

# **THE ONGOING CLEAN-AIR DEBATE**

## **THE SCIENCE BEHIND EPA'S RULE ON SOOT**

**KAY JONES AND BEN LIEBERMAN**

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### **EXECUTIVE SUMMARY**

The Environmental Protection Agency's 1997 standard for fine particulate matter is perhaps the most controversial environmental rule enacted during the Clinton administration. Critics both inside and outside the administration raised doubts about the claimed public-health benefits to be derived from this costly new standard, and EPA's own science advisory committee questioned its scientific support. Indeed, this rule, along with a concurrent new standard for ozone, drew more opposition than any other in the 30-year history of the Clean Air Act.

Implementation of the fine particulate matter rule has been delayed by litigation, but a recent Supreme Court decision should allow EPA to move forward. Meanwhile, the research on the health effects of fine particulate matter has continued, including an extensive reanalysis of the two key studies that were heavily relied upon by EPA in promulgating the rule. The agency has cited this research as vindication of its regulatory agenda and as justification for moving forward with it as soon as possible.

In truth, the evidence has yet to implicate fine particulate matter as a serious public-health threat. The recent research has only reinforced the original doubts as to the necessity of a new standard.

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### INTRODUCTION

Of all the environmental regulations enacted during the Clinton administration, the Environmental Protection Agency's 1997 rules setting new standards for ozone and particulate matter (smog and soot) remain among the most controversial. If implemented, these rules would likely become the costliest in the 30-year history of the Clean Air Act (CAA) and impact an unprecedented number of entities.

Perhaps most controversial of all is the science underlying EPA's claim that tightening the already strict existing standard for particulate matter was necessary to protect the public health. In fact, when the rules were finalized in 1997, there were still many unanswered questions about the reliability of the supporting evidence. Those both inside and outside the administration raised doubts about whether the benefits would exceed the costs.

Litigation has held up implementation of this rule and garnered most of the attention since 1997. On February 27, 2001, the Supreme Court removed several (but not all) of EPA's legal hurdles to moving forward, thus focusing attention once again on implementation.

In the meantime, research on the health effects of particulate matter has continued. This ongoing research, including an extensive reanalysis of two key particulate matter studies, has been cited by EPA as vindication of its regulatory agenda. However, as will be discussed below, recent findings have only reinforced the original doubts as to the necessity of a new particulate matter rule.

### BACKGROUND

Title I of CAA regulates ambient concentrations (the amount in the air) of six so-called criteria pollutants—nitrogen oxides, sulfur dioxide, lead, carbon monoxide, ozone, and particulate matter.<sup>1</sup> EPA sets National Ambient Air Quality Standards (NAAQS) for each criteria pollutant, and states must submit plans for meeting those standards. States with areas not in attainment with the NAAQS are subject to increased EPA controls and potential penalties.

In the nearly 30 years this program has been in place, significant reductions have been measured in ambient concentrations for all six criteria pollutants.<sup>2</sup> In

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fact, most of the nation is in compliance with the current NAAQS, and those areas not yet in attainment have shown marked improvement.

EPA is also required to review existing NAAQS every five years.<sup>3</sup> The agency must then tighten any existing standard, if, based on the latest evidence, it is no longer sufficient to protect public health with an adequate margin of safety. Revising a standard is a complex process, involving a thorough agency assessment of the relevant health research, called a Criteria Document, which is reviewed by EPA's Clean Air Scientific Advisory Committee (CASAC). From this, EPA develops a Staff Paper, also reviewed by CASAC, which contains the agency's recommendations. EPA then generates a Regulatory Impact Analysis, and proposes a new standard if deemed necessary. The five-year deadline to complete this process is very tight, especially for a pollutant like particulate matter, where the underlying science is complex. But if EPA fails to comply, any citizen or public-interest group may sue, compelling the agency to do so.<sup>4</sup>

### THE REVISED STANDARD

In 1994, the American Lung Association successfully sued EPA for failing to complete a timely review of the particulate matter standard, which was last revised in 1987.<sup>5</sup> The resulting court order required an accelerated review process, to be completed in 1996. Based on this review, EPA chose to specifically target fine particulate matter—particles smaller than 2.5 microns in diameter (PM 2.5). On December 13, 1996, EPA proposed its new standard for PM 2.5, while keeping in place the existing rule for particulate matter less than 10 microns in diameter (PM 10, of which PM 2.5 is a subset).<sup>6</sup> The agency's initial proposal included a 24-hour standard of 50 (subsequently changed to 65) micrograms per cubic meter, and an annual standard of 15 micrograms per cubic meter, considered by most to be very stringent.<sup>7</sup> Although not covered under the court order, EPA concurrently proposed a new standard for ozone.<sup>8</sup>

EPA initially estimated the implementation costs of the PM 2.5 rule at \$6.3 billion.<sup>9</sup> Some non-governmental analysts estimated costs for the rule in excess of \$50 billion annually.<sup>10</sup> EPA calculated benefits ranging from \$69 billion to \$144 billion annually, based on estimated reductions in cardiopulmonary-disease-related deaths and cases of chronic bronchitis.<sup>11</sup>

### OPPOSITION TO THE NEW STANDARD

The proposed rules faced an unprecedented level of opposition. Groups as diverse as the National Black Chamber of Commerce and the American Farm Bureau Federation feared the costs of these measures would be higher than estimated by EPA and would vastly outweigh what they believed to be questionable benefits.<sup>12</sup> Even within the Clinton administration, the rules faced criticism from the Departments of Treasury, Transportation, Commerce, Energy, and Defense, as well as the Small Business Administration, Office of Science and Technology Policy, Council of Economic Advisors, and others.

*Revising a standard is a complex process, involving a thorough agency assessment of the relevant health research.*

Several agencies argued that the actual implementation costs would likely be considerably higher than initially estimated by EPA. Others questioned the scientific support. For example, the Office of Science and Technology Policy stated:

the database for actual levels of PM 2.5 is also very poor, and only a handful of studies have actually studied PM 2.5 effects, per se. And current data do not support clear associations...so that causality for the observed mortality and morbidity effects cannot be established.<sup>13</sup>

A series of Congressional hearings highlighted numerous weaknesses in the case for the new standard, most notably the lack of clear support from the agency's own Clean Air Scientific Advisory Committee. George Wolff, CASAC chair, informed Congress of deficiencies in the science supporting the PM 2.5 standard, most of which could not be adequately addressed due to the abbreviated nature of the review process.<sup>14</sup> In particular, CASAC was concerned about copollutants—pollutants whose concentrations correlate with PM2.5 and which may be the actual causative agent for the adverse health effects observed. According to Wolff, “ozone, sulfur dioxide, or carbon monoxide can be as important, and in some cases, more important than PM.”<sup>15</sup> Further, to the extent PM is the problem, the evidence did not clearly establish that it is PM 2.5 and not the larger particles regulated by the PM 10 standard.<sup>16</sup>

In addition, non-pollution-related confounding variables may have skewed the results. Smoking behavior is especially troublesome, as the same health effects believed to be correlated with PM 2.5 exposure are far more strongly correlated with smoking; thus even slight errors in categorizing the smoking histories of study subjects can create a phantom PM 2.5 effect.<sup>17</sup>

Pollution and non-pollution confounders are particularly problematic when trying to discern causation and dose-response relationships from epidemiologic studies showing weak correlations, as EPA did here.

The case for the new PM 2.5 standard rested almost entirely on two large epidemiologic studies, the Harvard Six Cities study and the American Cancer Society study.<sup>18</sup> Both studies concluded that a causal association exists between exposure to PM 2.5 and excess mortalities and incidence of cardiopulmonary disease. Otherwise, very little was known about PM2.5. CASAC was given little information regarding its makeup, ambient concentrations, levels of exposure, or plausible biological mechanisms by which it affects human health.<sup>19</sup> In fact, much of the case for regulating PM 2.5 came from extrapolations of PM 10 studies.

Although CASAC agreed that a new PM 2.5 standard was advisable, Wolff stated that “only a minority of the Panel members supported a range that includes the present EPA proposals.”<sup>20</sup>

As a consequence of these and other criticisms, both the Senate and House introduced bills to block implementation of the new rules.<sup>21</sup> These bills enjoyed

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substantial bipartisan support, and represented the first serious congressional challenge to major Clean Air Act regulations. However, the bills were ultimately withdrawn when it became clear that they lacked the two-thirds support necessary to override an expected presidential veto.

In spite of the controversy, EPA finalized the rules on July 18, 1997.<sup>22</sup> EPA's victory was temporary, however, as the rules were immediately challenged in court. Over 40 parties, including both large and small businesses and several state governments, sought to overturn the new standards. The US Court of Appeals invalidated the rules on May 14, 1999, essentially forcing the agency to start over in setting new standards.<sup>23</sup> The decision was largely based on factors other than the underlying science. EPA appealed the case to the US Supreme Court, which released its opinion on February 27, 2001.<sup>24</sup>

In most respects, the Supreme Court's decision is a victory for EPA. Although there still are important implementation details to be worked out by the US Court of Appeals, the Supreme Court decision will likely allow the agency to move forward with a new fine particulate matter standard.

### **THE CURRENT STATE OF THE SCIENCE SUPPORTING THE PM 2.5 STANDARD**

In promulgating the new PM 2.5 standard, EPA had to rely heavily on the Harvard Six Cities and American Cancer Society studies. Members of Congress, CASAC, state-level environmental officials, and industry groups had critical concerns about these studies. Yet, both EPA and the researchers who conducted the work refused all requests for access to the underlying data, effectively denying any chance of independent review. To the limited extent PM 2.5 data were available to other researchers, some concluded that PM 2.5 has not been implicated as a public-health threat.<sup>25</sup>

Given the disproportionate weight accorded these two studies and the widespread questions about their reliability, the refusal to share the data heightened suspicions that the PM 2.5 standard had shaky support. The episode led to new legislation mandating the release of data from federally funded research, when that research is relied upon in setting regulations (although EPA has yet to comply with these provisions).<sup>26</sup>

In a compromise between Congress and EPA, the Health Effects Institute (HEI), an independent research organization sponsored by both government and industry, funded an extensive reanalysis of these two studies. Known as the Reanalysis Project, the results were released in July 2000.<sup>27</sup> EPA immediately claimed its 1997 conclusions regarding PM 2.5 were validated. EPA Administrator Carol Browner stated that HEI "re-evaluated the science and confirmed our results."<sup>28</sup> John Bachmann, EPA Associate Director for Science Policy, asserted that "there is no mistaking that particulate matter is the culprit," and that the reanalysis "strengthens our ongoing scientific re-

view.”<sup>29</sup> In addition, Senators Max Baucus (D-Mont.) and Joe Lieberman (D-Conn.) responded by warning their colleagues that any attempt to “attack future proposed standards as ‘inadequate’ ... will not be tolerated.”

After the Supreme Court’s decision, the agency will revisit the issue and decide whether to go forward with the proposed PM 2.5 standard. EPA is currently reviewing all new research on particulate health effects and will publish a revised Criteria Document in the near future. The Criteria Document will review the HEI reanalysis of the Harvard Six Cities and American Cancer Society studies, as well as other recent additions to the literature. A discussion of the HEI reanalysis and two other key studies follows below.

#### **THE HARVARD SIX CITIES STUDY REANALYSIS**

This study involved the comparison of chronic mortality data (deaths potentially attributable to long-term exposure to air pollution) to air pollution levels in six cities with different annual PM 2.5 levels (the average level over the span of a year) covering the period 1980 to 1988. The possible influence of cofactors (non-pollution-related variables such as education level, smoking history, or income, that can also influence the health effects at issue) was included in the original study as well as the reanalysis. The relative risks (the extent health risks change with changing levels of exposure to a pollutant) of PM2.5, sulfur dioxide, and other air pollutants were reported. However, these other pollutants were not directly compared with PM2.5 in multi-pollutant models (a simultaneous study of two or more pollutants to determine the one most strongly associated with the health effects at issue). An article in *Science* described this reanalysis as “a major victory” for EPA.<sup>30</sup> However, the key results as reported by the Reanalysis Project but not highlighted were:

- u there was no significant association between PM2.5 and mortality among non-smokers;
- u four of the six cities did not show a statistically significant difference in mortality risk with increasing PM 2.5 levels;
- u the relative risks were essentially the same for other pollutants as for PM 2.5. The reanalysis team did not conduct multi-pollutant modeling to ascertain which pollutant or pollutants were most strongly associated with mortality.

#### **THE AMERICAN CANCER SOCIETY STUDY REANALYSIS**

The original study was a chronic-mortality study involving 50 cities (increased to 63 by the Reanalysis Project), using PM2.5 and sulfur dioxide data for the years 1979 to 1983. The reanalysis expanded the original analysis to examine the singular and combined effects of non-pollution cofactors as well as air pollutants other than PM 2.5. The key results contained in the Reanalysis Project report were:

*To the limited extent PM 2.5 data were available to other researchers, some concluded that PM 2.5 has not been implicated as a public-health threat.*

- u there was no significant association between PM 2.5 levels and mortality for persons with more than a high school education, regardless of age, smoking status, or level of exercise;<sup>31</sup>
- u when all of the other cofactors which influenced the PM 2.5 relative risks were combined, the association between PM 2.5 and mortality was not significant;
- u when sulfur dioxide was included in a multi-pollutant model, it displaced PM 2.5 as the pollutant of concern. The relative risk for sulfur dioxide was statistically significant, while the relative risk for PM 2.5 with the inclusion of sulfur dioxide in the model failed to achieve significance.

#### **THE NATIONAL MORBIDITY, MORTALITY, AND AIR POLLUTION STUDY (NMMAPS)**

*Contrary to the statements made by EPA and others, there is no evidence that the PM 2.5 standard is supportable at this time.*

In addition to the Reanalysis Project, HEI undertook this original study on particulate matter and health. As with the above two studies in the Reanalysis Project, NMMAPS has also been publicized as providing support for EPA's PM 2.5 agenda, although it addressed PM 10 and not PM 2.5. This publicity included another article in *Science* touting it as perhaps the most definitive study on the subject.<sup>32</sup> The study attempted to correlate the incidence of acute mortality (sudden deaths caused by short-term exposure to pollutants) with the level of PM 10. The goal was to determine whether the acute mortality rate increased on days with higher-than-average PM 10 pollution. The following NMMAPS results are noteworthy:

- u when the 90 city results are examined individually, only nine show a statistically significant association between daily differences in PM 10 and acute mortality—81 cities show no significant association;
- u there was no statistically significant association between PM 10 and acute mortality in four of the seven regions studied;<sup>33</sup>
- u the effect of other air pollutants, in particular ozone, was not fully addressed;<sup>34</sup>
- u the smoking status of study subjects was not taken into consideration.

#### **THE WASHINGTON UNIVERSITY/EPRI VETERANS' COHORT MORTALITY STUDY<sup>35</sup>**

This chronic-mortality study is unique in that it examines a highly sensitive captive population for which detailed personal histories are known, in some 32 cities across the nation. The study population of 90,000 male US veterans was highly susceptible to air pollution effects because the individuals studied had preexisting hypertension heart disease. The data for particulate matter of various sizes were available back to 1953, while the PM 2.5 data were limited to a narrower period, 1979 to 1984. The results of this study contrast rather

dramatically with the public pronouncements from EPA (but generally concur with HEI's actual results) in that it found:

- u no statistically significant association between mortality and PM 2.5 with or without the inclusion of any other variables;
- u a stronger association between both ozone and nitrogen dioxide and mortality than particulate matter and mortality.

## **CONCLUSION**

Contrary to the statements made by EPA and others, there is no evidence that the PM 2.5 standard is supportable at this time. In fact, CASAC's 1996 conclusion still holds true today, that "the diversity of opinions also reflects the many unanswered questions and uncertainties associated with establishing causality of the association between PM 2.5 and mortality."<sup>36</sup>

## NOTES

<sup>1</sup> Clean Air Act, 42 U.S.C. §§ 108-109.

<sup>2</sup> Environmental Protection Agency, “Latest Findings on National Air Quality: 1999 Status and Trends,” August 2000. Although many attribute these positive air quality trends to the federal government’s involvement since the 1970 CAA, it should be noted that the declines in air pollution began before 1970, thus it is likely that state and local controls as well as technological advances have made substantial contributions to cleaner air. See Indur Goklany, “Clearing The Air: The Real Story of the War on Air Pollution,” (Washington, DC: Cato Institute, 1999).

<sup>3</sup> 42 U.S.C. § 109(d).

<sup>4</sup> 42 U.S.C. § 304(a)(2).

<sup>5</sup> *American Lung Association v. Browner*, 84 F.Supp. 345 (D. Ariz. 1994).

<sup>6</sup> 61 Fed. Reg. 65,637 (December 13, 1996).

<sup>7</sup> The 24-hour standard (the daily average) is designed to protect against short-term spikes in particulate concentrations, while the annual standard protects against long-term exposures. The unit of measurement is the mass of particles 2.5 microns or less in size per cubic meter of air.

<sup>8</sup> 61 Fed. Reg. 65,715 (December 13, 1996).

<sup>9</sup> EPA, “Regulatory Impact Analysis for Proposed Particulate Matter National Ambient Air Quality Standard,” December 1996 (EPA Regulatory Impact Analysis). EPA subsequently revised the cost estimate to \$8.6 billion.

<sup>10</sup> Anne E. Smith, et al., “Costs, Economic Impacts, and Benefits of EPA’s Ozone and Particulate Matter Standards,” Reason Public Policy Institute, June 1997.

<sup>11</sup> EPA Regulatory Impact Analysis, Table 9-11. EPA subsequently reduced its estimate of annual deaths attributed to PM 2.5 from 20,000 to 15,000, after Dr. Kay Jones (the lead author of this monograph) discovered that the agency made an error in interpreting its data; Kay Jones, “Is EPA Misleading the Public About the Health Risks from PM 2.5?” report prepared for Citizens For A Sound Economy Foundation, May 1997.

<sup>12</sup> National Black Chamber of Commerce, “New Rules Will Crush Efforts to Rebuild, Revitalize Inner Cities, Minority Leaders Tell Administration,” June 5, 1997, press release; American Farm Bureau Federation, “Flawed Air Standards Would Choke Agriculture,” July 22, 1997, press release.

<sup>13</sup> Memorandum from Rosina Bierbaum, Acting Associate Director at the White House Office of Science and Technology Policy, to Sally Katzen, Office of Management and Budget, entitled “OSTP Questions For EPA On Its Proposed Revisions To The Ozone and Particulate Matter Air Quality Standards,” November 15, 1996.

<sup>14</sup> George T. Wolff, “The CASAC Review Of The Ozone And PM Standards,” written testimony before the House Subcommittees on Health and Environment and Oversight and Investigations, April 10, 1997.

<sup>15</sup> *Ibid.*

<sup>16</sup> *Ibid.*

<sup>17</sup> Jones, “Is EPA Misleading the Public,” pp. 14-18.

<sup>18</sup> Douglas W. Dockery, et al., “An Association Between Air Pollution and Mortality in Six U.S. Cities,” *New England Journal of Medicine*, vol. 329 (1993), pp. 1753-1759 (cited below as Harvard Six Cities study); C.A. Pope, et al., “Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults,” *American Journal of Respiratory Critical Care Medicine*, vol. 151 (1995), pp. 669-674 (cited below as American Cancer Society study).

<sup>19</sup> Wolff, “The CASAC Review Of The Ozone And PM Standards.”

<sup>20</sup> *Ibid.*

<sup>21</sup> H. R. 1984 and S. 1084, 105th Congress (1997).

<sup>22</sup> 62 Fed. Reg. 38,652 (July 18, 1997); 62 Fed. Reg. 38,856 (July 18, 1997). The 24-hour standard for PM 2.5 was changed to 65 micrograms per cubic meter.

<sup>23</sup> *American Trucking Associations v. Environmental Protection Agency*, 175 F.3d 1027 (D.C. Cir. 1999) *rehearing granted in part, denied in part* 195 F.3d 4 (D.C. Cir. 1999).

<sup>24</sup> *Whitman v. American Trucking Associations*, 531 U.S. \_\_\_\_ (2001).

<sup>25</sup> Suresh Moolgavkar, et al., “Particulate Air Pollution, Sulfur Dioxide, and Daily Mortality, A Reanalysis of the Steubenville Data,” *Inhalation Toxicology*, vol. 7 (1995), pp. 35-44; Jones, “Is EPA Misleading the Public,” pp. 18-19.

<sup>26</sup> Jennifer Zambone, “The Data Access Law: Decreasing Secret Science While Increasing Accountability” (Washington, DC: Competitive Enterprise Institute, June 7, 1999).

<sup>27</sup> Health Effects Institute, “Synopsis of The Particle Epidemiology Project,” press release, July 2000.

<sup>28</sup> Carol Browner, National Press Club, October 3, 2000; available at [epa.gov/opa/admspchs](http://epa.gov/opa/admspchs).

<sup>29</sup> Bureau of National Affairs Daily Environment Report, “Independent Review of Studies Used by EPA Verifies Link Between Particulates, Mortality,” August 1, 2000, p. AA-1.

<sup>30</sup> Jocelyn Kaiser, “Panel Backs EPA and ‘Six Cities’ Study,” *Science*, vol. 289, August 4, 2000, p. 711.

<sup>31</sup> The importance of education status strongly suggests that socioeconomic or demographic factors have a more significant public-health impact than particulate matter exposure, and that these factors have not been adequately addressed in the original study or the reanalysis.

<sup>32</sup> Jocelyn Kaiser, “Evidence Mounts That Tiny Particles Can Kill,” *Science*, vol. 289, July 7, 2000, pp. 22-23; but see Suresh Moolgavkar, “Consideration of Copollutants,” *Science*, vol. 290, October 20, 2000, p. 453.

<sup>33</sup> The NMMAPS investigators did not provide any rationale for their regional boundaries used in the Regional Adjustment Model, other than citing EPA’s prior designation. There is no obvious logic for their boundary assumptions. For example, the 11 Texas cities were split into two geographical regions, and the San Joaquin Valley was similarly divided. In addition, Oakland, Sacramento, San Jose, Stockton, and Modesto, California, and Denver and Colorado Springs, Colorado, were all considered Northwest cities. This unexplained regionalized approach may well have biased the results.

<sup>34</sup> This is due to data trimming (the removal of high and low values so they don’t unduly influence the statistical analysis), as well as the averaging time used for the ozone data. The ozone and mortality association found in the Veterans’ Cohort study supports this criticism.

<sup>35</sup> Frederick Lipfert, et al., “The Washington University-EPRI Veterans’ Cohort Mortality Study: Preliminary Results,” *Inhalation Toxicology*, vol. 12, supp. 4 (2000), pp. 41-73.

<sup>36</sup> George T. Wolff, Closure Letter on Draft OAQPS Staff Paper on Particulate Matter from Chairman of Clean Air Scientific Advisory Committee to EPA Administrator, June 13, 1996.

## ABOUT THE AUTHORS

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Ben Lieberman is a senior policy analyst at CEI. His most recent work has focused on the effect of EPA regulations on energy prices. Mr. Lieberman also covers the consumer impact of environmental regulations, such as those mandating low-flush plumbing fixtures and energy-efficient appliances and residences. He received his JD from the George Washington University.