Legal Backgrounder

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IS REVISION OF THE $PM_{2.5}$ NAAQS REQUISITE TO PROTECT PUBLIC HEALTH?

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The Clean Air Act ("CAA" or "Act"), requires EPA to review its National Ambient Air Quality Standards ("NAAQS" or "standards") at least every five years and to revise them "as may be appropriate" in accordance with sections 108 and 109(b) of the Act. CAA § 109(d)(1). Under section 109(b), EPA must set primary NAAQS at the level that is "requisite to protect the public health" with an "adequate margin of safety." In *Whitman v. American Trucking Associations*, the Supreme Court of the United States explained that for a primary NAAQS to be "requisite" it must be "not lower or higher than . . . necessary." 531 U.S. 457, 475-76 (2001) ("*Whitman*"). In 2002, the United States Court of Appeals for the District of Columbia Circuit upheld EPA's 1997 NAAQS for $PM_{2.5}$ (i.e., airborne particles with a diameter about $1/30^{th}$ the diameter of a human hair) as satisfying the criterion set out by the Supreme Court in *Whitman*. *See American Trucking Associations v. EPA*, 283 F.3d 355 (D.C. Cir. 2002) ("*ATA*").

EPA has now proposed to revise the 1997 $PM_{2.5}$ NAAQS based on its "provisional[ ]" determination that the annual and 24-hour primary standards, "taken together," are not "requisite" to protect public health, and that revision of the standards is "needed to provide increased public health protection." National Ambient Air Quality Standards for Particulate Matter, 71 Fed. Reg. 2620, 2643 (Jan. 17, 2006). A key question in this rulemaking is whether the standards approved by EPA Administrator Carol Browner in 1997 and upheld by the D.C. Circuit as requisite to protect public health are, in fact, no longer "requisite." As explained below, belief that "increased public health protection" is "needed" is not the statutory test for revising NAAQS previously determined to be requisite under the *Whitman* standard. Moreover, the new science that has become available since EPA established the 1997 NAAQS does not support a decision to make those standards more stringent.

The 1997 Primary $PM_{2.5}$ NAAQS. Although much about NAAQS standard-setting is disputed, there is *no* dispute that CAA § 109 does *not* impose a "zero risk" standard. *See, e.g.*, 71 Fed. Reg. at 2622; National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,653 (July 18, 1997); s*ee also Whitman*, 531 U.S. at 494 (Breyer, J., concurring) ("The statute, by its express terms, does not compel the elimination of all risk.") (emphasis omitted).

In 1997, EPA promulgated the primary $PM_{2.5}$ NAAQS based on studies showing associations

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between levels of particles in ambient (i.e., outside) air and rates of "premature mortality, aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions and emergency room visits, school absences, work loss days, and restricted activity days), changes in lung function and increased respiratory symptoms, changes to lung tissues and structure, and altered respiratory defense mechanisms." 62 Fed. Reg. at 38,656. EPA recognized that these NAAQS were not risk-free, and acknowledged the existence of key scientific uncertainties that required the Administrator to make policy judgments in evaluating the risks associated with alternative standard levels. *See id.* at 38,677.

Reflecting that science alone did not dictate the level or format for standards, EPA supplemented its review of the science with risk assessment. The EPA Staff, in preparing technical and policy recommendations to the Administrator in a "Staff Paper," estimated, for example, that in Southeast Los Angeles County, the primary $PM_{2.5}$ NAAQS it promulgated would reduce the population risk of mortality associated with short-term PM exposure by 320 statistical deaths annually (in a population of 3.6 million), leaving an estimated population risk of 390 statistical deaths. EPA, Review of the National Ambient Air Quality Standards for Particulate Matter: OAQPS Staff Paper at VI-6, VI-51 (1996) ("1996 Staff Paper"). EPA also predicted a reduction of 970 statistical deaths annually in this population associated with long-term PM exposure upon attainment of the NAAQS, leaving an estimated population risk of 360 annual statistical deaths. Memorandum to J. Bachmann, EPA, from E. Post & J. Voyzey, Abt Associates, Inc., at Exhibit 4.2 (June 5, 1997). Given this information, Administrator Browner concluded that the primary $PM_{2.5}$ NAAQS she promulgated was "requisite," i.e., would protect public health with an adequate margin of safety. 62 Fed. Reg. at 38,677.

In 2002, the D.C. Circuit upheld Administrator Browner's conclusion. First, the court found that EPA had set forth in the record "document[ed] evidence of the old PM standard's inadequacy." *ATA*, 283 F.3d at 365. Second, the court held that, in establishing a revised standard, EPA had properly "reject[ed] . . . lower [$PM_{2.5}$] standards, demonstrating that the Agency not only recognized, but acted upon, its statutory obligation to set the primary NAAQS at levels no lower than necessary to reduce public health risks," as required by the Supreme Court in *Whitman*. *Id.* at 369. Finally, citing Justice Breyer's concurring opinion in *Whitman*, the court observed that section 109 of the Act calls upon EPA to make judgments regarding acceptable risks; the CAA must be construed to "permit EPA to 'consider whether a proposed rule promotes safety overall.'" *Id.* at 375 (emphasis omitted).

Evidence Regarding Whether a More Stringent Primary NAAQS is "Requisite". As noted above, in *ATA*, the D.C. Circuit held that EPA had properly determined that the primary $PM_{2.5}$ NAAQS that are now in effect are requisite to protect public health with an adequate margin of safety and thus that these NAAQS satisfied the requirements of the statute. As a result, revising those standards on the grounds that they are *not* requisite to protect public health can be justified only if the science has changed since they were promulgated in a way that undermines the basis for Administrator Browner's "requisite to protect" determination. Otherwise, the Agency would be reaching contrary conclusions without an adequate and reasoned basis — the epitome of arbitrary and capricious action. *See, e.g., Motor Vehicle Manufacturer's Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 42 (1983) (presumption "against changes in current policy that are not justified by the rulemaking record").

For example, if new health evidence demonstrated that, at the level of the 1997 NAAQS, public health risks are greater or otherwise of more concern than EPA understood them to be based on the evidence available in 1997, there might be a basis to revisit Administrator Browner's judgment that the 1997 NAAQS are "requisite." Alternatively, if the health risks EPA considered in 1997 are *more certain* now than they were in 1997, this might also provide a basis to revisit that judgment. On the other hand, if risks and

uncertainties have not changed, there would be no basis to revisit Administrator Browner's judgment. What does the record show?

The health effects discussed in the EPA Staff's 2005 advice to the Administrator are — with one exception — essentially those that were considered by the Administrator in promulgating the 1997 NAAQS. Like the 1996 Staff Paper, the current Staff Paper discusses associations between short-term and long-term PM exposures and premature mortality, hospitalization, and medical visits related to respiratory and cardiovascular system effects. *See* EPA, Review of the National Ambient Air Quality Standards for Particulate Matter: OAQPS Staff Paper (2005) ("2005 Staff Paper"). The one type of effect discussed in the 2005 Staff Paper but not the 1996 Staff Paper is developmental effects. Yet the 2005 Staff Paper acknowledges that this evidence is "still preliminary." 2005 Staff Paper at 3-24. As a result, EPA's analysis of the science in support of possible standard revision continues to focus on the same types of potential effects.

EPA's 2005 risk assessment of the new $PM_{2.5}$ data adds Boston, Detroit, Phoenix, St. Louis, San Jose, and Seattle to Los Angeles and Philadelphia, the cities evaluated for the 1997 NAAQS review, and includes both a larger area and population for Los Angeles. E. Post, et al., Particulate Matter Health Risk Assessment for Selected Urban Areas (2005) ("2005 Risk Assessment"). Although the 2005 Risk Assessment is hundreds of pages long, the EPA Staff's conclusion based on that document is simple: "estimated mortality risks are not completely eliminated when current $PM_{2.5}$ standards are met in a number of example urban areas, including all such areas that do not meet the standards based on recent air quality data." 2005 Staff Paper at 5-15. For this reason — the fact that estimated mortality risks are not "completely eliminated," i.e., not driven down to zero, by the existing NAAQS – EPA said it would be appropriate to make those NAAQS more stringent to provide "increased public health protection." *Id.* at 5-45.

It is not surprising, however, that statistical risk exists at the current standard level. Indeed, as noted above, Administrator Browner acknowledged the existence of remaining risk when she promulgated the NAAQS. Moreover, that a lower standard will provide "increased public health protection" can be said of any alternative standard down to "zero" (assuming no threshold has been established for the concentration-response relationship). But these simple facts tell one nothing about whether any standard revision is "requisite" under the Act.

In recent analyses, Dr. Anne Smith has taken the next step. She compares EPA's own analysis of the science used to set the current $PM_{2.5}$ NAAQS with EPA's analysis of the science that exists today. Addressing the studies of premature mortality, Dr. Smith observes that the public health risk upon attainment of the 1997 $PM_{2.5}$ NAAQS shown by EPA's 2005 Risk Assessment is generally *lower* than the risk EPA calculated in 1997 for attainment of that same standard. *See* A.E. Smith, Insights into Trends in $PM_{2.5}$ Mortality Risk Estimates (Oct. 27, 2005), at 3, 5. For example, Dr. Smith shows that in EPA's 1997 risk assessment, upon attainment of the 1997 $PM_{2.5}$ NAAQS, 1.7% of all-cause mortality in Los Angeles was estimated to be associated with short-term $PM_{2.5}$ exposure. (The 1.7% figure was EPA's median risk estimate, with a 95% confidence interval that extended from 1.0% to 2.3%.) In EPA's 2005 Risk Assessment, based on more recent science, the median estimate of all-cause mortality in Los Angeles associated with short-term $PM_{2.5}$ exposure had fallen to 0.5% upon attainment of *that same standard* (with a 95 percent confidence interval of -0.1 to 1.1%).

In other words, Dr. Smith reports that, for Los Angeles, EPA's 2005 best estimate of public health risk associated with attainment of the *current* $PM_{2.5}$ NAAQS *is below even the bottom end of the range of*

the Agency's 1997 risk estimates. Furthermore, the 95% credible interval now includes the possibility that there is *no* mortality risk whatsoever at attainment. Dr. Smith reports similar results for other cities. *Id.* at 4.

Dr. Smith notes that many additional studies of PM and health effects have been published since EPA established the 1997 $PM_{2.5}$ NAAQS. Some show a statistically significant relationship between $PM_{2.5}$ and mortality; others do not. The same was true of the record in 1997. Moreover, even for studies that show statistical significance, Dr. Smith notes that the statistical significance disappears depending on which of a number of plausible analytical approaches one applies. A.E. Smith, Technical Comments on the Proposed Rule for National Ambient Air Quality Standards for Particulate Matter (April 17, 2006), at 5-10. In short, substantial uncertainties remain about the relationship between $PM_{2.5}$ and public health effects and these uncertainties are similar in kind to, and equal to or greater than, those that existed in 1997.

This leaves the key question: If the public health risks that exist under the current NAAQS are *lower* now than those which EPA itself determined — in a decision affirmed by the D.C. Circuit — reflect the level that is "requisite" to protect public health, what authority does EPA have under the Act to determine now that those NAAQS are in fact *not* requisite to protect the public health with an adequate margin of safety?

Conclusion. Crucial legal questions exist regarding whether revision of the $PM_{2.5}$ NAAQS is "requisite" to protect public health under the standard announced by the Supreme Court in *Whitman*. As the D.C. Circuit observed, EPA "acted upon . . . its statutory obligation to set the primary NAAQS at levels no lower than necessary to reduce public health risks" when it established the current $PM_{2.5}$ NAAQS. *ATA*, 283 F.3d at 369. If EPA's risk assessment based on the new science, as reported by Dr. Smith, is correct — that is, that the public health risks associated with attaining the existing standards are now lower and more uncertain than they were thought to be when EPA promulgated those standards in 1997 — how can revision of those standards be "requisite"?

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