EPA's Case for New Ozone and Particulate Standards: Would Americans Get Their Money's Worth?

by Stephen Huebner and Kenneth Chilton

Policy Study Number 139

June 1997
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Introduction

On November 27, 1996, the U.S. Environmental Protection Agency (EPA) proposed new National Ambient Air Quality Standards (NAAQS) for ground-level ozone ($\text{O}_3$, commonly called smog) and fine particles 2.5 microns or less in diameter ($\text{PM}_{2.5}$). The new standards represent the most extensive increase in the reach of environmental regulation since the 1990 Clean Air Act Amendments; they would at least triple the number of areas that do not meet federal air quality requirements.

The NAAQS proposal has stirred up an intense debate. On one side, the American Lung Association and environmental organizations such as the Natural Resources Defense Council are pushing for the tightest possible standard.

On the other side of the issue, industry groups such as the National Association of Manufacturers and the American Petroleum Institute raise concerns about the high costs of tightening pollution standards.$^1$ Both the environmentalists and the industrialists claim to have the facts on their side, as well as the recommendations of EPA’s scientific oversight committee, the Clean Air Scientific Advisory Committee (CASAC).

The issue is further complicated by EPA’s decision to propose new standards for ozone and fine particulates simultaneously. As a result of a lawsuit by the American Lung Association, the EPA is under a court order to make its final decision on particulates by July 19. However, the ozone-standard review is not on a similar court-ordered schedule. The agency defends its decision to review the two standards simultaneously by claiming that the two pollutants share many contributory sources, thus warranting an integrated approach.

Whatever the rationale for proceeding with the two standards in tandem, the practical effect is to blur the merits of the case for each of them individually. While the scientific research on ozone is extensive, the science on fine particulates is in its infancy. Medical research on ozone shows that the adverse physical reactions to this pollutant are generally mild, reversible, and largely avoidable (by restricting physical activity when ozone levels are high). Little is known about $\text{PM}_{2.5}$ and how it harms humans. Two large-scale studies show a link between elevated levels of fine par-

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articles and premature death. This relationship has not been established with the degree of certainty that many medical experts and others would like, however.

When the distinction between the effects caused by ozone and particulates is not made clear, the benefit-cost relationships are also distorted. The high costs of the ozone NAAQS are offset in the public mind by the high benefits claimed to be coming from the particulate standard. The costs of reducing ambient ozone levels to meet the proposed NAAQS alone are formidable, while the benefits to public health are miniscule. In short, the ozone proposal flunks a cost-benefit test.

For the fine particulate standard, EPA has calculated benefits that are many times the costs. These high benefit estimates are derived mainly from the agency’s valuation of $4.8 million per prolonged life (regardless of length of prolongation) multiplied by 21,000 lives estimated to be “saved.” In April 1997, the number of lives that are projected to be saved was revised downward to 15,000.

The following study is an objective analysis of two important issues in the debate over new air quality standards for ozone and fine particulates: the science and the economics. The first section briefly reviews EPA’s standard-setting process. The next two sections explain the scientific and medical evidence of the human health effects of ozone and fine particulates, respectively. The two subsequent sections address the costs and benefits of the proposed standards, with particular attention given to EPA’s regulatory impact analyses. Finally, policy recommendations are given based on both the scientific and economic evidence.

**EPA’s Standard-Setting Process**

The Clean Air Act is arguably the single most significant U.S. environmental statute. While the act has undergone several revisions since its inception, including the Clean Air Act Amendments of 1990, its basic mission remains unchanged: to establish and enforce air quality standards that protect public health with an adequate margin of safety.

To carry out this mission, EPA established NAAQS for six common air pollutants. These pollutants, known as “criteria” pollutants, are: carbon monoxide, lead, nitrogen dioxide, ground level ozone (smog), sulfur dioxide, and particulate matter (PM) with a diameter of 10 microns or less (PM_{10}). EPA sets two types of standards: primary and secondary. Primary standards are meant to protect human health; secondary standards are intended, for the
most part, to protect vegetation and physical structures.

According to the Clean Air Act, EPA is supposed to review its air quality standards every five years to ensure that they reflect the latest scientific and medical information. Because EPA did not review the particulate matter NAAQS on its required five-year schedule, the American Lung Association sued the agency. As a result, EPA is now on a court-ordered deadline to complete its review by July 19, 1997. The agency has decided to simultaneously review the ozone NAAQS on this accelerated schedule.

The Clean Air Act is arguably the single most significant U.S. environmental statute

As a result of its ozone review, EPA plans to change the primary standard from a level of 0.12 parts per million (ppm) averaged over one hour to a level of 0.08 ppm averaged over eight hours. The rationale for changing from a one-hour to an eight-hour averaging time is that longer exposures may be more consistent with exposure risks faced by the population groups of most concern — children playing outdoors and outdoor workers. The proposal also changes how particle concentrations are measured to test for attainment to a “concentration-based form,” which uses the three-year average of the annual third-highest maximum concentrations to determine attainment, as opposed to the current form, which (in essence) allows one exceedance a year.

For particulates, EPA has proposed retaining the current annual standard for daily average levels of PM$_{10}$ at 50µg/m$^3$ (micrograms per cubic meter). EPA also has proposed modifying the maximum 24-hour PM$_{10}$ standard, set at 150µg/m$^3$, by making the form more stable. More importantly, the agency has proposed enacting new standards for fine particulate matter, which has recently been identified as a possible threat to human health. The standards would allow an annual average fine particle concentration of 15µg/m$^3$ and a 24-hour concentration of 50µg/m$^3$.

The EPA says that the scientific evidence shows a clear need for new ozone and fine particulate air quality standards. According to EPA Administrator Carol Browner, “We are constantly reviewing the science associated with these standards, but we do not often propose revisions to them. I have done so in the case of ozone and particulate matter because of compelling new scientific evidence.”

According to the EPA, its review of the scientific and technical
literature relevant to ozone and particulate matter encompasses thousands of peer-reviewed studies.\textsuperscript{5} As part of the review process for each standard, the EPA produces two documents known as the “Criteria Document” and the “Staff Paper.”\textsuperscript{6} The Criteria Document is a lengthy (three volume) compilation intended to reflect all of the available scientific information. The Staff Paper is a scientific and technical assessment based on a subset of the Criteria Document studies and serves as the basis for the EPA administrator’s policy decisions.

In addition to these documents, the agency conducted risk assessments to estimate the harm Americans are suffering from current pollution levels and the improvement in public health from the proposed standards.

With such an extensive review, it would seem that the EPA administrator’s proposals would be hard to criticize. Such is not the case, however.

**Scientific Evidence on the Health Effects of Ozone**

The science on ozone includes over two decades of medical research on human physical responses to elevated levels of ozone. Although ozone has been demonstrated in clinical studies to cause undesirable physical reactions at levels that occasionally occur in ambient air, these effects are minor, temporary, and, for the most part, unnoticeable unless an individual is engaged in moderate to heavy exercise.

It should be recognized that all health effects from ozone cannot be eliminated, because physical responses can be demonstrated at background levels — levels produced by natural processes. The Clean Air Scientific Advisory Committee noted this in its closure letter to EPA Administrator Browner:

\begin{quote}
The Panel felt that the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations. Based on information now available, it appears that ozone may elicit a continuum of biological responses down to background concentrations.\textsuperscript{7}
\end{quote}

According to EPA’s Staff Paper, one-hour background ozone concentrations in the United States range from 0.03 ppm to 0.05 ppm during the summer, but can be as high as 0.060 ppm to 0.075 ppm at sites in the western United States. The document says a reasonable estimate of eight-hour background concentrations is also from 0.03 ppm to 0.05 ppm.\textsuperscript{8}
The Staff Paper identifies several health effects of concern based on clinical and epidemiological studies. Clinical results identify effects such as increased respiratory symptoms — wheezing, coughing, tightness in the chest, and decreased lung function. Epidemiological data suggest some increase in hospital visits and admissions for respiratory causes including asthma. Animal tests at very high doses raise concerns about possible impairment of lung defense mechanisms and irreversible changes in lung structure.

The EPA identified several populations that are at increased risk from ozone exposure: children, asthmatics, and adults who work or exercise moderately outdoors during the summer months. Children are a concern because they breathe a greater volume of air in proportion to their body mass than adults do. They also tend to spend more time outdoors and are less likely to notice respiratory symptoms and reduce activity. Finally, it is argued that children's respiratory systems, because they are not fully developed, are more susceptible to the threats posed by air pollution. EPA identifies asthmatics as a sensitive population because ozone may aggravate their condition and induce asthma attacks. Adults who work or exercise outdoors, such as construction workers, are identified as a population at risk because of their repeated, lengthy exposures to ozone while undergoing fairly heavy physical exertion.

Since proposing the standard in November 1996, EPA has revised its estimates of the risks to human health posed by ozone exposure. The result is less public health benefits expected from the proposed NAAQS. Table 1 presents EPA's original and revised risk assessments for several health effects.

**Respiratory Symptoms**

As to the most common human health effect, respiratory symptoms, EPA has identified a number of studies that purport to show adverse human reactions to ozone exposure at levels as low as 0.08 ppm (the level of the proposed standard).

The EPA Staff Paper estimates the relationship between changes in lung function and various combinations of exercise levels and ozone concentrations for a two-hour exposure with increasing levels of intermittent exercise. Typical subjects experience less than a 5 percent loss in lung function even at the highest ozone levels recorded in the United States in 1996 (about twice the current standard).9

Several recent clinical studies found decreases in lung func-
tion among moderately exercising individuals exposed to ozone over longer periods. One study measured breathing capacity after 6.6-hour exposure to various ozone levels. The study subjects — healthy males — who exercised at a ventilation rate of 40 liters per minute (L/min) for six 50-minute periods, experienced an average decline in lung function of 7 percent at 0.08 ppm and 0.10 ppm ozone levels. Other clinical studies found similar results.

The Staff Paper conjectures that people with preexisting illnesses that limit pulmonary function (e.g. chronic obstructive pulmonary disease, ischemic heart disease) may suffer more significant effects from ozone exposure than healthy people. But the document also notes that, “Unfortunately, not enough is known about the responses of these individuals to make definitive conclusions regarding their relative sensitivity to O₃.”

**Hospital Admissions**

<table>
<thead>
<tr>
<th>Health Endpoint</th>
<th>Revised Estimate</th>
<th>Original Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased lung function in children (FEV₁ ≥ 15%)</td>
<td>850,000</td>
<td>1.5 - 2 million</td>
</tr>
<tr>
<td>Decreased lung function in children (FEV₁ ≥ 20%)</td>
<td>240,000</td>
<td>440,000</td>
</tr>
<tr>
<td>Moderate to severe chest pain in children</td>
<td>160,000</td>
<td>300,000</td>
</tr>
<tr>
<td>Moderate to severe cough in children</td>
<td>30,000</td>
<td>90,000</td>
</tr>
</tbody>
</table>

*FEV₁ (Forced Expiratory Volume in one second) is the volume of air that can be rapidly exhaled in one second.*

**Source:** Memorandum, “Supplemental Ozone Exposure and Health Risk Analyses,” Harvey M. Richmond, EPA OAQPS Risk and Exposure Group, to Karen Martin, EPA OAQPS Health Effects and Standards Group, February 11, 1997. This memorandum provides revised risk assessments for nine major urban areas. The figures presented here are national estimates, which are approximately three times the nine-city estimates (based on a telephone conversation with Harvey Richmond).
EPA identifies increased hospital admissions for respiratory causes, including asthma episodes, as another significant effect of elevated ozone concentrations. The agency points to several studies conducted in the northeastern United States and southeastern Canada that show an association between high levels of ozone during the summer months and small increases in daily respiratory-related hospital admissions.

A study published in 1992 by Thurston et al. is relied upon heavily in making the hospital-admission ozone-concentration connection. The researchers examined data from three New York metropolitan areas on daily hospital admissions for asthma and all respiratory causes, as well as air pollution data. The results for New York City show that each 0.10 ppm change in the ozone level is associated with a change of between 0.7 and 1.6 asthmatic admissions per million people. The corresponding change in admissions for all respiratory causes is between 0.8 and 1.9 per million population.

EPA extrapolated the results of this study to estimate the reduction of asthmatic hospital admissions in New York City that would result from attaining the proposed NAAQS compared to reaching the current standard. According to EPA’s recent risk assessments, the proposed standard would prevent about 30 asthmatic admissions in New York City during the ozone season. This represents only one-tenth of 1 percent of the 28,000 total New York City asthmatic admissions each year.

**Long-Term Health Effects**

EPA also raises the concern that repeated, long-term exposures to elevated levels of ozone may cause chronic health effects. It is hypothesized that repeated lung inflammation due to ozone exposure may lead to impaired lung defense and irreversible changes in lung structure. Neither of these claims is supported by the available human-health evidence, however.

As for repeated lung inflammation, the existence of the effect on some individuals is not disputed. Rather, the debate is about whether the effect is long-lasting. Infections such as the common cold and mild influenza often induce more severe airway inflammation than a typical ozone exposure. Yet there is little concern about the adverse consequences produced by these more common assaults on the respiratory tract.

**Impaired Lung Defense.** It has been suggested that ozone may impair the body’s ability to defend against particles and bacteria. A normally functioning human respiratory tract has a number of
mechanisms that protect against inhaled particles and microbes. Ozone has been hypothesized to impair these defenses, for example, by limiting the respiratory tract’s ability to clear harmful inhaled substances. However, most of the studies on this effect have used animals.

One study shows that rats exposed to ozone and then asbestos retain more of the asbestos fibers in the lungs after 30 days than rats only exposed to asbestos, although the initial amount of fibers deposited in the lungs was the same. This suggests that the effectiveness of the mucociliary clearance mechanism in ozone-exposed rats was reduced. However, according to the EPA Criteria Document, animals repeatedly exposed to ozone generally do not exhibit impaired mucociliary clearance. Furthermore, few studies have examined ozone’s effect on human mucociliary clearance, and the results of these few studies conflict.16

There is no conclusive evidence of chronic respiratory disease or dysfunction in humans due to ozone exposure

Other studies show that exposure to ozone and then bacteria increases mortality in mice. However, a similar increase in mortality is not observed in other rodent species, suggesting that ozone’s effects on different species are not comparable.17 This limits the usefulness of animal studies in determining ozone’s effects on human lung defense mechanisms.

Changes in Lung Structure. In support of its proposed standard, EPA claims that repeated ozone exposure may permanently damage lung tissue in a way that is “something like repeated sunburns of the lungs.”18 This claim is based on the following reasoning: it is known that repeated sun exposures can cause irreversible damage to the skin, therefore ozone exposures over months or years might cause irreversible lung tissue damage.19

This claim may sound plausible, but such assertions require scientific validation. There is no conclusive evidence of chronic respiratory disease or dysfunction in humans due to ozone exposure. Indeed, the “sunburn” analogy is at variance with the agency’s own staff report, which concluded:

Taken as a whole, these studies suggest that it is not possible to conclude if there is an effect of O₃ on the health effects studied [chronic respiratory dysfunction and disease]. . . . [T]he appropri-
ate conclusion to be drawn at this time is that associations between O₃ exposure and chronic health impacts have not been sufficiently demonstrated in humans.²⁰

Supporters of the new ozone standard cite research suggesting that ozone may induce structural changes in the lungs of rats. The EPA Staff Paper points to several papers based on a study by the National Toxicology Program and the Health Effects Institute.²¹ Rats were exposed to 0.0, 0.12, 0.5, or 1.0 ppm ozone for six hours per day, five days per week, for 20 months. Changes in the animals’ lung structure were observed at 0.5 ppm and 1.0 ppm — levels well beyond any found in ambient air. No changes were observed in the rats exposed to 0.12 ppm ozone (this is the level allowed for one hour a year under the present standard). Furthermore, pulmonary function was not affected at any exposure level.²²

The results of rat studies should not be interpreted to mean that the same (extraordinarily high) ozone levels would have similar effects on humans. Significant physiological differences between species may cause them to be affected by ozone exposure differently. Recall the differences found in the responses of mice and other rodents in the studies of ozone’s effects on lung defense mechanisms.

The EPA Staff Paper states that the animal toxicology data “provides a biologically plausible basis” for the possibility that repeated ozone exposure over a lifetime may be detrimental to human health, “although such relationships remain highly uncertain.”²³ [emphasis added]

Based on its review of the available scientific evidence, the EPA staff concluded that ozone has not been shown to cause adverse chronic health effects in humans with any degree of certainty: “[I]t is highly uncertain whether there are resultant functional or impaired health outcomes in humans chronically exposed to O₃, particularly because the human exposure scenario involves much longer-term exposures than can be investigated in the laboratory.”²⁴

Summary

The scientific and medical evidence on ozone is fairly extensive. Ozone causes short-term physical effects in some individuals, although these effects should not be considered “adverse” in most cases. The hypothesis that current ozone levels in U.S. cities cause long-term, chronic health effects is not supported by the scientific evidence, despite substantial research. Epidemiological
research indicates a possible link between ozone levels and hospital visits and admissions for respiratory problems. But the expected reductions in these effects from meeting the proposed standard instead of the current standard are very small. In short, the proposed new ozone standard is not likely to provide much meaningful health benefit for most Americans.

Scientific Evidence on the Health Effects of Fine Particulates

Particulate air pollution has been blamed for a variety of adverse health effects in numerous studies. Most are epidemiological studies which compare the incidence of health effects with air pollution levels as they fluctuate over time or across geographic regions. Among the health problems identified are decreased lung function, work and school absences, chronic bronchitis, and mortality. The vast majority of research on particulate air pollution has been on PM$_{10}$ (coarse-mode particles 10 microns or less in diameter) and total suspended particulates (TSP). Evidence of the health effects of fine particulates is more recent and more sparse.

In its latest review, EPA concluded that the National Ambient Air Quality Standards in place for PM$_{10}$ adequately protect public health, and, therefore has reaffirmed them with minor modifications. The area of controversy is the scientific underpinnings of the proposed new standard for PM$_{2.5}$. For this reason, this section will focus only on the scientific evidence on that issue.

In testimony before the Senate Committee on Environment and Public Works, EPA Administrator Carol Browner suggested that the scientific evidence on fine particulates is extensive. “[A] number of the new health and atmospheric science studies have highlighted significant health concerns with regard to the smaller ‘fine’ particles,” she testified. “EPA analyzed peer-reviewed studies involving more than five and a half million people that directly related effects of ‘fine’ particle concentrations to human health.”

The scientific evidence on fine particulates is far less extensive than Administrator Browner’s words infer, however. The fine particle fraction of particulate matter has only recently been identified as a human health concern, and there are relatively few studies that link PM$_{2.5}$ concentrations with adverse health effects. EPA identifies 27 studies in its Staff Paper that show associations between indicators of fine particulates and health effects. Only seven of these studies use PM$_{2.5}$ as the indicator of fine particulates, and two more use PM$_{2.1}$, a good surrogate. The remaining eighteen
studies use other indicators (see Table 2).

EPA believes the fine particulate NAAQS would prevent 15,000 premature deaths each year.\textsuperscript{26} When the standard was proposed in November, the estimate was 20,000 lives “saved” (although a figure of 21,000 was assumed for the purpose of calculating monetary benefits).\textsuperscript{27} EPA also estimates that the fine particulate standards would result in over 9,000 fewer hospital admissions; 60,000 fewer cases of respiratory symptoms associated with chronic bronchitis; over 250,000 incidences of respiratory symptoms (coughing and breathing trouble) in children; and 250,000 incidences of aggravated asthma.\textsuperscript{28}

The Evidence on Mortality

Clearly, mortality is the health effect of greatest concern. The Dockery et al. (1993) and Pope et al. (1995) studies, which show an association between fine particles and premature mortality, are relied on most heavily in making the PM\textsubscript{2.5}-mortality case. An “association” means that mortality tends to be higher when fine particulate concentrations are elevated.

The first of the two mortality studies was published in 1993 by Douglas Dockery of the Harvard School of Public Health and other researchers.\textsuperscript{29} This study, known as the Harvard Six Cities Study, followed over 8,000 adults in six U.S. cities from the mid-1970s to 1989. After controlling for individual-level risk factors (age, sex, smoking, body mass, hypertension, diabetes, and occupational exposure) the study found that residents of the most polluted city, Steubenville, Ohio, were 26 percent more likely to die prematurely from “all causes” than residents of the least polluted city studied, Portage, Wisconsin. (For comparison, smoking has been found to increase the risk of developing lung cancer by as much as 3,000 percent.)\textsuperscript{30}

The second major mortality study was funded by the American Cancer Society (ACS) and published in 1995. Led by Brigham Young University economist C. Arden Pope, this study followed over 500,000 people between 1982 and 1989 in 151 U.S. cities. PM\textsubscript{2.5} data were collected from 1979 to 1983 in 50 of the cities.\textsuperscript{31} After controlling for individual-level risk factors (age, sex, smoking, occupational exposure, education, and alcohol use), the study found a 17 percent greater chance of premature death from “all causes” in the most polluted areas relative to the least polluted.

The results of these studies are consistent with the outcomes from a number of PM\textsubscript{10} studies. Proponents of new PM\textsubscript{2.5} standards argue that this consistency of outcomes is clear evidence that fine
Table 2

<table>
<thead>
<tr>
<th>Health Effect</th>
<th>Pollution Indicator Used</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>PM$_{2.5}$</td>
<td>Schwartz et al. (1996)</td>
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<tr>
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<td>PM$<em>{2.5}$, PM$</em>{10/15}$</td>
<td>Dockery et al. (1993)</td>
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<tr>
<td></td>
<td>SO$_4^{2-}$</td>
<td>(“Six City” Study)</td>
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<td></td>
<td>PM$_{2.5}$, SO$_4^{2-}$</td>
<td>Pope et al. 1995</td>
</tr>
<tr>
<td></td>
<td>Black smoke$^a$</td>
<td>Ito et al. (1993)</td>
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<td></td>
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<td>Katsouyanni et al. (1990)</td>
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<td>Touloumi et al. (1994)</td>
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<td></td>
<td>Carbonaceous Material$^a$</td>
<td>Shumway et al. (1988)</td>
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<tr>
<td></td>
<td>Coefficient of Haze$^a$</td>
<td>Kinney and Ozkaynak (1991)</td>
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<td></td>
<td></td>
<td>Fairley (1990)</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>H$^+$, SO$<em>4^{2-}$, PM$</em>{2.5}$</td>
<td>Thurston et al. (1994)</td>
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<td>SO$_4^{2-}$</td>
<td>Burnett et al. (1994)</td>
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<td></td>
<td>SO$_4^{2-}$, O$_3$</td>
<td>Thurston et al. (1992)</td>
</tr>
<tr>
<td>Respiratory symptoms, bronchitis, decreased lung function</td>
<td>PM$_{2.5}$, SO$_4^{2-}$, H$^+$</td>
<td>Ostro et al. (1991)</td>
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<td>PM$<em>{2.5}$, H$^+$, “PM$</em>{2.5}$ Sulfur”</td>
<td>Schwartz et al. (1994)</td>
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<td>PM$_{2.5}$</td>
<td>Neas et al. (1995)</td>
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<td>PM$_{2.1}$, H$^+$, SO$<em>4^{2-}$, PM$</em>{10}$</td>
<td>Dockery et al. (1996)</td>
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<td>PM$_{2.1}$, H$^+$, SO$<em>4^{2-}$, PM$</em>{10}$</td>
<td>Raizenne et al. (1996)$^p$</td>
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<td>SO$_4^{2-}$</td>
<td>Ostro et al. (1993)</td>
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<td>SO$_4^{2-}$</td>
<td>Abbey et al. (1995) (3 papers)</td>
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<td>PM$_{15/10}$</td>
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<td>TSP</td>
<td>Ware et al. (1986)</td>
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<tr>
<td></td>
<td>H$^+$, SO$_4^{2-}$</td>
<td>Koenig et al. (1993)</td>
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</tbody>
</table>

$^a$ Black smoke, carbonaceous material, and coefficient of haze are optical measurements that are not directly related to fine particulate concentrations.

$^b$ Pollutant data is the same as for Dockery et al. 1996.

particulates cause mortality. Studies conducted in different geographic locations with different pollution and weather patterns, they argue, are unlikely to repeatedly yield similar results by chance.

**Why the Epidemiological Evidence on Mortality Is Flawed**

Although epidemiological studies show an association between particulates and mortality, their results should be read with caution. The risks detected in the fine particulate studies are small relative to other risks detected by epidemiology, and may be distorted by a number of biases and uncertainties. It is therefore difficult to draw definite conclusions from the results.

A July 1995 *Science* article quotes Dr. Dimitrios Thichopoulos, head of the Harvard School of Public Health’s epidemiology department, on the limits of epidemiology. He said that studies will inevitably generate false positive and false negative results “with disturbing frequency.” Most epidemiologists are aware of the problem, Trichopoulos added, “and tend to avoid causal inferences on the basis of isolated studies or even groups of studies in the absence of compelling biomedical evidence.”

A convincing case against fine particulates would include evidence in addition to epidemiological findings, for example from toxicology, to support the hypothesis that particulates cause mortality. This evidence currently does not exist. Furthermore, the epidemiological studies are plagued by a variety of uncertainties, not the least of which is the possibility of confounding.

**Confounding by Copollutants**

Confounding is the influence of unmeasured or unidentified variables on the studied health effect. These “uncontrolled” factors may be associated with the exposure to particulates. For example, temperature, humidity, or the existence of other air pollutants may cause mortality rates to rise and fall with, and thus appear to be caused by, fine particulate concentrations.

Many of the components of air pollution tend to be correlated
with each other, meaning that high levels of one pollutant tend to coincide with high levels of another. For example, in many U.S. cities sulfur dioxide (SO₂), ozone (O₃), nitrogen dioxide (NO₂), and carbon monoxide (CO) are frequently correlated with particulate concentrations, making it impossible to determine which pollutant, or group of pollutants, is causing health problems.

The EPA Staff Paper recognizes the difficulty of determining which one(s) of multiple, correlated pollutants is responsible for the health effects of concern:

Inherent in epidemiological studies such as those cited in this review is the question as to whether, or to what extent, the observed effects attributed to PM exposures are confounded by other pollutants commonly occurring in community air, such as SO₂, ozone, NO₂, and CO... It may not be possible to separate individual effects of multiple pollutants when those pollutants are highly correlated within a given area.33 [Emphasis added.]

**Unknown Biological Mechanism**

Medical science has not yet discovered a biologically plausible mechanism to explain how fine particulates cause deaths. Although a variety of airborne particles are suspect, it is not clear which may be the most important, or exactly what characteristics of the particle cause the harm. This information would be necessary to conclude that fine particles cause mortality. The EPA Staff Paper recognizes this uncertainty:

One of the most notable aspects of the available information on PM is the lack of demonstrated mechanisms that would explain the mortality and morbidity effects associated with PM at ambient levels reported in the epidemiological literature. The absence of such mechanistic information limits judgments about causality of effects and appropriate concentration-response models to apply in quantitatively estimating risks.34

The statistical association shown in both the Six City and ACS studies is either between fine particulate matter and cardiovascular and pulmonary deaths grouped together, or between fine particulate matter and deaths due to “all causes.” Curiously, results for deaths due to nonmalignant respiratory disease alone were neither stable nor statistically significant in the Six City study as would be expected.35 The ACS study does not report results for respiratory causes of death, although it did find no association between fine particles and lung cancer deaths.

It is unlikely that many of the deaths due to cardiovascular disease could be caused by air pollution.36 Cardiovascular disease
includes congenital heart disease, hypertensive heart disease, valvular heart disease, as well as heart attacks and strokes. Similarly, the “all cause” category includes deaths due to murder, accidents, suicide, and other causes that cannot plausibly be linked to fine particulates. Indeed, one group of medical doctors suggested in their public comments to the EPA that the studies’ authors may have conducted statistical “fishing expeditions.”

How “Premature” Are Anticipated Deaths?

The importance of the association between fine particulates and mortality logically depends upon the extent of the life-shortening effect and the previous state of health of the individuals affected. According to the Staff Paper, “Available epidemiological evidence provides a very limited basis for testing hypotheses as to whether and to what extent lifespans are shortened by only a few days or by years.” The American Lung Association estimates that the average life shortening by particulates is two years. Nonetheless, EPA implicitly assumes a much longer shortening of life in calculating health benefits for the proposed standard (addressed later in this analysis).

Concentration-response

In estimating changes in health effects from lower particulate concentrations, EPA assumes the relationship between particulates and death is linear (i.e. an increase in fine particulate concentration from, say, 5µg/m³ to 10µg/m³ would cause the same number of additional deaths as an increase from 35µg/m³ to 40µg/m³).

However, there may be a threshold concentration below which the effects of particulates are very low or undetectable. An analysis of Philadelphia air quality and mortality data suggests that the concentration-response function is not linear.

The EPA Staff Paper cautions that the assumption of a linear concentration response function “significantly affects the confidence with which risks and risk reductions can be estimated.” Dr. Thomas Starr, an environmental health science expert with ENVIRON International, expanded on this in testimony before the Senate Subcommittee on Clean Air, Wetlands, Private Property and
Nuclear Safety:

Because most days of the year have low to mid-range levels of PM, the estimated health benefit over an entire calendar year of daily PM exposures is dominated by the contribution from the many days with low to moderate levels of PM. This is precisely the exposure range for which the empirically determined log-linear dose-response relationships are most uncertain.42

Thus, a large part of the expected health benefits is driven by exposure to low or moderate particulate levels, although these levels may actually not increase risk at all, due to the existence of a threshold.

Data Limitations

Our modest understanding of the health effects of fine particles is exacerbated by the lack of monitoring data. Currently, there are only 51 PM$_{2.5}$ monitors operating in the United States,43 whereas there are nearly 1,000 ozone monitors and over 1,700 PM$_{10}$ monitors.44 To make claims for the lifesaving benefits of reducing levels of fine particles — such as avoiding “15,000 premature deaths” — PM$_{2.5}$ concentrations must be projected for many cities where monitoring data do not exist.

Other Health Effects

EPA has attributed several other negative effects on human health to particulate air pollution. These include hospital admissions and emergency room visits, school absences, work days lost, restricted activity days, decreased lung function, respiratory symptoms, possible lung damage, and effects on host defense mechanisms. Again, most of this evidence associates TSP and PM$_{10}$ with the health effects of concern; very little of it is relevant to the need for a new fine particulate standard.

The Staff Paper identifies sixteen studies that show positive associations between exposure to indicators of fine particles (e.g. PM$_{2.5}$, PM$_{2.1}$, SO$_4^{-2}$, O$_3$) and health effects other than mortality. Four associate fine particulate indicators with hospital admissions and twelve associate indicators with respiratory symptoms, bronchitis, or decreased lung function (see Table 2).

But the fine particulate indicator that EPA has chosen to regulate is PM$_{2.5}$. Thus, the strongest evidence to support the agency’s proposal would be studies that seek to identify the effect of PM$_{2.5}$ (or a closely related measurement, PM$_{2.1}$) rather than a surrogate measure, such as O$_3$, or one component of PM$_{2.5}$, say SO$_4^{-2}$.
EPA claims that the proposed fine particulate standard would result in “over 9,000 fewer hospital admissions each year, and many fewer emergency room visits, especially in the elderly and those with existing heart and lung disease.” Of the four studies identified in the Staff Paper to support the claim that elevated particulate concentrations result in hospitalization, three do not use PM$_{2.5}$ as the particulate indicator, but instead use SO$_4^{2-}$ and O$_3$.

Similarly, the Staff Paper identifies twelve studies that associate fine particle indicators with respiratory symptoms, bronchitis, or decreased lung function. Only three use PM$_{2.5}$ as the fine particle indicator, and two more use PM$_{2.1}$.

Consequently, most of the studies EPA identifies to support the fine particulate standard do not study the effects of PM$_{2.5}$, but instead consider other pollutants, some of which are components of PM$_{2.5}$, namely PM$_{2.1}$ and SO$_4^{2-}$, but many of which are only indirectly related to PM$_{2.5}$.

Summary

Unlike the scientific evidence on ozone’s health effects, the science for fine particulates is highly uncertain. EPA justifies its proposed PM$_{2.5}$ standard by claiming that it is supported by an extensive body of evidence. According to Administrator Browner, EPA has based its standards on “compelling” evidence that particulate matter causes premature death and other health effects at current levels in many U.S. cities.

The available evidence is far from “compelling,” however. The science is relatively undeveloped, leaving room for any number of uncertainties to affect the precise relationship between particulates and mortality. For example, confounders cannot be ruled out as the cause of the association. Additionally, no biological mechanism which could plausibly cause human mortality is known. CASAC said as much in its closure letter when it pointed to “the many unanswered questions and uncertainties regarding the issue of causality.” As a result, the committee came to “no consensus on the level, averaging time, or form” for a PM$_{2.5}$ standard.

Indeed, February 5, 1997, testimony by the chair of CASAC before the Senate Subcommittee on Clean Air, Wetlands, Private Property and Nuclear Safety revealed just how tepid the support for the proposed fine particle standard was. Only two of the 21 members of CASAC endorsed a range for an annual PM$_{2.5}$ standard as strict as 15µg/m$^3$ to 20µg/m$^3$. Yet EPA has proposed an annual limit of 15µg/m$^3$. Eight of the members did not support any annual PM$_{2.5}$ standard. (See Table 3.)
## Table 3

### Summary of CASAC Panel Members’ Recommendations for an Annual PM$_{2.5}$ Standard (all units µg/m$^3$)

<table>
<thead>
<tr>
<th>Name</th>
<th>Discipline</th>
<th>PM$_{2.5}$ Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ayres</td>
<td>M.D.</td>
<td>yes$^b$</td>
</tr>
<tr>
<td>Hopke</td>
<td>Atmospheric Scientist</td>
<td>20-30</td>
</tr>
<tr>
<td>Jacobson</td>
<td>Plant Biologist</td>
<td>yes</td>
</tr>
<tr>
<td>Koutrakis</td>
<td>Atmospheric Scientist</td>
<td>yes$^{b,c,d}$</td>
</tr>
<tr>
<td>Larnitz</td>
<td>Statistician</td>
<td>25-30$^e$</td>
</tr>
<tr>
<td>Legge</td>
<td>Plant Biologist</td>
<td>no</td>
</tr>
<tr>
<td>Lippmann</td>
<td>Health Expert</td>
<td>15-20</td>
</tr>
<tr>
<td>Mauderly</td>
<td>Toxicologist</td>
<td>20</td>
</tr>
<tr>
<td>McClellan</td>
<td>Toxicologist</td>
<td>no$^f$</td>
</tr>
<tr>
<td>Menzel</td>
<td>Toxicologist</td>
<td>no</td>
</tr>
<tr>
<td>Middleton</td>
<td>Atmospheric Scientist</td>
<td>yes$^{b,c}$</td>
</tr>
<tr>
<td>Pierson</td>
<td>Atmospheric Scientist</td>
<td>yes$^{b,g}$</td>
</tr>
<tr>
<td>Price</td>
<td>Atmospheric Scientist/</td>
<td>yes$^h$</td>
</tr>
<tr>
<td></td>
<td>State Official</td>
<td></td>
</tr>
<tr>
<td>Shy</td>
<td>Epidemiologist</td>
<td>15-20</td>
</tr>
<tr>
<td>Samet$^a$</td>
<td>Epidemiologist</td>
<td>no</td>
</tr>
<tr>
<td>Seigneur</td>
<td>Atmospheric Scientist</td>
<td>no</td>
</tr>
<tr>
<td>Speizer$^a$</td>
<td>Epidemiologist</td>
<td>no</td>
</tr>
<tr>
<td>Stolwijk</td>
<td>Epidemiologist</td>
<td>25-30$^e$</td>
</tr>
<tr>
<td>Utell</td>
<td>M.D.</td>
<td>no</td>
</tr>
<tr>
<td>White</td>
<td>Atmospheric Scientist</td>
<td>20</td>
</tr>
<tr>
<td>Wolff</td>
<td>Atmospheric Scientist</td>
<td>no</td>
</tr>
<tr>
<td><strong>EPA Staff</strong></td>
<td></td>
<td><strong>12.5-20</strong></td>
</tr>
</tbody>
</table>

**Notes:**

a Not present at meeting; recommendations based on written comments.
b Declined to select a value or range.
c Concerned upper range is too low based on national PM$_{2.5}$ PM$_{10}$ ratio.
d Leans toward high end of staff-recommended range.
e Desires equivalent stringency as present PM$_{10}$ standards.
f If EPA decides a PM$_{2.5}$ NAAQS is required, the 24-hour and annual standards should be 75 and 25 µg/m$^3$, respectively with a robust form.
g Yes, but decision not based on epidemiological studies.
h Low end of EPA’s proposed range is inappropriate; desires levels selected to include areas for which there is broad public and technical agreement that they have PM$_{2.5}$ pollution problems.

**Source:** CASAC Closure Letter on the Staff Paper for Particulate Matter, June 13, 1996, docketed as EPA-SAB-CASAC-LTR-96-008, Table 1.
Economic Analysis

The Clean Air Act requires that air quality standards be established to protect public health with an adequate margin of safety. Other factors, notably economic cost, may not be considered. EPA Administrator Browner supported these provisions in her testimony to the Senate Committee on Environment and Public Works, stating: “Costs of meeting the standards and related factors have never been considered in setting the national ambient air quality standards themselves. . . . I continue to believe that this is entirely appropriate.”

Shortly following the announcement of its proposed National Ambient Air Quality Standards for ozone and particulate matter, the EPA released a Regulatory Impact Analysis (RIA) for each. These documents estimate the annual cost to comply with the standards in the year 2007, as well as the value of the benefits that would result.

According to EPA, the purpose of the RIAs is to inform the public. They are not to play a role in the decision to enact new air quality standards: “As interpreted by the agency and the courts, this decision is a health-based decision that specifically is not to be based on cost or other economic considerations.”

Setting air quality standards without considering costs sounds very high minded. But most economists would question the wisdom of ignoring the relationship between costs and benefits of public policy actions. An estimate of the costs and benefits of an action (of reducing ozone levels, for example) gives the decision maker crucial information about what must be foregone in terms of other resource uses (say cancer screening or educational spending). Where added costs exceed benefits, other potentially more valuable applications of these resources cannot be pursued. Economists refer to the value of these foregone alternatives as the “opportunity cost” of pursuing pollution reductions. While the tradeoffs between spending to reduce ozone levels and spending for other public health benefits are not direct, they are no less real.

Basing regulatory decisions on a cost-benefit comparison can roughly approximate outcomes that are efficient in an economic sense. Basing decisions only on whether they will produce benefits, however large or small, virtually ensures inefficient outcomes.

The key to creating the most benefit for society from air pollution regulation is to set standards at levels that provide more incremental benefits than incremental costs. Once the cost of
removing an additional unit of pollution exceeds the benefit from doing so, further air pollution reductions will harm, not help, the public as a whole.

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_The key to creating the most benefit for society from air pollution regulation is to set standards at levels that provide more incremental benefits than incremental costs._

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**Economic Impact of the Proposed Ozone NAAQS**

The available evidence suggests that the added (marginal) cost of current ozone reduction efforts exceeds the marginal benefit, and that a new ozone standard will only result in a more unfavorable tradeoff between costs and benefits.

**Ozone RIA Methodology and Results**

EPA’s Regulatory Impact Analysis projects costs and benefits for the proposed standard in the year 2007. The RIA does not directly analyze the proposed 0.08 ppm, eight-hour standard based on the three-year average of the annual third-highest daily maximum concentration. Instead, it estimates costs and benefits for two standards which should bound the proposed standard.50

The first step in the analysis was to estimate 2007, or “baseline,” air quality. This was done by projecting 1990 emissions levels to 2007 based on assumptions about population growth and industrial development (which increase estimated emissions) and assumptions about Clean Air Act controls that will be implemented during the 17-year period (which decrease estimated emissions). Air quality modeling was used to estimate the ozone levels that would result from these emissions levels. On average, air quality is expected to improve throughout the United States by about 12 percent during this time frame. EPA applies this estimate to all 1990 concentrations to arrive at 2007 air quality.

To determine whether different assumptions about 2007 air quality would significantly affect the RIA’s results, EPA projected costs under the most stringent scenario, assuming only a 6 percent improvement in air quality instead of 12 percent. The agency reports that this did not change the cost projection. Intuitively, this is an implausible result, since it should cost more to clean dirtier air.

To derive the cost estimates, EPA used the air quality projec-
The agency then projected the emissions reductions that would be necessary to meet the proposed standard, creating goal levels called “emissions targets.” EPA then identified control measures that could be used to meet the emissions targets from a set it calls “conventional” controls. These include reformulated fuels, enhanced vehicle inspection and maintenance (I/M), and metal product surface coatings. EPA did not include controls for which there is a “lack of available data to fully characterize the cost effectiveness of the measure,” or for which “time and resource constraints” prevented their consideration.51

The controls were ranked according to their cost per ton, then sequentially added to an area’s control strategy until the area could

Table 4

<table>
<thead>
<tr>
<th>Health Effect</th>
<th>Low Estimate</th>
<th>Best Estimate</th>
<th>High Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough</td>
<td>$1.26</td>
<td>$7.00</td>
<td>$13.84</td>
</tr>
<tr>
<td>Pain upon deep inhalation</td>
<td>$1.26</td>
<td>$4.41</td>
<td>$28.04</td>
</tr>
<tr>
<td>Mortality</td>
<td></td>
<td>$4.48 million</td>
<td></td>
</tr>
<tr>
<td>Hospital admissions: all respiratory illnesses</td>
<td></td>
<td></td>
<td>$11,972</td>
</tr>
<tr>
<td>Hospital admissions: pneumonia</td>
<td></td>
<td>$15,110</td>
<td></td>
</tr>
<tr>
<td>Hospital admissions: chronic obstructive pulmonary disease</td>
<td></td>
<td>$15,502</td>
<td></td>
</tr>
<tr>
<td>Presence of any of 19 acute respiratory symptoms</td>
<td>$3.72</td>
<td>$29.33</td>
<td>$55.94</td>
</tr>
<tr>
<td>Self-reported asthma attacks</td>
<td>$11.82</td>
<td>$32.48</td>
<td>$53.80</td>
</tr>
</tbody>
</table>

meet its emissions targets or until all controls had been applied, whichever came first. Most areas were not able to meet their emissions targets by implementing all of the available conventional controls on the list. Once an area ran out of conventional controls, no more costs were attributed to it, regardless of how far from attainment it was.

Areas able to meet 75 percent or more of their volatile organic compound (VOC) and nitrogen oxide (NOX) targets were considered “within the range of uncertainty,” and designated as attainment areas. Areas not able to meet 75 percent of their emissions reductions were classified as “residual nonattainment” areas. Since most areas were not projected to be able to reduce their emissions levels enough to meet the standard, the control cost presented in the RIA is considered a “partial attainment” control cost.52

To arrive at a benefit estimate, the agency projected the reduction in adverse health effects that would result from the improved air quality under the proposed standard. It then applied monetary values to these health effects as listed in Table 4. Benefits were estimated for full attainment and partial attainment of the proposed standard, the latter to ensure comparability with the partial attainment cost estimate.

The results of EPA’s Regulatory Impact Analysis for ozone are presented in Table 5. The costs and benefits of partial attainment of the proposed standard should be between those of the 8H1AX-80 and the 8H4AX-80 standards. The costs and benefits presented are incremental to those of meeting the current standard.

Table 5 shows that, in each instance, the partial attainment
costs equal or exceed the partial attainment benefits. Because the benefits are expressed in a range, it is not possible to say by how much the costs exceed the benefits. Notice that Americans already will pay more to partially attain the current standard than cost-benefit analysis indicates doing so is worth.

According to an EPA fact sheet, the costs of reaching full attainment, incremental to the current standard, might be between $1 billion and $10 billion, “[u]sing a simplistic calculation technique.” The full attainment benefits estimated in the RIA are between $0.1 billion and $2.8 billion.

Most of the areas projected to be nonattainment under the proposed ozone standard would not be able to reach attainment using all “conventional” control measures available to them.

Why the Ozone RIA Understates Costs

Quantifying the costs and benefits of a regulation such as the proposed NAAQS for ozone is a difficult and inherently uncertain process. Nonetheless, cost-benefit analyses such as the RIA can potentially serve as a useful tool to guide policymaking. Even the most carefully conducted cost-benefit analysis will contain uncertainties, but hopefully they do not distort the results in any particular direction. Unfortunately, the RIA for the proposed ozone standard systematically overstates the benefits and understates the costs.

The RIA Only Presents Partial Attainment Costs

Most of the areas projected to be nonattainment under the proposed ozone standard would not be able to reach attainment using all “conventional” control measures available to them. Truncating costs at this point is unrealistic, of course. Once an area runs out of conventional control measures, it will have to continue to pursue the standard, with either much higher-cost emissions reduction methods or more intrusive ones.

In practice, EPA does not use a “show-me-your-best-effort” approach to enforcing air quality standards. An area that fails to meet the standard faces the prospect of having federal highway funds withheld.

The RIA’s method of truncating costs at “conventional” control measures is likely to have a very large effect on the overall cost
estimate. Indeed, this methodology attributes no costs to several of the country’s cities with the worst air pollution levels. For example, no costs are estimated for Houston, Los Angeles, New York, and San Diego in the RIA. These four areas are classified under the current ozone standard as severe, extreme, severe, and serious nonattainment areas, respectively. In 1996, Los Angeles registered two one-hour ozone concentrations above 0.20 ppm, and had as many as 49 exceedances of the 0.12 ppm one-hour NAAQS at a single monitor. (Downwind from Los Angeles, San Bernardino had ozone concentrations as high as 0.24 ppm, and as many as 65 exceedances at a single monitor.)

EPA estimates that the 8H4AX-80 alternative would result in 37 nonattainment areas (202 counties). Of these 37 areas, only one would be able to meet the standard with conventional emissions controls. Under the 8H1AX-80 alternative, 75 nonattainment areas (427 counties) are projected. Of these areas, only three would be able to meet the standard with conventional controls.

EPA has estimated that the proposed, eight-hour, 0.08 ppm, third-maximum-concentration standard would result in 335 nonattainment counties, based on 1993 to 1995 data. For comparison, the American Petroleum Institute (API) also estimates the number of nonattainment areas that would result from the proposed standards. Unlike the EPA estimation procedure, which only considers counties with ozone monitors, API allows any county in the United States to be designated nonattainment. (In practice, EPA designates all counties within a metropolitan statistical area, including those without monitors, as nonattainment if other counties within the area violate the standard.) API estimates that 603 counties would violate the proposed ozone NAAQS.

EPA recognizes that the cost picture painted by its RIA is incomplete; the report states: “While this RIA presents full attainment benefits as a measure of the proposed NAAQS, there is no scientifically supportable method for determining the costs of full attainment. Therefore, this analysis understates costs by allowing for residual nonattainment . . . .” But the degree to which costs are understated is certainly not clear to the average citizen exposed to EPA’s publicity campaign.

The RIA Completely Excludes Costs of Marginal Nonattainment Areas

Of the 37 nonattainment areas under the 8H4AX-80 scenario, 23 would be “marginal” areas, meaning ozone levels are within 115 percent of the standard (below 0.092 ppm). For the 8H1AX-80 sce-
nario, 35 of the 75 nonattainment areas would be marginal areas.60 Surprisingly, EPA attributes no costs for these marginal areas to come into compliance.

This means that the RIA only counts costs for areas with eight-hour ozone levels above 0.092 ppm. So the RIA effectively estimates costs for a 0.092 ppm standard, although benefits are estimated for one set at 0.08 ppm. Interestingly, EPA says that an eight-hour, 0.09 ppm standard set at no more than the third highest average daily maximum ozone concentration is equivalent to the current ozone standard.61 This would imply that the costs estimated in the RIA are for a standard less stringent than the current NAAQS.

The RIA Excludes Administrative Costs

The Regulatory Impact Analysis does not attempt to estimate costs for several tasks that are currently required of nonattainment areas. These requirements include: instituting a new source review (NSR) program, developing an emissions inventory, developing emissions statements, and establishing periodic inventories. Nonattainment areas currently incur costs to fulfill these administrative requirements, and it is unlikely that the costs will disappear with the adoption of a new standard. These costs are dismissed by the authors of the RIA as small and, thus, are not counted.62

Why the RIA Overstates Benefits

EPA claims that the RIA understates benefits because it only counts the direct benefits of reducing ozone; whereas, there may be benefits associated with reducing toxic ozone precursors and associated oxidant products. EPA also says that NOX controls may reduce particulate matter concentrations and therefore create additional benefits (although these benefits are already counted in the particulate matter RIA). The agency cites a number of other benefit categories which it was unable to quantify, for example, susceptibility to respiratory infection and ecosystem damage. But it is also very possible that EPA overstated its benefit estimate.

Benefit Estimates Include Reduced Mortality

More than 98 percent of the upper-bound benefit estimates for the two alternative standards evaluated result from counting mortality benefits.63 The upper bound estimate for partial attainment is 110 to 250 avoided deaths per year (the low bound and best estimates are for no avoided deaths).64

The RIA states:
Although the Agency recognizes that a high degree of uncertainty exists in the estimation of ozone-induced mortality, the evidence linking a causal relationship between ozone exposure and mortality is significant enough in these new studies to warrant inclusion of this category in the analysis.\textsuperscript{65}

This statement is inconsistent with the Criteria Document, the Staff Paper, and the extensive literature on ozone’s human health effects.

EPA’s estimate of mortality due to ozone exposure is based on a 1995 study that shows an association between ozone and mortality during summertime in Philadelphia.\textsuperscript{66} The study does not conclude that ozone causes the mortality. In fact, it clearly states that “in our current state of knowledge, a specific component of air pollution cannot be singled out as being responsible for the association between air pollution and mortality.”\textsuperscript{67} EPA has mischaracterized the results of this paper. The inclusion of mortality estimates in the RIA upper bound benefit estimate is not scientifically justified.

Risk Assessments Have Been Revised

Since the RIA was conducted, EPA has revised its risk assessments. To the extent that the public health benefits expected from the proposed NAAQS are lower, the monetized benefit calculation in the RIA should also be lower.

Other Cost-Benefit Estimates

Economist Susan Dudley estimates the costs of full compliance with the current and proposed ozone standards. According to her analysis, reaching the current standard would cost between $22 billion and $53 billion per year. Attaining the proposed standard would cost an additional $54 billion to $328 billion per year.\textsuperscript{68} These estimates may represent an upper bound, but they are no less plausible than EPA’s underestimate.

Dudley also points out that lower tropospheric ozone concentrations may actually create negative health effects. Ozone serves the important function of shielding the earth’s surface from harmful UV-B radiation. Reducing tropospheric (ground-level) ozone concentrations will increase human exposure to UV-B radiation. According to Dudley’s estimates, “implementation of the proposal will result in between 2,000 and 11,000 new cases of nonmelanoma skin cancer; 130 to 260 new cases of cutaneous melanoma, 25 to 50 melanoma-caused deaths, and 13,000 to 28,000 incidents of
cataracts.” These effects are estimated at $333 million to $1.3 billion, using EPA’s values.\footnote{69}

Reducing tropospheric (ground-level) ozone concentrations will increase human exposure to UV-B radiation

The President’s Council of Economic Advisers has also taken interest in the costs and benefits of the proposed NAAQS. CEA projects the costs at between $11.6 billion to $60 billion and the benefits at $200 million to $1 billion.\footnote{70}

Yet another study, funded by the American Petroleum Institute, estimates that the costs for the Chicago area alone would be $2.5 billion to $7 billion annually, incremental to the current standard.\footnote{71} The lower-bound estimate for Chicago alone is equal to EPA's upper-bound estimate for the entire nation. The corresponding health benefits for Chicago are projected to be $33 million.\footnote{72}

Summary

EPA’s Regulatory Impact Analysis estimates that the proposed ozone standard would cost between $600 million and $2.5 billion, and provide benefits valued at between $4 million and $1.5 billion. These projections are unlikely to be accurate, since the RIA undercounts costs and overstates benefits.

The RIA only counts low-cost, or “conventional,” control measures. As a result, the analysis provides a complete cost estimate for only one to three cities in the United States, out of 37 to 75 areas expected to be in violation. In addition, the RIA attributes no costs to areas with ozone concentrations up to 0.92 ppm (marginal nonattainment areas), which account for 47 to 62 percent of all expected nonattainment areas.\footnote{73} The RIA also neglects to count administrative costs.

The upper-bound benefit estimate of $1.5 billion is almost certainly an overstatement, since it is driven mostly by reduced mortality. Furthermore, EPA’s revised risk assessments should result in lower benefit estimates.

Other cost-benefit estimates are less favorable than EPA’s and indicate that the proposed standard could cost many billions of dollars more than it generates in health benefits.

Economic Analysis of the Proposed PM$_{2.5}$ NAAQS

27
EPA predicts that the PM$_{2.5}$ standard will result in much higher benefits than the ozone standard. This is mostly due to the large reduction in premature mortality EPA expects from reaching the standard, although, as pointed out in the health effects section of this paper, this health benefit may never materialize. Like the ozone RIA, the particulate RIA almost certainly understates the true costs of attaining the proposed NAAQS and overstates the benefits.

**PM$_{2.5}$ RIA Methodology and Results**

The methodology used in the Regulatory Impact Analysis for the proposed PM$_{2.5}$ standard is very similar to that used for the ozone RIA. Fortunately, the PM$_{2.5}$ RIA directly analyzes the proposed 15µg/m$^3$ (annual mean) and 50µg/m$^3$ (24-hour average) standards.

In conducting the particulate matter RIA, agency staff divided the country into seven regions and estimated baseline air quality and average PM$_{2.5}$ concentrations under the proposed standard for each region. The national results are based on the sum of the cost and benefit estimates for the seven regions. Like the ozone Regulatory Impact Analysis, the PM$_{2.5}$ RIA first estimated 2007 air quality based on 1990 emissions and assumptions about population growth and industrial development. EPA also assumed that the 1990 Clean Air Act Amendments (CAA) and the current standard for PM$_{10}$ would be fully implemented by 2007.

Next, the agency identified emissions targets and control measures that areas could use to achieve the necessary emissions reductions. Again, EPA included what it considers to be “a reasonable set of control measures.” It chose a cutoff cost of $1 billion per µg/m$^3$ to define “reasonable.” It then sequentially added an area’s control costs until the area could meet its target reductions, or until the set of reasonable control measures had been exhausted.

The agency estimated benefits by first predicting the changes in incidence of health and welfare effects that would result from the changes in air quality expected under the standard. It then applied monetary values to these health effects.

Like the ozone RIA, the particulate RIA only estimates partial attainment costs but estimates benefits for full and partial attainment. The costs and benefits presented are incremental to those required to meet the current standard. The RIA projects partial attainment costs for the proposed PM$_{2.5}$ standards of $6.3$ billion per year (1990 dollars). The analysis estimates partial attainment benefits of $58$ billion to $119$ billion, and full attainment benefits of $69$ billion to $144$ billion.
These cost and benefit projections suggest that the partial attainment benefits would be many times greater than the partial attainment costs. There is reason to be skeptical about this analysis' costs and benefits.

Why the Particulate RIA Understates Costs

The Regulatory Impact Analysis is likely to understate costs because it only considers low-cost control measures. Excluding controls which cost over an arbitrary ceiling of $1 billion per µg/m³ allows EPA to present partial attainment costs that appear to be quite modest.

EPA says a $1 billion per µg/m³ threshold was set “to eliminate extreme measures that are unrealistically cost-ineffective.” The agency says that “attempts to move beyond the currently projected level of partial attainment would cost significantly more than this.” It then confidently asserts that lower-cost control strategies will be identified in the future.

Of the 126 areas projected to violate the proposed standard, 57 would not be able to meet the standard using the measures that cost less than the $1 billion per µg/m³ threshold. EPA calls these areas “residual nonattainment” areas.

None of the seven U.S. regions modeled in the RIA could meet the fine-particulate standards; the reductions achieved ranged from 15 percent to 98 percent of those needed. The average PM₂.₅ abatement across the seven regions was 53 percent of the needed reductions. The sum of the regional shortfalls is 13.4µg/m³, or on average 1.9µg/m³ per region.

EPA performed a sensitivity analysis for two cities, Denver and Philadelphia, for the RIA. This calculation demonstrates how quickly marginal cost rises above EPA’s $1 billion per µg/m³ cutoff. In Philadelphia County, the control measures costing less than this cutoff figure would reduce PM₂.₅ levels by just 20 percent from the 2007 baseline. An additional 1 percent reduction would result from a $2 billion per µg/m³ cutoff, but the cost would double. The RIA reports similar results for Denver.

An EPA contractor found that Philadelphia would face costs of $4.28 billion per µg/m³ or more, and still not attain the standard. Based on this figure, Dr. Thomas Hopkins, an adjunct fellow of the Center for the Study of American Business and a professor of economics at Rochester Institute of Technology, estimates that full compliance might necessitate expenditures totalling $55 billion a year.

Another troubling aspect of the cost estimate is that EPA only
considers the 470 counties nationwide that currently have PM$_{10}$ monitors.\textsuperscript{83} It is likely that counties outside of this set will be found to violate a PM$_{2.5}$ standard when more PM$_{2.5}$ concentration data become available. This would also tend to raise the full costs of attaining the proposed standard.

\begin{quote}
\textbf{The health effects claims about fine particulates are plagued with uncertainties, which necessarily translate into highly uncertain benefit estimates.}
\end{quote}

\section*{Why the Particulate RIA Overstates Benefits}

The particulate RIA also is likely to overstate benefits for several reasons. Some are related to the uncertainty involved in the science, as discussed previously. Another has to do with the extent of shortened lifespan assumed from fine particulate exposure.

\textbf{Scientific Uncertainties.} The health effects claims about fine particulates are plagued with uncertainties, which necessarily translate into highly uncertain benefit estimates. The RIA assumes that 21,000 lives will be saved each year as a result of lowering fine particulate concentrations.\textsuperscript{84} Using the more recent estimate of 15,000 lives saved a year instead of 21,000 (at a value of $\$4.8$ million a life) would lower the benefit estimate by $\$29$ billion. This illustrates the importance of both the high value assigned to prolonged life and of the high mortality estimates in EPA’s benefit calculations.

\textbf{Extent of Life Shortening.} As discussed in the particulate health-effects section, the age or health of those presumed to be dying from particulate exposure has not been determined. EPA values each life at $\$4.8$ million, an average figure it derived from 26 value-of-life studies.\textsuperscript{85} This figure represents an average for an individual of middle age with half a lifetime remaining and would not be appropriate for valuing populations that are, on average, either older or younger.

If people are dying from particulates, however, they are probably not of average age. Instead, they are most likely elderly individuals who would otherwise die within days or years.\textsuperscript{86} The RIA estimates that about 85 percent of the premature mortality related to particulates occurs in the population over age 65.\textsuperscript{87}

Hopkins points out that EPA’s $\$4.8$ million valuation per life leads to a substantial overstatement of benefits. He suggests that
EPA adjust its valuation downward to more accurately reflect the actual length of prolongation that might result from lower fine-particulate levels. Hopkins notes that the American Lung Association puts the average life shortening due to fine particulates at two years. He also points to a National Research Council estimate that values mortality due to pollution exposure much differently than the RIA does. It values lives lost as a result of air pollution at $1.3 million each.\textsuperscript{88}

**Summary**

EPA’s Regulatory Impact Analysis projects costs of $6.3 billion and benefits of $58 billion to $119 billion per year from partial attainment of its proposed air quality standard for fine particulates. These cost and benefit estimates are far different than the actual costs and benefits would be.

The low cost estimate results from counting only less expensive control measures and only covers about half of the needed PM\textsubscript{2.5} reductions (the less expensive half). Because expenditures on pollution abatement follow the typical pattern of rising marginal costs, we can expect the cost of full attainment to be a substantial multiple of EPA’s partial attainment estimate of $6.3 billion. One rough estimate is a full attainment cost of $55 billion a year.

The extraordinary benefit estimates are the result of high mortality projections, although these estimates lack strong scientific support. Hopkins notes, “One rarely encounters public policy options capable of yielding benefits this large. EPA’s benefit claims, however, lack a solid foundation.”\textsuperscript{89} The uncertainty in the fine-particulate science is exemplified by EPA’s reduction of its “lives saved” estimate by 25 percent in April 1997 to correct for a “technical error.” EPA has also overvalued the mortality benefits by applying values appropriate for individuals of middle age rather than elderly individuals with preexisting conditions.

**Conclusion and Recommendations**

The Environmental Protection Agency’s simultaneous proposal of ozone and fine particulate National Ambient Air Quality Standards creates the perception that the standards will yield large public-health benefits at relatively modest costs. But upon closer examination, it appears evident that neither of the two standards would be a wise public-health investment.

The ozone standard’s inability to pass a cost-benefit test on its own is masked by the high benefits projected for the particulate...
standard. But the fine-particulate proposal’s benefits are based on inadequate science. The extensive scientific literature on ozone and a fair amount on PM_{10} allows the EPA administrator to say that the standards are based on “hundreds of peer-reviewed studies,” even though the PM_{2.5} proposal is only based on a handful.

In truth, the ozone standard would create only small public-health benefits. Recently, the estimates of these benefits have become even smaller as a result of EPA’s revisions to its health risk assessments. EPA claims the PM_{2.5} standard would create substantial public health benefits by reducing thousands of cases of premature mortality and morbidity. These claims appear to be much larger than the scientific evidence can support.

So why has EPA proposed air quality standards that are of uncertain benefit for Americans? Quite simply, because the Clean Air Act requires it to do so. The act’s goal of protecting public health “with an adequate margin of safety” does not distinguish between cost-effective and cost-ineffective air quality standards, as long as they result in some amount of health benefit.

Members of the Clean Air Scientific Advisory Committee (CASAC) recognized the flaw in the act’s goal. After explaining that health effects from ozone cannot be entirely eliminated, they wrote that “the paradigm of selecting a standard at the lowest-observable-effects level and then providing an ‘adequate margin of safety’ is no longer possible.”

In other words, the Clean Air Act’s goal cannot literally be achieved, at least for ozone. EPA can attempt to prevent all health effects caused by air pollution, but doing so will divert large amounts of resources from the pursuit of other important social objectives.

As for fine particulates, the CASAC closure letter endorsed a PM_{2.5} standard in principle, but cautioned that, “there was no consensus on the level, averaging times, or form.” CASAC also called attention to “the many unanswered questions and uncertainties regarding the issue of causality.” The panel also noted that the court-ordered NAAQS review process simply did not allow enough time to properly study PM_{2.5} health effects:

[T]he deadlines did not allow adequate time to analyze, integrate, interpret, and debate the available data on this very complex issue. Nor does a court-ordered schedule recognize that achieving the goal of a scientifically defensible NAAQS for PM may require iterative steps to be taken in which new data are acquired to fill obvious and critical voids in our knowledge.

Caution is needed in the case of a new fine-particulate standard; aiming the country’s pollution-abatement efforts at the wrong
agent would be a costly mistake.

So how should air quality standards be set? First, Congress should change the Clean Air Act’s basic objective from “protecting the public health with an adequate margin of safety” to “protecting public health against unreasonable risk of important health effects.”

The Clean Air Act’s goal cannot literally be achieved, at least for ozone

Second, Congress should require that air quality standards pass a cost-benefit analysis. Americans expect their elected officials to protect them from air pollution that might significantly harm their health. They do not expect, however, that the costs of this protection will be grossly disproportionate to the benefits.

The EPA Administrator must announce her decision on the particulate matter standard by July 19, although she is not required to do so for ozone. What should she do?

In the case of particulate matter, EPA should affirm the current PM\textsubscript{10} standard and wait for the science to “catch up” before establishing a PM\textsubscript{2.5} standard. In the case of ozone, “staying the course” — leaving the standard unchanged — would be prudent.

Complying with the letter of the law could necessitate setting a standard even tighter than the one proposed. A strict interpretation of the Clean Air Act leaves little justification for a standard above background levels. EPA could very well be sued for setting a standard at which some individuals experience health effects, even though such pristine air would be prohibitively costly to achieve. If the Act is not changed, the proposed ozone standard is likely to be but a way station along the road to an unachievable standard.

Air quality has improved remarkably over the last quarter-century. From 1970 to 1994, VOC emissions declined 24 percent, and between 1985 and 1994, ozone concentrations fell 12 percent. Likewise, PM\textsubscript{10} emissions decreased 78 percent from 1970 to 1994, and total suspended particulate concentrations fell 20 percent between 1988 and 1994.\textsuperscript{93} Air quality will continue to improve as U.S. cities make progress toward current ozone and particulate standards. Changing the definition of healthful air with regard to ozone and particulates will disrupt this current progress in exchange for dubious future benefits.

Administrator Browner should not propose new ozone and fine particulate standards in July. Instead, she should appeal to Con-
gress to change the act’s goal and to allow cost-benefit analysis in standard setting.

These simple yet revolutionary changes would go a long way to add more value for each dollar spent for cleaner air. They would also allow resources to be targeted toward the most pressing public health issues, rather than toward lesser, high-cost, low-benefit priorities. Americans deserve protection from harm caused by air pollution. They also deserve rational air quality standards based on sound science. To achieve both of these important objectives requires fundamental reform of the Clean Air Act.

Notes


7. Clean Air Scientific Advisory Committee (CASAC) closure letter to EPA Administrator Carol Browner on the primary standard portion of the OAQPS Staff Paper for Ozone (November 31, 1995), p. 2.


9. Ibid., figure V-1.


ment (produced by Argonne National Laboratory, Argonne, Illinois, for U.S. Environmental Protection Agency, January 1997), Table 6.

22. For example, one study found that “Animals exposed for 20 months to 0.5 or 1.0 ppm ozone demonstrated dramatic increases in the volume of interstitium and epithelium along the alveolar ducts.” Ling-Yi Chang, Barbara L. Stockstill, Margaret G. Menache, Robert R. Mercer, James D. Crapo, *Consequences of Prolonged Inhalation of Ozone on F344/N Rats: Collaborative Studies. Part VIII: Morphometric Analysis of Structural Alterations in Alveolar Regions*, Health Effects Institute, Research Report No. 65, March 1995, pp. 3-39.
25. Testimony of EPA Administrator Carol Browner before the U.S. Senate Committee on Environment and Public Works, February 12, 1997
31. C. Arden Pope III, Michael J. Thun, Mohan M. Namboodiri, Douglas W. Dockery, John S. Evans, Frank E. Speizer, Clark W.

32. Taubes, pp. 164-169.
34. Ibid. p. VII-42.
35. Statistical significance implies a good chance that the detected relationship actually exists, in this case 95 percent.
36. Death codes 401 to 440 according to the International Classification of Diseases, 9th revision.
37. William Landau, Gregory Evans, Raymond Slavin, written comment to EPA on proposed National Ambient Air Quality Standard for PM$_{2.5}$, March 7, 1997.
42. Testimony of Thomas B. Starr before the United States Senate Subcommittee on Clean Air, Wetlands, Private Property and Nuclear Safety, Committee on Environment and Public Works, April 24, 1997.
47. CASAC closure letter to EPA Administrator Carol M. Browner on the Staff Paper for Particulate Matter (June 13, 1996).

50. Both proposals would set an eight-hour standard at 0.08 ppm, but one would measure the second-highest average daily maximum [8H1AX-80] and the other the fifth highest [8H4AX-80].


52. Ibid., section V.


58. Obtained through personal communication with Mitchell Baer, a Senior Regulatory Analyst at API.


60. Ibid., section VI-B(1).

61. Ibid., pp. I-5.

62. Ibid., p. V-3

63. Ibid., pp. IX-22, IX-23.

64. Ibid., Tables E-II, E-12, E-13


66. Ibid., p. IX-7.


68. Susan E. Dudley, *Comments on the U.S. Environmental Protection..."
Agency’s Proposed National Ambient Air Quality Standard for Ozone (prepared for The Regulatory Analysis Program, Center for Study of Public Choice, George Mason University, March 12, 1997), Appendix C.

69. Ibid., Appendix B.

70. Memorandum from Alicia Munnell, Council of Economic Advisers, to Art Frass, Office of Management and Budget, December 13, 1996.

71. Socio-Economic Study of Possible Eight-Hour Ozone Standard (Sacramento: Sierra Research, Inc., prepared for American Petroleum Institute, June 4, 1996), p. ES-16. This study provides cost estimates for the entire Lower Lake Michigan Region. Costs for the Chicago area are about half these costs.


73. As discussed previously, 23 of the 37 nonattainment areas under the 8H4AX-80 scenario, and 35 of 75 under the 8HIAX-80 scenario, are projected to be marginal.


76. Ibid., p. 7-6.

77. Ibid., p. 7-14.

78. Ibid., p. 7-8.

79. Calculation based on Table 7-4 in PM RIA.

80. U.S. EPA, PM RIA, p. 7-6


82. Ibid., p. 16.


84. Ibid., Table 9.8.

85. Ibid., Table 9.6.

86. Robert W. Crandall, Frederick H. Reuter, Wilbur A. Steger, "Clearing the Air: EPA’s Self-Assessment of Clean-Air Policy,”


89. Hopkins, p. 6.

90. CASAC closure letter to EPA Administrator Carol Browner on the primary standard portion of the OAQPS Staff Paper for Ozone (November 31, 1995), p. 2.

91. CASAC closure letter to EPA Administrator Carol Browner on the Staff Paper for particulate matter (June 13, 1996).


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