Airing on the Side of Caution o

In May 1999, a federal appeals court ruled that the U.S. Environmental Protection Agency (EPA) had violated the U.S. Constitution when it strengthened regulations for ground-level ozone and particulate matter (PM). EPA administrator Carol Browner called the decision "one of the most bizarre and extreme decisions ever rendered" in environmental law and said that if it were allowed to stand, 1 million Americans would suffer serious respiratory illnesses and 15,000 would die prematurely. Browner also stated that the court "never challenged the science on which the new standards are based."

In contrast, the U.S. Chamber of Commerce, which brought the suit against the EPA challenging the proposed rules, crowed in a subsequent press release that it had "smoked" the EPA on Clean Air Act rules. Chamber president Thomas J. Donohue said in the release, "This ruling strikes right at the heart of EPA's abuse of regulatory authority—and that's a big win for businesses large and small." The press release stated that "according to the court ruling, the standards selected by EPA were arbitrary and not based on sound science." Said Donohue, "This ruling will force the EPA to regulate according to clear standards. They just can't pick numbers out of thin air."

The divergent reactions to the ruling aren't simply the usual posturing of legal adversaries responding to an important court decision. Instead, they reflect the critical role science played in the May 1999 holding by the U.S. Court of Appeals for the District of Columbia, which the court reaffirmed in November 1999. As the EPA has said, the court did not challenge the validity of the agency's scientific basis for establishing the PM and ozone standards. But it did challenge how the EPA selected the particular regulatory levels since the scientific record in both rules did not indicate unequivocally where the standards should be set. The agency failed to identify an "intelligible principle" that would guide such choices, the court said, and thereby exceeded the power it was granted by Congress.

"It is a rare circumstance where a scientist can look at the existing data at any one time and prove beyond uncertainty that a specific level [of pollution] is the right one to set [for the standard]," says Joe Mauderly, vice president of the Lovelace Respiratory Research Institute in Albuquerque, New Mexico, and chairman of the Clean Air Scientific Advisory Committee (CASAC), an independent panel established under the Clean Air Act to assess the scientific evidence used by the EPA in rule making. "At higher levels of exposure, the evidence is clearer," he says. But at lower levels, he says, there is generally suggestive evidence, or not much evidence at all. "[Although] we continually improve our understanding of the relationship between air pollution and health," he says, "it is very unlikely that we are going to see situations where the opinion will be unanimous, where regulators and industry agree, and the data are so incontrovertible that there is no uncertainty about [a particular] level of pollutant."

Because scientific uncertainty attends so many rule makings, the ruling leaves open the question of when the EPA may make what is essentially a policy determination versus when those determinations should be made by Congress. For this reason, observers consider the ruling to have potentially significant implications beyond just the ozone and PM rules that may affect other EPA regulations and regulations by other agencies. In late January, the U.S. Department of Justice filed a petition seeking Supreme Court review of the appeals court's decision.

Particulate Matters

For now, the court ruling leaves in limbo the EPA's first-ever attempt to specifically regulate fine particles measuring 2.5 micrometers or less in diameter ($PM_{2.5}$), and its first revision of the ground-level ozone standard since 1979, when the standard was set at 0.12 parts per million (ppm) over a one-hour period. In June 1997, the agency issued the new standard, limiting ozone concentrations to 0.08 ppm averaged over an eight-hour interval. Along with the ozone rule, EPA issued a new PM standard that limited annual concentrations of $PM_{2.5}$ to 15 micrograms per cubic meter while also retaining the prior limits on PM_{10} (fine particles measuring 10 micrometers or less in diameter). According to the EPA, epidemiological studies indicated that concentrations of smaller particles at levels below the current PM_{10} standard produce increased hospital admissions for respiratory problems and premature mortality.

Critics of the PM standard have said that the EPA lacks sufficient data on the health effects of $PM_{2.5}$ and has extrapolated primarily from PM_{10} epidemiological studies. "When you rely on epidemiological studies, you cannot demonstrate linear effects," says Mark Burtschi, director of air quality for the National Association of Manufacturers. As a result, he says, the EPA has difficulty justifying why a standard was set at a particular level and why that level is, as the Clean Air Act mandates, "requisite to protect public health."

However, John Bachmann, associate director for science/policy and new programs with the EPA's Office of Air Quality Standards and Planning, says acting on a greater degree of scientific uncertainty is more reasonable where the effects are as serious as early mortality. "We didn't have the reinforcement from all disciplines [at the time the standard was issued]," he acknowledges, "but an overwhelming number of studies suggested that PM was either acting alone [in producing health effects] or was a contributor."

Ronald White, director of national programs for the American Lung Association, agrees that the $PM_{2.5}$-specific data were limited when the EPA established the standard, but says that was also the case when the EPA switched from a total suspended particles standard to the PM_{10} standard without objection from the courts. Although the EPA's standard isn't based on an extensive body of $PM_{2.5}$ research, he says, studies used surrogate pollutants such as sulfates, which are 2.5 micrometers or less in diameter. For these reasons, White says, it is not an "insignificant" body of science that supports the EPA's standard.

Out of the Ozone

Critics of the EPA's ozone standard have claimed that it, too, lacks sufficient scientific support, based in part on a statement from the CASAC that insufficient scientific evidence exists to pinpoint whether the revised

Pulling Standards Out of Thin Air?

standard ought to be set at 0.07, 0.08, or 0.09 ppm. "The panel made it clear that there was not a good scientific basis for picking one level over another," says Mauderly. Because the scientific evidence did not yield guidance about where to set the standard, it became a policy decision, he notes. "But," he says, "I don't know that that is an unusual circumstance."

In the absence of scientific evidence indicating that 0.08 ppm was more protective of public health than either the original one-hour 0.12 ppm standard or its equivalent, an eight-hour 0.09 ppm standard, industry attorney William Brownell says the EPA acted arbitrarily because it failed to identify why the agency opted for 0.08 ppm. "There are lots of technical documents, lots of risk assessments," he says. "But how to define the point at which the risk is acceptable or unacceptable, that's what was never defined [by the EPA] in this case." The District of Columbia Circuit Court agreed. The court said that when the EPA selects a nonzero standard for nonthreshold pollutants such as ozone, which pose possible adverse health effects at any exposure level, the agency must explain the degree of imperfection permitted. Basing the decision on the increased uncertainty of health effects at lower exposures is a sufficient criterion only if some principle reveals how much uncertainty is too much. And, the court said, none does. The court said that because the EPA did not articulate an "intelligible principle," it was theoretically free to set the ozone standard between zero and upward to the concentrations that produced the London fog of 1952, which is believed to have killed 4,000 people in a week.

Balance of Power

The EPA believes the Clean Air Act's directive that standards be set at a level protective of public health with an adequate margin of safety would prevent it from setting the standard at the London fog levels and from regulating to prevent insignificant effects. The agency also says its regulatory decisions are guided by criteria mandated by the Clean Air Act and subject to CASAC review, and that they require a balancing of public health factors including the health effects, the types of evidence, and the uncertainties of the evidence.

The District of Columbia Circuit Court, however, suggested that such a balancing of factors should itself be guided by objective criteria. The court stated that "an agency wielding the power over American life possessed by EPA should be capable of developing the rough equivalent of a generic unit of harm that takes into account population affected, severity, and probability." But, says the EPA in its request for reconsideration, "Even assuming such a quantitative approach were possible, the line-drawing question would remain," because the agency would then have to determine how many generic units of harm were too many.

William Becker, executive director of the State and Territorial Air Pollution Program Administrators and the Association of Local Air Pollution Control Officials, doubts that the litigation will lead to the EPA or the Supreme Court rescinding the rules, which have not been vacated by the court, although he believes some modification to the rules is possible. But, he notes, "The standards are far-reaching wherever they set them," which may partly account for the scrutiny they have received. Says Becker, "[The Clean Air Act program] has great costs and great benefits, and we think the benefits far outweigh the costs. But because of the breadth of the program, it's not surprising that industry is going to question the outcome." However, he adds, "I've been on this job 20 years and lived through revised [National Ambient Air Quality Standards, NAAQS] for most of them. EPA conducted far more extensive analysis and studies on $PM_{2.5}$ and the eight-hour ozone standard than on any other NAAQS they've promulgated."

Although the court ruling prevents the EPA from enforcing either the PM standard or the ozone revised standard, the agency has proposed to reinstate the original one-hour 0.12 ppm ozone standard and is considering designating areas as attainment or nonattainment based on the new eight-hour 0.08 ppm standard, according to Bachmann. The uncertain future of the PM standard may not delay implementation if it is eventually upheld, because three years of monitoring data is required before states must submit implementation plans demonstrating how they will control $PM_{2.5}$. Meanwhile, work is continuing on the agency's reassessment of the scientific data for the PM standard, Bachmann says, which so far indicate that "we were on the right track in regulating fine particles."

White believes that the public health effects of the court's decision on PM and ozone pollution will be minimal if the matter can be resolved in the courts relatively quickly. But the outcome of the litigation will be crucial, he says, not just for the ozone and PM rules but for public health and environmental protection in general. "Clearly it has the potential to confound the entire regulatory process of the nation if it is upheld, which is why we do expect it to be presented to the Supreme Court for review," he says.

Because the stakes are so high, attorney C. Boyden Gray, who filed friends of the court briefs on behalf of Representative Thomas Bliley (R–Virginia) and Senator Orrin Hatch (R–Utah) opposing the EPA's revised rules, questions whether appeal to the Supreme Court is the wisest action. Gray, who served as White House Counsel under President Bush, says that the EPA might be better off revising the ozone and PM regulations and offering a better rationale rather than risking the imposition of more onerous obstacles on agency rule making. "If the EPA loses in the Supreme Court," he says, "they could lose more than these two rules—they could lose other things for other agencies." For now, it appears that's a chance the agency is willing to take.

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