cost.” 576 U.S. 743, 752 (2015). One of those settings, the Court explained, was this one: establishing (and revising) NAAQS under Section 7409. “Read naturally, that discrete criterion does not encompass cost; it encompasses health and safety.” *Id.* at 755. “*American Trucking* thus establishes the modest principle that where the Clean Air Act expressly directs EPA to regulate on the basis of a factor that on its face does not include cost, the Act normally should not be read as implicitly allowing the Agency to consider cost anyway.” *Id.* at 755–56.

It beggars belief to suggest that courts’ repeated holding that cost considerations are irrelevant in setting NAAQS was hiding the secret exception that Petitioners urge here. The idea that cost considerations are permissible—nay,

required—at “step one” would create a gaping hole in the public-health-centric scheme of Section 7409.

Petitioners’ approach is also practically unworkable: how would EPA assess the cost of revising a standard without considering what level the standard might be revised to? At that point, the exercise is exactly the one forbidden by *American Trucking* and this Court’s precedent.

Finally, Petitioners cannot avoid this Court’s precedent by arguing that the Court has only interpreted the word “appropriate” in the context of *how* to revise a NAAQS, not *whether* to do so in the first place. Industry Br. 37–38. That is simply not true. In every case about EPA *revising* the NAAQS, the Agency (and the Court) faced the question of *whether* the standards should be revised in the first place. *See, e.g., Nat’l Ass’n of Mfrs.*, 750 F.3d at 924 (explaining that EPA’s request for comment on all issues related to revising the particulate matter NAAQS “necessarily encompassed the question of whether any revision of the particulate matter NAAQS was warranted”).

At any rate, the same word in the same sentence of the same subsection surely cannot bear the two disparate meanings that Petitioners seek to give it. This question has been definitively resolved. Petitioners’ argument must be rejected.

B. Section 7409’s health-based standard does not violate nondelegation doctrine.

The same binding precedent that sinks Petitioners’ costs argument also scuttles State Petitioners’ nondelegation argument. State Petitioners contend that if EPA *cannot* consider costs when revising NAAQS, then the authority conferred by Section 7409 constitutes an impermissible delegation of legislative power. But the Supreme Court rejected that very argument in *American Trucking*, 531 U.S. at 474, right on the heels of holding that Section 7409 *prohibits* cost considerations. The Court held that “[t]he scope of discretion § 109(b)(1) allows is in fact well within the outer limits of our nondelegation precedents.” *Id.* at 474; *see also Murray Energy*, 936 F.3d at 624 (rejecting non-delegation challenge to Section 7409(d)(1)).

As in *Murray Energy, id.*, “State Petitioners do not argue that the Act lacks an intelligible principle.” They cannot, for the Supreme Court explicitly held “that Congress provided one when it directed EPA to set NAAQS ‘requisite to protect public health’—meaning ‘sufficient, but not more than necessary.’” *Id.* (quoting *Am. Trucking Ass’ns*, 531 U.S. at 473–74). Congress has enacted, and the Supreme Court has upheld, any number of health- or safety-based standards that the Executive is charged with applying without regard to costs. *See Am. Trucking Ass’ns*, 531 U.S. at 473 (collecting cases).

EPA’s authority to determine the standards requisite to protect public health, is not, as State Petitioners suggest, discretion without meaningful constraints. The Supreme Court rejected the same straw-man argument that EPA could impose “zero-risk” standards, explaining that it is “not conclusive for delegation purposes that . . . ozone and particulate matter are ‘nonthreshold’ pollutants that inflict a continuum of adverse health effects at any airborne concentration greater than zero, and hence require the EPA to make judgments of degree.” *Id.* at 475. Congress need not “provide a ‘determinate criterion’ for saying ‘how much [of the regulated harm] is too much,’ . . . how ‘imminent’ was too imminent, or how ‘necessary’ was necessary enough, or even—most relevant here—how ‘hazardous’ was too hazardous.” *Id.*

Finally, State Petitioners’ suggestion that Congress neglected to address “basic and consequential tradeoffs involved” in setting health-based standards is historically false. The structure of the Clean Air Act indicates a well-thought-out scheme in which national minimum standards are absolute but, for example, states have flexibility to adopt a mix of controls to meet those standards, and feasibility is accounted for in setting technology-based performance standards for varying air pollutant source categories. *See id.* at 470. And, “rather than watering down the nationally applicable standards,” Congress enacted provisions to “allow[] EPA to relax enforcement” of the NAAQS “on a case-by-case basis.” *Murray Energy*, 936

F.3d at 623 (listing non-attainment flexibilities); *see also Am. Petroleum Inst.*, 665 F.2d at 1185–86 (describing compliance extensions for states not meeting standards).

Legislative history shows that Congress grappled with the tradeoff between health and cost considerations. The Senate Report on the 1970 Clean Air Act Amendments explained that “considerable concern was expressed regarding the use of the concept of technical feasibility as the basis of ambient air standards.” S. Rep. No. 91-1196, at 2–3 (1970). Still, the Committee determined that “the health of people is more important than the question of whether the early achievement of ambient air quality standards protective of health is technically feasible.” *Id.* “[T]he Committee determined that existing sources of pollutants either should meet the standard of the law or be closed down, and in addition that new sources should be controlled to the maximum extent possible to prevent atmospheric emissions.” *Id.* The House Report, too, emphasized “the predominant value of protection of public health.” H.R. Rep. No. 95-294 at 49 (1977); *see Lead Indus. Ass’n*, 647 F.2d at 1152.

In sum, “the absence of any provision requiring consideration” of cost-related factors “was no accident; it was the result of a deliberate decision by Congress to subordinate such concerns to the achievement of health goals.” *Id.* at 1149. “Congress was well aware that, together with Sections [7408 and 7410],

Section [7409] imposes requirements of a ‘technology-forcing’ character.” *Id.* (quoting *Union Elec. Co. v. EPA*, 427 U.S. 246, 257 (1976)).

The upshot of State Petitioners’ argument is that Congress is constitutionally prohibited from directing expert administrative agencies to identify a health-based threshold for pollutant exposure. That cannot be the case. To the contrary, the authority to set health-based air quality standards “fits comfortably within the scope of discretion permitted by [Supreme Court]”—and this Court’s—“precedent.” *Am. Trucking Ass’ns*, 531 U.S. at 476.

C. Attainability is not a relevant factor to EPA’s decision to revise the PM_{2.5} standard.

Finally, Industry Petitioners’ argument that EPA must consider attainability when revising the annual PM_{2.5} standard likewise overlooks settled precedent. Industry Br. 38–41. “Attainability,” as Petitioners appear to use that term, is a genre of the cost- or feasibility-related considerations barred by the Supreme Court’s decision in *American Trucking*, 532 U.S. at 468. This Court has rejected the precise argument Petitioners now make, repeatedly affirming EPA’s decision not to consider local or regional feasibility when determining the adequacy of the national standard.

For example, and most recently, the petitioners in *Murray Energy*, 936 F.3d at 622, made the identical argument Industry Petitioners make here: that EPA should have accounted for background ozone in revising the ozone standards.

Rejecting that argument, this Court explained that the Clean Air Act’s public health standard forecloses consideration of attainability for the same reason it forecloses consideration of costs. *Id.* at 623. Congress recognized that setting a standard based only on protecting health and welfare could result in a scenario where “some states could not achieve attainment because of the presence of background ozone.” *Id.* But, “rather than watering down the nationally applicable standards,” Congress provided mechanisms by which EPA could “relax enforcement on a case-by-case basis,” such as an exceptional events demonstration. *Id.* (citing 42 U.S.C. § 7619(b)). Such mechanisms “make little sense under Petitioners’ reading of the Act,” *id.*, for there would be no need for such an exception if EPA were already required to consider background pollution when setting the NAAQS.

This Court has reached the same conclusion in earlier cases, as well. In *American Petroleum Institute v. Costle*, 665 F.2d 1176, this Court rejected an argument that EPA was required to consider “natural ozone levels and other physical phenomena” that would have supposedly prevented Houston from meeting the standard. *Id.* at 1184. In doing so, this Court explained that EPA was not required to “tailor national regulations to fit each region or locale.” *Id.* at 1185. The Court likewise noted that Congress developed programs to help states comply

with the standard recognizing that some may struggle to meet the national standard. *Id.* at 1185–86.

As in their direct cost argument, Industry Petitioners try to distinguish these precedents by differentiating EPA’s decision *whether* to revise a standard from its decision of *how* to revise the standard. *See* Industry Br. 39. For the reasons described above, the Court should reject this atextual and illogical distinction. *See supra* Part II.B.

Industry Petitioners’ attainability argument fails for another reason: Petitioners are simply wrong that background PM_{2.5} will prevent attainment of the new PM_{2.5} standard in any area. In arguing otherwise, Petitioners ignore EPA’s well-reasoned analysis of background PM_{2.5}.⁸

EPA presented two estimates for background PM_{2.5}, one based on modeling and one based on monitoring data. RTC 125, JA_{_}; 89 Fed. Reg. at 16218. These data showed background PM_{2.5} levels between 0.5–3.0 µg/m³, *far* below the 9 µg/m³ standard. RTC at 125, JA_{_}; 89 Fed. Reg. at 16218. In any event, EPA noted that, if any state believes that it cannot meet the new standard because of background PM_{2.5} from, for example, wildfire events, it may request that exceptional event-influenced data be excluded from EPA’s calculation of whether

⁸ EPA interprets this Court’s case law to allow EPA to consider proximity to background PM_{2.5} as one factor when choosing among a range of reasonable values supported by the air quality criteria. RTC at 124–25, JA_{_}–_{_}.

air quality exceeds or violates a NAAQS for purposes of Clean Air Act regulatory actions like designations. RTC at 125, JA_ ; *see, e.g., Murray Energy*, 936 F.3d at 623.

Industry Petitioners contend that the monitoring data used in EPA's assessment of background PM_{2.5} is unrepresentative. Industry Br. 40. But their argument ignores that both monitoring *and* modeling data tell a consistent story about the level of background PM_{2.5}. RTC at 124–25, JA_ _ . And although Industry Petitioners assert that background PM_{2.5} will prevent certain areas from meeting the new annual PM_{2.5} standard, the only evidence they cite is one industry comment, which pronounces, without support, that a lower PM_{2.5} standard would be “very close to the background PM_{2.5} concentrations in many specific areas, particularly in the West.” *See* Industry Br. 40 (citing Essential Minerals Association Comments 3, JA_). That baseless conclusion is entitled to no weight given EPA's thorough, contrary analysis.

EPA's revision of the annual PM_{2.5} standard accords with Congress's directive that EPA set standards based on human health and welfare without regard to costs or feasibility. Petitioners' dissatisfaction with the statutory exceptional events mechanism, *see* Industry Br. 41–42, is not at issue in the challenged Rule.

III. EPA’s decision to revise the annual PM_{2.5} standard to 9 µg/m³ is well reasoned and supported by the record.

The Clean Air Act expressly leaves the determination whether an air quality standard protects public health with an adequate margin of safety to the Administrator’s judgment. 42 U.S.C. § 7409(b)(1); *see Am. Trucking Ass’ns*, 531 U.S. at 475–76 (upholding the Administrator’s discretion to determine what standard is requisite to protect the public health with an adequate margin of safety). The Administrator lawfully exercised that judgment here, explaining in detail why revising the standard to 9 µg/m³ was necessary to meet the statutory standard. That decision, based on EPA’s scientific and policy expertise in interpreting and applying scientific evidence on the public health effects of air pollution, is entitled to deference and should be upheld.⁹

A. EPA provided a thorough explanation for revising the annual PM_{2.5} standard to 9 µg/m³.

As already described, EPA’s framework for determining whether and how to revise the particulate matter standards followed its longstanding practice,

⁹ In *Loper Bright Enterprises v. Raimondo*, the Supreme Court held that the Administrative Procedure Act and historical judicial practice “specifies that courts, not agencies, will decide ‘all relevant questions of law’ arising on review of agency action.” 144 S. Ct. at 2261 (emphasis in original and added). *Loper* does not overturn or modify the many decisions of this Court and others that have long applied deference to technically-based *factual* determinations made by expert agencies. To the contrary, *Loper* stated that “Section 706 [of the Administrative Procedure Act (APA)] *does* mandate that judicial review of agency policymaking and factfinding be deferential.” *Id.* (emphasis in original).

consistent with the statute. The Administrator’s conclusion that the scientific evidence warranted revising the annual standard level from 12 $\mu\text{g}/\text{m}^3$ to 9 $\mu\text{g}/\text{m}^3$ is reasonable and well-supported by the record. *See Am. Trucking Ass’ns*, 531 U.S. at 475–76.

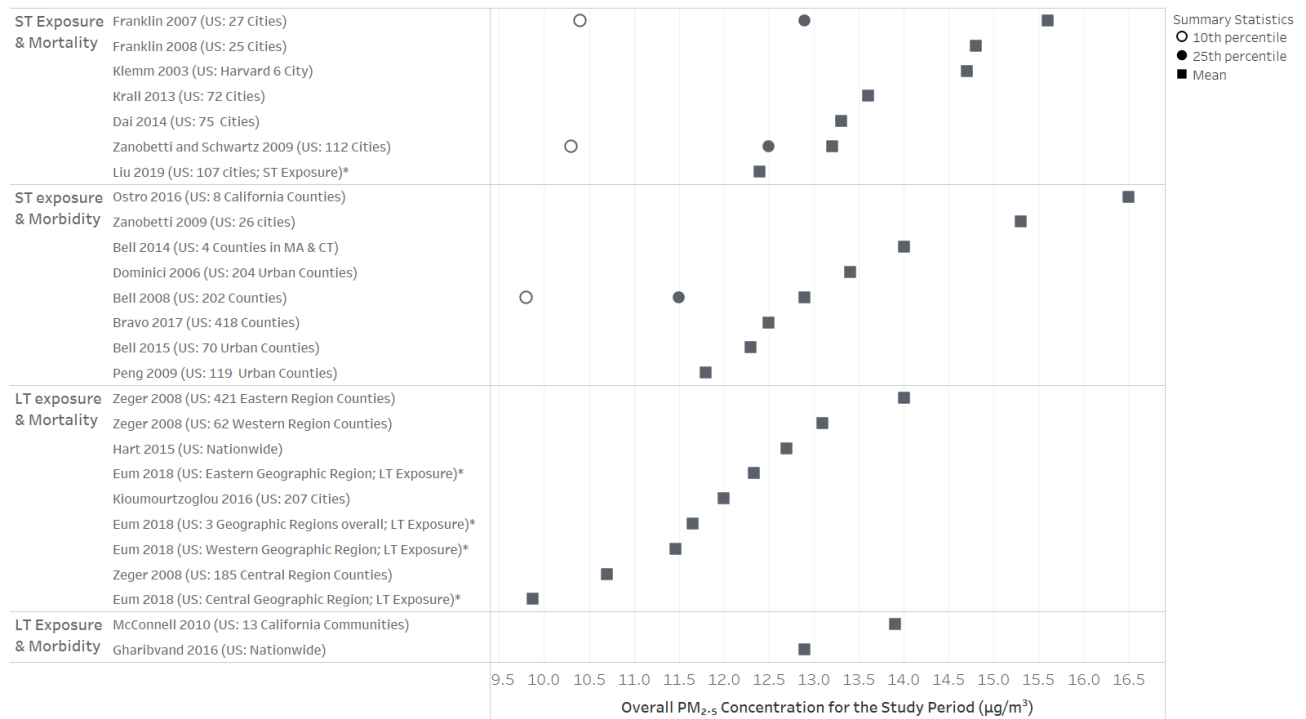
The Administrator first assessed whether the 12 $\mu\text{g}/\text{m}^3$ annual $\text{PM}_{2.5}$ standard was requisite to protect the public health with an adequate margin of safety. *See* 42 U.S.C. § 7409(b)(1); 89 Fed. Reg. at 16273–76. The Administrator’s judgment that the existing level was *not* adequate was informed mainly by the scientific evidence in the 2019 Science Assessment and 2022 Supplement, which show statistically significant associations between health effects and $\text{PM}_{2.5}$ concentrations well below 12 $\mu\text{g}/\text{m}^3$. *Id.* at 16274. The Administrator also considered CASAC’s advice, EPA’s 2022 Policy Assessment, and public comment. *Id.* at 16275–76.

Upon concluding that the annual $\text{PM}_{2.5}$ standard was not adequate to protect public health, the Administrator next considered what level *would* make the standards requisite to protect public health with an adequate margin of safety. The Administrator looked to the mean $\text{PM}_{2.5}$ concentrations where health effects were observed in all key epidemiologic studies (shown in Figures 2 and 3, *id.* at 16244–45, reproduced below with means represented by squares),¹⁰ and set the standard

¹⁰ Both long-term (“LT”) and short-term (“ST”) exposure are relevant to EPA’s determination of an adequate standard. *See supra* p.9. Figures 2 and 3 also show

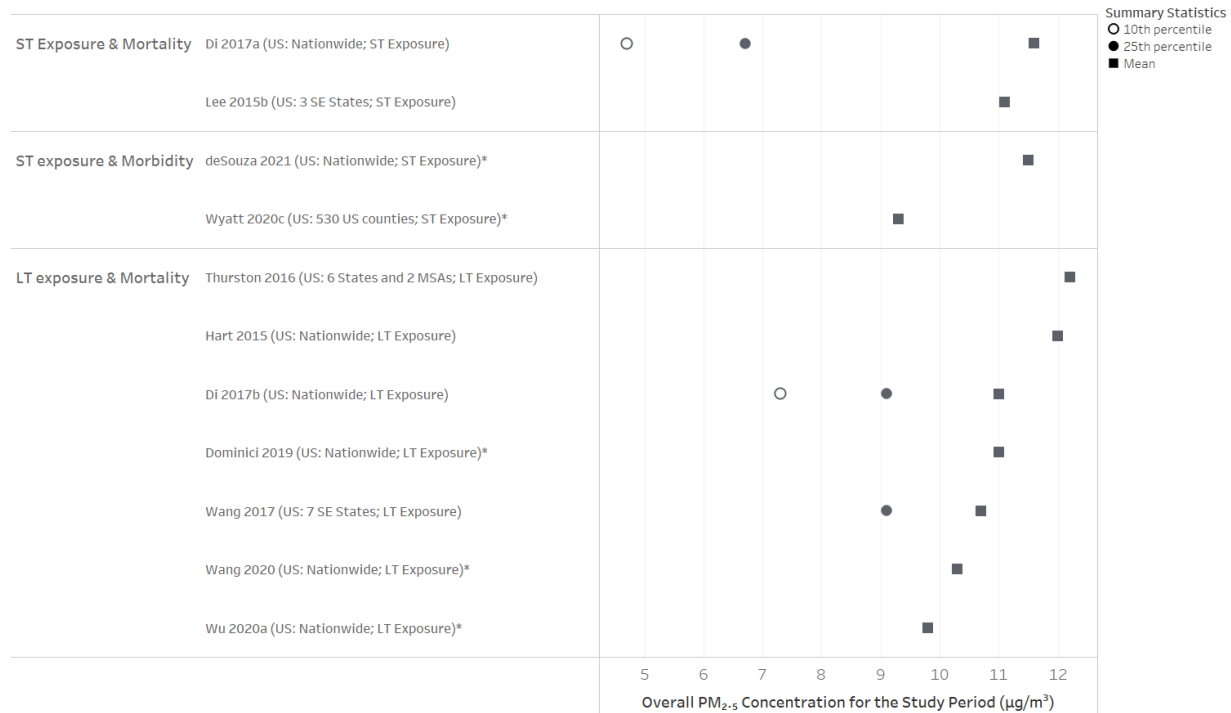
slightly below the lowest mean PM_{2.5} concentration, which was 9.3 μg/m³. *Id.* at 16280.

Figure 2: Monitor-based PM_{2.5} Concentrations in Key U.S. Epidemiologic Studies (Asterisks denote studies included in the 2022 Supplement).



10th and 25th percentile figures, which EPA considers relevant to setting a standard requisite to protect public health “with an adequate margin of safety.”

Figure 3: Hybrid model-predicted PM_{2.5} concentrations in key U.S. epidemiologic studies (Asterisks denote studies included in the 2022 Supplement).



The Administrator acknowledged that this approach diverged from the 2020 Decision’s approach but explained that it was consistent with previous particulate matter NAAQS reviews in 1997, 2006, and 2012, which this Court upheld. *Id.* at 16279; see *Nat’l Ass’n of Mfrs.*, 750 F.3d at 924 (upholding EPA’s selection of “the 12.0 µg/m³ level [which] was somewhat below the lowest long-term mean concentration shown by certain key epidemiologic studies to cause adverse health effects”); *Am. Farm Bureau Fed’n*, 559 F.3d at 526 (concluding that 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”); *ATA III*, 283 F.3d at 372 (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”).

This new standard was also consistent with CASAC’s advice and EPA’s risk assessment. A majority of CASAC supported setting a standard between 8 and 10 $\mu\text{g}/\text{m}^3$. 89 Fed. Reg. at 16281. And EPA’s risk assessment likewise demonstrated that 9 $\mu\text{g}/\text{m}^3$ fell “within the range of concentrations in which there is the most confidence in the associations and thus, confidence that estimated risk reductions will actually occur.” *Id.* at 16282–83.

1. EPA thoroughly evaluated and rejected a less stringent standard of around 10 $\mu\text{g}/\text{m}^3$.

Industry Petitioners contend that EPA’s own evidence and reasoning should have pointed the Administrator toward a higher standard of 10 $\mu\text{g}/\text{m}^3$. Industry Br. 43–44. This argument disregards the administrative record, which shows that EPA thoroughly considered a range of standards between 8 $\mu\text{g}/\text{m}^3$ and 10 $\mu\text{g}/\text{m}^3$. 89 Fed. Reg. at 16282–85.

As to the more stringent standard, the Administrator explained that he lacked confidence that setting the standard at 8 $\mu\text{g}/\text{m}^3$ would actually lead to additional public health improvements. 89 Fed. Reg. at 16282–83, 16285; RTC at 46–47, JA_ _.

On the flip side, the Administrator explained that a less stringent standard would allow PM_{2.5} concentrations at or above the level strongly associated with serious health effects, so would deviate from past approaches for selecting an appropriate standard. 89 Fed. Reg. at 16284. The Administrator added that setting a standard slightly below the lowest reported mean (9.3 µg/m³) rather than slightly above provides requisite protection in the face of uncertainty, ensuring that those “less well-studied exposure levels and population groups for which the evidence is limited or lacking” would be provided an adequate margin of safety. *Id.* at 16284.

Petitioners emphasize that EPA recognized that data from the highest reporting monitor in a given area, also called a “design value,” will likely be 15 to 18% higher than average ambient air conditions, so a standard that is set slightly higher than the lowest reported mean would likely protect most people—those that do not live close to the design value monitors—from adverse health effects. Industry Br. 43–44; States’ Br. 36. That is true, but it does not take Petitioners where they want to go. The statements quoted in Petitioners’ briefs merely summarize the results of certain epidemiologic studies. *See* 89 Fed. Reg. at 16241. But as EPA further explained, the Administrator must set a standard that protects the health of the most vulnerable people, including, notably, those individuals who live near design value monitors. *See id.* at 16263; *see also* RTC at 59, JA₁; 2022 CASAC Review at 8, JA₁ (expressing concern about individuals “living near the

monitoring location where the design value was recorded”); *Nat’l Ass’n of Mfrs.*, 750 F.3d at 926 (upholding EPA’s decision to set a standard based on the monitoring data from the most polluted areas). The Administrator explained that setting a standard slightly below the lowest reported mean PM_{2.5} concentration would ensure that the standard protects public health with an adequate margin of safety. 89 Fed. Reg. at 16285.

2. EPA properly considered current air quality conditions in revising the annual PM_{2.5} standard.

Industry Petitioners also argue that EPA overstated the benefits of revising the PM_{2.5} standard to 9 µg/m³ because its risk assessment in the 2022 Policy Assessment ignored that many areas had PM_{2.5} concentrations lower than the 12 µg/m³ standard. Industry Br. 41–42. That argument conflicts with this Court’s precedent and the administrative record.

This Court has already considered and rejected Petitioners’ precise argument in *American Petroleum Institute*, 684 F.3d 1342. There, the petitioners argued that EPA’s risk assessment for revised nitrogen dioxide NAAQS was flawed because EPA compared estimated risk reductions from the potential revised NAAQS against the then-applicable standard rather than current air quality conditions, which were better than the existing standard. *Id.* at 1351. The Court upheld EPA’s approach, explaining that the Clean Air Act requires EPA to set NAAQS “with ‘an adequate margin of safety,’ which means the agency is to ‘err on the side of

caution.” *Id.* at 1352 (quoting *Am. Farm Bureau Fed’n*, 559 F.3d at 533). The Court explained that even though “air quality had improved and was expected to keep improving, it was certainly possible this trend would be reversed.” *Id.* The Court thus concluded that “it was not unreasonable for EPA to measure expected benefits from the new NAAQS in part upon the assumption that, if the new NAAQS were not adopted, then each area would in the future just meet the existing standard.” *Id.* And, as a factual matter, the Court recognized that EPA did consider current air quality conditions. *Id.* at 1352–53.

EPA’s risk assessment here took the same approach. Risk assessments simulate air quality conditions by estimating the health risks associated with different standards based on a range of air quality conditions. 2022 Policy Assessment at 3-136–3-137, JA___. PM_{2.5} concentrations can vary by time of day, season, geographic location, and proximity to sources and major roads. *Id.* § 2.3.2, JA___. EPA’s risk assessment uses air quality modeling to estimate the variable and heterogeneous exposures people experience across and within the different cities being studied. *Id.* § 3.4.1.4, JA___.

Here, EPA’s risk assessment identified 47 areas around the country based on various criteria, assessed particulate matter exposure for people living in those areas, and estimated health risk from that exposure. *Id.* § 3.4.1.5, JA___. To evaluate the expected health risks from a lower annual standard level, EPA

estimated the change in risk associated with moving from “just meeting” the annual PM_{2.5} standard of 12 µg/m³ to “just meeting” the revised 9.0 µg/m³ standard. *Id.* § 3.4.1.3, JA_ __. EPA also estimated risks under “recent conditions” in the same study areas. *Id.* App’x C, JA_ __; RTC at 33, JA_ _.

The record thus invites two responses to Industry Petitioners’ “current conditions” argument. Industry Br. 41–42. First, as demonstrated, EPA *did* consider current air quality conditions. But second, as in *American Petroleum Institute*, EPA’s decision to assume hypothetical air quality conditions just meeting alternative standards, rather than conditions reflecting actual present air quality conditions, was reasonable and appropriate. The relevant question is whether the existing standard protects public health, and that requires EPA to consider that current air quality could degrade to the level of the standard. *Accord Am. Petroleum Inst.*, 684 F.3d at 1352. Industry Petitioners’ attempt to distinguish *American Petroleum Institute* as relevant only to “setting” NAAQS and not determining whether to revise them, *see* Industry Br. 42, fails for the reasons described above. *Supra* Part II.A.

Moreover, EPA’s decision to revise the annual PM_{2.5} standard to 9 µg/m³ did not turn on a specific projection of lives saved (under either scenario). *See* 89 Fed. Reg. at 16266–67. It was based on EPA’s assessment of the risk of adverse health effects from exposures to a PM_{2.5} standard above 9 µg/m³, drawing from the entire

body of scientific evidence. Put differently, the Administrator is to determine *what national standard* is requisite to protect public health, independent of whether or how many areas already achieve air quality consistent with that (or a different) standard. *See Am. Lung Ass’n*, 134 F.3d at 392 (six communities experiencing adverse health effects from pollution can constitute a risk to public health). The risk assessment is a tool that allows the Administrator to see how public health effects vary with different standards, used to inform the determination of what standard is requisite to protect public health with an adequate margin of safety.

B. EPA reasonably explained its decision to place less weight on uncertainties than in the 2020 Decision.

The Court should also reject Petitioners’ argument that the Final Rule does not adequately account for uncertainties in the evidence on health effects of particulate matter air pollution. Industry Br. 42–43; States’ Br. 33–38.

Uncertainties are inherent in scientific studies. *See Mississippi*, 744 F.3d at 1344; *Lead Indus. Ass’n*, 647 F.2d at 1154 (“[S]ome uncertainty about the health effects of air pollution is inevitable.”). Indeed, Congress’s decision to provide the Administrator authority to set a standard “in his judgment” reflects “awareness of the uncertainties and limitations in the data.” *Id.* at 1155 n.50 (citing H.R. Rep. No. 95-294 at (1977)). EPA is required to set NAAQS despite these uncertainties. 89 Fed. Reg. at 16275; 42 U.S.C. § 7409(b). The Administrator’s NAAQS determination necessarily invokes his science and public health policy judgment,

based on his assessment of the strength and uncertainties of the scientific evidence. *See* 89 Fed. Reg. at 16276; *see also Am. Trucking Ass'ns*, 531 U.S. at 475–76.

Unlike in 2020, in 2024, the Administrator concluded uncertainties were not substantial enough to avoid the conclusion that a 12 $\mu\text{g}/\text{m}^3$ standard did not protect public health. 85 Fed. Reg. at 82717. The Administrator further concluded that uncertainties did not outweigh the evidence that supported revising the standards to 9 $\mu\text{g}/\text{m}^3$, even as he concluded that there remained too much uncertainty to support a revision *below* that level. 89 Fed. Reg. at 16285. The Administrator's judgments on each of these points were based on his consideration of both the scientific evidence that was before EPA in 2020 and the new evidence reviewed in the 2022 Supplement. Contrary to Petitioners' contentions (Industry Br. 42–43; States' Br. 38–39), the Administrator identified existing uncertainties and thoroughly explained why, notwithstanding these uncertainties, the annual $\text{PM}_{2.5}$ standard must be revised in order to protect public health.

The Administrator explained that, based on his judgment, the results of the epidemiologic evidence were unlikely to be explained by chance, confounding, or bias, and placed weight on their results in judging the adequacy of standard. *Contra* States' Br. 35; Industry Br. 43. Both the 2022 Supplement and the 2019 Science Assessment showed “consistent, positive associations reported across studies” unlikely to be “the result of unmeasured confounding and other biases.”

89 Fed. Reg. at 16256 (citation omitted); *see also id.* at 16274. The Administrator acknowledged uncertainties but explained that he was focusing on evidence where associations between PM_{2.5} and adverse health effects are strongest—that is, the means of studies showing effects found to have a causal relationship with particulate matter exposure. 89 Fed. Reg. at 16283. He also noted that EPA is required to set standards with an “adequate margin of safety,” a requirement “intended to address uncertainties associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards that research has not yet identified.” *Id.* at 16273. Thus, after considering the evidence, “including the associated limitations and uncertainties, in combination with the exposure/risk information,” the Administrator concluded that any less stringent standard would not satisfy the Clean Air Act’s requirements. *Id.* at 16285.

As explained in the Final Rule, the Administrator’s assessment of uncertainties changed between 2020 and 2024 in part because new studies supported and extended the evidence presented in the 2019 Science Assessment. For example, the 2022 Supplement included new epidemiologic studies that directly addressed uncertainties in the scientific evidence discussed in the 2020 Decision. *See* 89 Fed. Reg. at 16222, 16252. The 2022 Supplement includes epidemiologic studies that evaluate confounding (the potential that the health

effects described in the science are caused by factors other than particulate matter) using alternative methods. *Id.* at 16257. These studies continued to show that PM_{2.5} concentrations below 12 µg/m³ are associated with mortality and morbidity, strengthening the conclusion that unmeasured confounding and other biases are unlikely to explain the health effects observed across epidemiologic studies. *Id.* at 16257, 16276.

Several new accountability studies evaluated in the 2022 Supplement likewise reduced uncertainties. The 2020 Decision had expressed concern that accountability studies generally included only areas with initial ambient air conditions higher than the 12.0 µg/m³ standard. *See* 89 Fed. Reg. at 16252, 16276. The 2022 Supplement filled that gap, assessing accountability studies that analyzed areas with ambient PM_{2.5} concentrations at or below 12 µg/m³. Those studies showed decreases in health effects after a policy or intervention improving ambient air quality conditions, and thereby supported a conclusion that a standard below 12 µg/m³ would increase public health protection. 89 Fed. Reg. at 16276.

Ignoring this record evidence, State Petitioners misleadingly cite the Administrator's decision in 2020 to argue that accountability studies cannot disentangle health impacts from background trends. State Br. 37. But in *this* action, EPA relied on new accountability studies and explained that those studies decreased uncertainties. Petitioners offer no evidence to rebut that explanation.

The 2024 decision also included hybrid-modeling based studies among the key epidemiologic studies, whereas the 2020 Decision did not. The Administrator explained that such hybrid model-based epidemiologic studies “are an advancement in the available science,” and that such modeling approaches “have reduced exposure measurement error and uncertainty in the health effect estimates.” 89 Fed. Reg. at 16248, 16275.

Petitioners raise a handful of other arguments on the uncertainties in the scientific evidence but miscomprehend or misconstrue the Administrator’s statements and treatment of that evidence in the Final Rule. For instance, State Petitioners contend that there are uncertainties in the absolute results of a risk assessment. States’ Br. 36–37. This is true—and it is why the Administrator did not use “the absolute results of the risk assessment . . . for purposes of selecting the level of the annual standard that is requisite.” 89 Fed. Reg. at 16266–67; RTC at 35 JA_. Rather, EPA considered the risk assessment a useful tool because “the general magnitude of the risk estimates provide support for significant public health impacts, particularly for lower alternative annual standard levels.” 89 Fed. Reg. at 16275. In selecting $9 \mu\text{g}/\text{m}^3$ as the standard, however, the Administrator followed the Agency’s longstanding practice of setting the standard slightly below the lowest mean concentration of key epidemiologic studies on health effects from

particulate matter exposure. *See Nat'l Ass'n of Mfrs.*, 750 F.3d at 924; *Am. Farm Bureau Fed'n*, 559 F.3d at 526–27; *ATA III v. EPA*, 283 F.3d at 372.

Similarly, Industry Petitioners point out that uncertainty remains about the health effects associated with exposures to even lower concentrations of PM_{2.5}. Industry Br. 43. But the Administrator acknowledged this uncertainty and explained that he lacked confidence that setting the standard at 8 µg/m³ would actually lead to additional health improvements. 89 Fed. Reg. at 16282–83, 16285; RTC at 46–47, JA ___.

Thus, EPA provided cogent and thorough reasons for assessing remaining uncertainties differently.

IV. EPA lawfully revised the annual PM_{2.5} standard based on public health, not other considerations.

State Petitioners take an additional, but equally mistaken, tack to challenge EPA's revision of the particulate matter standards. First, State Petitioners attack EPA's motives. They argue that the Final Rule was unlawful because it was purportedly driven not by what standard is "requisite to protect public health," per 42 U.S.C. § 7409(b)(1), but by separate political, climate policy, and environmental justice concerns. *See States' Br.* 23–24. Second, State Petitioners argue that EPA's action should be viewed skeptically because EPA has never previously revised standards in reconsideration proceedings and because, in Petitioners' view, there were not compelling reasons for reconsidering the 2020

Decision. Finally, State Petitioners contend that EPA failed to acknowledge its change in position or consider potential reliance interests in revising the annual PM_{2.5} standard. Each of these arguments misses the mark.

A. State Petitioners' unfounded allegations about EPA's motivation for the Final Rule are belied by the record.

State Petitioners urge the Court to reject the Final Rule because, in their view, EPA's reconsideration was based on impermissible considerations. Specifically, they contend that the Final Rule was not driven by public health considerations, but rather a separate political agenda to advance climate change and environmental justice. *See, e.g., States' Br. 25.*¹¹ Petitioners' allegations are incorrect and unfounded.

EPA's decision must be judged on the grounds "upon which the record discloses that its action was based." *See, e.g., SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943). Those grounds are clear and consistent. EPA announced in June 2021 that it would reconsider the 2020 Decision "because the available scientific evidence and technical information indicated that the current standards may not be adequate to protect public health and welfare, as required by the Clean Air Act." 89 Fed. Reg. at 16203. In its press release at the time, as in the Final Rule's

¹¹ State Petitioners' concern that EPA based its decision on factors *other than* public health is in some tension with their argument that EPA was obligated to consider cost, attainability, and related factors. *See States' Br. 39.*

preamble, EPA noted that EPA's 2020 Policy Assessment "concluded that the scientific evidence and information support revising the level of the annual standard for the PM NAAQS to below the current level of 12 micrograms per cubic meter[.]" Press Release, EPA-HQ-OAR-2015-0072-1273, JA₁; *see* 89 Fed. Reg. at 16203. From the outset, then, EPA's review of the particulate matter standards has focused on protecting public health.

Likewise, EPA's record explanation for the Final Rule, as well as the record itself, shows that the Administrator's decision was driven by public health effects. The 2020 Policy Assessment had concluded that the scientific evidence called into question whether the then-existing 12 $\mu\text{g}/\text{m}^3$ standard adequately protected public health. 2020 Policy Assessment 3-106, JA₁. New epidemiologic studies assessed in the 2022 Supplement provided additional evidence that exposure to particulate matter at levels below the then-existing standard were associated with significant health effects. *See* 89 Fed. Reg. 16274; *see also* 2022 Policy Assessment at 3-59 to 3-133, JA₁₋₂. Based on that evidence, CASAC recommended revising the standard to protect public health with an adequate margin of safety. 2022 CASAC Review at 2, JA₁.

State Petitioners offer nary a citation to the Final Rule preamble or any documents in the record to cast that explanation in doubt. And despite their charge that EPA undertook "a freewheeling review based on extra factors EPA thinks

relevant,” States’ Br. 23, they point to nowhere in the record where EPA considered any allegedly irrelevant factors, nor explain what makes those factors irrelevant.

Take, for example, State Petitioners’ assertion that EPA “wielded its NAAQS setting authority as a tool to . . . confront the climate crisis.” State Br. 23. The most State Petitioners muster in support is the preamble’s explanation that EPA’s review of the 2020 Decision was prompted by Executive Order 13990, 86 Fed. Reg. 7037 (Jan. 20, 2021), which directed review of certain agency actions. *See* 89 Fed. Reg. at 16210. The Order declared the new Administration’s policy to, among many things, “listen to the science,” “improve public health and protect our environment,” “ensure access to clean air and water,” *and*—the parts on which State Petitioners fixate—“to reduce greenhouse gas emissions” and “prioritize . . . environmental justice.” 86 Fed. Reg. 7037 (Jan. 20, 2021). State Petitioners refer to this as the “Climate Order,” *see, e.g.*, States’ Br. 23–24, but of course the Order *also* states a policy to “improve public health” and “ensure access to clean air.”¹² *See* RTC 134–35, JA__ (noting the same). These are considerations even State Petitioners must (and do, at 22) concede are appropriate considerations under Section 7409(b)(1).

¹² State Petitioners may be confusing Executive Order 13990 with Executive Order No. 14008, entitled “Tackling the Climate Crisis at Home and Abroad,” 86 Fed. Reg. 7619 (Jan. 27, 2021). The Final Rule only cites the former.

Next, consider State Petitioners' argument that EPA improperly sought to "advance environmental justice" in the Final Rule. *See* States' Br. 23. State Petitioners do not identify where in the rule they believe environmental justice was improperly considered. Part of EPA's statutory obligation is to consider the adequacy of the revised standard to protect "individuals who are particularly sensitive to the effects of pollution." *Lead Indus. Ass'n*, 647 F.2d at 115; *see also Am. Lung Ass'n*, 134 F.3d at 389. Both the 2019 Science Assessment and 2022 Supplement identified children, older adults, people with preexisting diseases, minority populations, and low socioeconomic status populations as at-risk populations. Accordingly, consistent with the statute, EPA set the primary annual PM_{2.5} standard at a level that protects at-risk populations. *See* RTC at 72, 123, JA_, _.

State Petitioners' winks and nods to purportedly improper motives cannot overcome the presumption of regularity that must attend EPA's straightforward explanation for its action. *See United States v. Chemical Found., Inc.*, 47 S. Ct. 1, 14–15 (1926). To overcome that presumption, State Petitioners would have to make a "strong showing of bad faith or improper behavior," or demonstrate a "significant mismatch between the decision the [Administrator] made and the rationale he provided." *Biden v. Texas*, 597 U.S. 785, 811–12 (2022). They have not.

There is no evidence in the record to support State Petitioners' charge that the Final Rule was based on anything besides the Administrator's conclusion about what standards were necessary to protect public health. Indeed, EPA expressly stated in its Response to Comments that it "has no intention or goal to reduce greenhouse gases through this rulemaking." RTC at 134–35, JA___. There is thus no basis to reject the Final Rule on the unsubstantiated accusation that climate or environmental justice considerations improperly influenced the Agency's course of action.

B. The record provides no basis for heightened "skepticism" of EPA's action.

What State Petitioners lack in record support, they attempt to make up in general suspicion.

First, State Petitioners contend that the Court should conclude that EPA "ventured beyond Section [7409]'s limits" because "EPA has never revised a NAAQS after a voluntary reconsideration." States' Br. 25. Although irrelevant, that is true, as far as it goes. EPA has formally announced a "reconsideration" of NAAQS on two other occasions. *See* 75 Fed. Reg. 2938 (Jan. 19, 2010) (reconsideration of 2008 ozone NAAQS); 87 Fed. Reg. 25485 (Apr. 29, 2022) (draft policy assessment for proposed reconsideration of the 2020 ozone NAAQS decision). But the Final Rule is the first time a proceeding described by EPA as a "reconsideration" has resulted in revised standards.

EPA *has*, however, exercised its discretionary authority to “review and revise air quality criteria or promulgate new standards” many times. At least six times since the 1977 Clean Air Act Amendments, EPA has reopened air quality criteria or standards before the next five-year review. *See* 48 Fed. Reg. 37519 (Aug. 18, 1983) (announcing draft addendum to carbon monoxide air quality criteria); 51 Fed. Reg. at 11058 (announcing plan for targeted reopening of 1982 PM criteria); 57 Fed. Reg. 35542, 35545 (Aug. 10, 1992) (ozone criteria reopened to address selected studies); 59 Fed. Reg. 58958, 58960–63 (Nov. 15, 1994) (addenda and supplement prepared to address new studies on sulfur oxides); 62 Fed. Reg. 38856 (July 18, 1997) (revising ozone standards just four years after prior review); 72 Fed. Reg. 71488, 71491 (Dec. 17, 2007) (noting addendum and supplement were prepared after the 1986 lead air quality criteria were issued).

EPA’s assertion of authority to revise criteria or standards in between five-year reviews is thus hardly novel. The fact that, when presented with new, relevant information, EPA has sometimes revised the criteria or the standards in a limited fashion, and sometimes not, does not establish that EPA *cannot* revise the criteria or the standards when the record *does* warrant doing so, as here. And that is particularly so when the statute so clearly grants EPA the authority to do just that. *See* 42 U.S.C. § 7409(d)(1) (“The Administrator may . . . revise criteria or

promulgate new standards[.]”); *see also id.* § 7408(c) (“The Administrator shall from time to time review, and, as appropriate, modify and reissue any criteria[.]”).

Second, State Petitioners suggest that skepticism is warranted because EPA initiated reconsideration “with little real reason.” States’ Br. 27. Although they admit that the body of relevant science has changed since the 2020 Decision, in State Petitioners’ judgment, those changes were not significant enough to warrant revising the standard. *Id.* at 28.

As an initial matter, State Petitioners’ argument ignores that the reason for reconsideration—as explained in the preamble and announced in a contemporaneous press release—was the Administrator’s belief, supported by the 2020 Policy Assessment, that even the scientific evidence in 2020 showed that the 12 µg/m³ standard did not adequately protect public health.

In any event, State Petitioners’ argument suffers from the same error addressed by this Court in *Mississippi v. EPA*, 744 F.3d at 1342–44. There, the petitioners argued that EPA must establish why a prior standard is inadequate to protect public health to justify lowering the standard. *Id.* But this Court held that, in assessing a NAAQS decision, “[t]he statutory framework requires us to ask only whether EPA’s proposed NAAQS is ‘requisite’; we need not ask why the prior NAAQS once was ‘requisite’ but is no longer up to the task.” *Id.* at 1343. Doing otherwise “would bind EPA to potential deficiencies in past reviews because

discrepancies between past and current judgments as easily reflect problems in the past as in the present.” *Id.*; *see also Murray Energy*, 936 F.3d at 609 (“[P]rior NAAQS are not sacrosanct and are not granted presumptive validity.”).

The Court should reject State Petitioners’ argument for the same reason. The question is not whether the science has *changed* enough to warrant a new standard; it is whether EPA’s proposed standard is “requisite to protect the public health,” based on the record and EPA’s explanation. *See Murray Energy*, 936 F.3d at 609; *Mississippi*, 744 F.3d at 1343. As discussed in Part III, *supra*, the Final Rule meets that standard.

Regardless, the changes in the body of scientific evidence between the 2019 Science Assessment and the 2022 Supplement were significant. *See id.* But even setting aside that new evidence, it is sufficient that the Administrator’s judgment about whether the standard was requisite to protect public health changed between 2020 and 2024. As this Court has recognized, the NAAQS review process includes “EPA’s public health policy judgments as well as its analysis of scientifically certain fact.” *Mississippi*, 744 F.3d at 1344.

State Petitioners’ criticism that it was EPA’s policy priorities, not the science, that changed between 2020 and 2024 is therefore both incorrect and irrelevant. “It is hardly improper for an agency head to come into office with policy preferences and ideas.” *Dep’t of Commerce v. New York*, 588 U.S. 752, 755

(2019). “As long as [an] agency remains within the bounds established by Congress, it is entitled to assess administrative records and evaluate priorities in light of the philosophy of the administration.” *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 59 (Rehnquist, J., concurring in part and dissenting in part). The Final Rule here is procedurally proper and supported by record evidence.

Finally, State Petitioners suggest that “skepticism” of EPA’s authority is nevertheless warranted by an alleged “mismatch” between EPA’s “general authority and the specific way EPA wielded it here.” States’ Br. 24. But this argument depends on the notion that EPA was trying to achieve “a broader climate agenda” rather than “protect public health”—which, as demonstrated, is entirely contrary to the record.

In any event, because State Petitioners’ skepticism is not about the scope of EPA’s statutory authority, but about the reasons EPA gave for its action, their invocation (at 24) of *West Virginia v. EPA*, 597 U.S. 697 (2022), and similar cases is out of place. Those cases articulate the major questions doctrine, an interpretive canon applied in extraordinary situations where agencies apply a novel statutory interpretation to advance significant newfound power. *See, e.g., West Virginia*, 597 U.S. at 724. They do *not* bear on courts’ assessment of EPA’s technical judgments or indicate that courts should disregard an agency’s record explanation for its

action. Those judgments are reviewed on the administrative record that was before EPA under an arbitrary-and-capricious standard.

At any rate, the power asserted here—to revise the NAAQS—is the exact authority EPA has exercised on countless occasions since the NAAQS program was created in the 1970 Clean Air Act Amendments. State Petitioners concede that EPA has authority to revise air quality standards, States’ Br. 24, and to do so “faster than the statute requires,” *id.* at 27. EPA did that here.

C. EPA acknowledged its change of position and addressed potential reliance interests.

State Petitioners’ final arguments fare no better. They contend that an agency changing positions must (a) acknowledge it is doing so, and (b) consider reliance interests. States’ Br. 30–31, 32 (citing *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 41–42, 43). This Court has already rejected the notion that EPA has a heightened obligation to explain why it reached a different decision in a later NAAQS review. *See Mississippi*, 744 F.3d at 1344–45. But even if those considerations were relevant, EPA adequately addressed both.

First, EPA was *not*, contrary to State Petitioners’ argument, changing positions on whether it could revise the NAAQS outside the five-year review process of Section 7409(d)(1)’s first sentence. EPA has never taken the position that it cannot revise the criteria or NAAQS sooner than once every five years. That authority is plainly conferred by Section 7409(d)(1)’s second sentence, and EPA

has exercised or proposed to exercise that authority several times. *See supra* Part IV.B.

Likewise, in having declined to finalize a reconsideration in the past, EPA did not take the position that it can or must consider costs when determining whether or how to revise NAAQS outside of the mandated five-year review. Industry Petitioners point to the President's statement in 2011 that he did not support interim action adopting a new standard when it was already being reconsidered under a new review. *See* Industry Br. 30; States' Br. 32. There, EPA had already begun updating the criteria as part of its next five-year review and thus deemed it appropriate to fold the reconsideration of the ozone NAAQS into that review. *See* 89 Fed. Reg. 75234, 75249 (Dec. 17, 2014). EPA has never taken the position that the Administrator could decline to revise NAAQS that are inadequate to protect public health simply because such a revision them could have economic impacts. *See Massachusetts v. EPA*, 549 U.S. 497, 533 (2007) (“[EPA’s] reasons for action or inaction must confirm to the authorizing statute”); RTC at 120, JA__.

Second, EPA adequately considered potential reliance interests. EPA explained that it “does not consider potential reliance interests a sufficient reason to alter the Administrator’s judgment as to the requisite degree of protection of the NAAQS for multiple reasons.” RTC at 128, JA__. The NAAQS process assumes frequent review and revision “as the scientific community engages in ongoing

research.” *Id.* The very idea, then, of a reliance interest in EPA’s judgments about the standards requisite to protect public health goes against the structure and purpose of the NAAQS. *See Mississippi*, 744 F.3d at 1344 (“the line marked by the term ‘requisite’” can shift with additional scientific knowledge).

In any event, State Petitioners do not identify any reliance interests that EPA failed to address. Instead, they merely hazard a guess that “NAAQS have no doubt engendered” “serious reliance interests.” States’ Br. 32 (quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016)). But EPA explained that because the 2020 Decision retained the particulate matter NAAQS, “there are no implementation activities that were triggered” by that decision “that could be disrupted by revising the NAAQS in this action.” RTC at 124, JA_. State Petitioners’ hand-waving about reliance interests should therefore be dismissed.

CONCLUSION

For the foregoing reasons, the Court should deny the petitions for review.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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