

U.S. REGULATORY POLICY

Critics see hidden goal in EPA data access rule

They say new policy aims to weaken air pollution regulations by barring key studies

By Warren Cornwall

When Scott Pruitt, administrator of the U.S. Environmental Protection Agency (EPA) in Washington, D.C., announced last week that the agency plans to bar regulators from considering studies that have not made their underlying data public, he said it was to ensure the quality of the research used to shape new rules. “The era of secret science at EPA is coming to an end,” Pruitt said at a 24 April event (which was closed to the press) unveiling the proposed “transparency” rule.

But longtime observers of EPA, including former senior agency officials, see a more troubling and targeted goal: undermining key studies that have helped justify stricter limits on air pollution. In particular, they say, the new policy is aimed at blocking EPA consideration of large epidemiological studies that have highlighted the health dangers of tiny particles of soot and other chemicals less than 2.5 microns in diameter. Those studies, which rest in part on confidential health information that is difficult to make public, have been under attack for decades from some industry groups and Republican lawmakers in Congress, who argue that the confidentiality masks flaws in the studies. The same interests lobbied heavily for the new EPA rule, and critics of the policy say it

is just new clothing for an old—and largely discredited—argument.

“It just keeps coming back in different forms. ... It’s like malaria. Or maybe herpes would be a better analogy,” says toxicologist Dan Costa of Chapel Hill, North Carolina, who recently retired after leading EPA’s air research program for 14 years.

At the heart of the fight is a type of pollution scientists believe is particularly le-

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thal, but relatively costly to control: tiny particles of soot and other chemicals produced by burning oil, coal, gasoline, wood, and other fuels, which can lodge deep in the lungs. In the mid-1990s, two major epidemiological studies—known as the Harvard Six Cities and American Cancer Society (ACS) studies—tracked the medical histories of thousands of people exposed to different levels of air pollution. The studies found that exposure to even relatively

low particulate levels increased premature deaths. Further studies have linked the pollution to other problems including asthma, heart disease, and heart attacks.

In response, EPA began tightening clean air regulations—and affected industries began to attack the findings. Industry representatives also urged Congress to pass legislation that would bar EPA from using nonpublic data in crafting regulations. In recent years that legislation, championed by Representative Lamar Smith (R-TX), head of the House of Representatives’s science committee, failed to gain approval. But after the election of President Donald Trump, Smith and his allies found a receptive audience in Pruitt, who agreed to implement similar policies as an EPA rule.

In the meantime, an array of studies, including a government-sponsored reanalysis of the original particulate data, has generally validated the findings (see sidebar, p. 473). “The bottom line is the results don’t go away. They’re real,” says C. Arden Pope III, one of the lead researchers on the Six Cities and ACS studies and now an epidemiologist at Brigham Young University in Provo, Utah.

In 2013, that scientific consensus prompted EPA to reduce allowable particulate levels to 12 micrograms per cubic meter of air, down from an earlier standard of 15 micrograms. At the same time, the agency calculated that the benefits of even tighter

Clever use of public data could sidestep new rule

By Susan Cosier

Critics of the Environmental Protection Agency's (EPA's) move last week to limit the agency's use of nonpublic data say it is a thinly veiled effort to prevent regulators from drawing on public health studies that have proved pivotal to justifying tougher air pollution limits (see main story, p. 472).

Recently, however, one research team has demonstrated what could be a way around the policy. They used publicly available data to produce high-quality findings on the ills of pollution that EPA's new policy might not be able to quash.

"This is a very highly contentious political climate, and we are taking the extra step to be as transparent as we can be," says biostatistician Francesca Dominici of the Harvard T. H. Chan School of Public Health in Boston, who led the studies.

In one, published in *The New England Journal of Medicine* in June 2017, she and her colleagues used publicly accessible air pollution data and records compiled by the federal government's Medicare health insurance program to show that even modest pollution reductions could save more than 10,000 lives per year. In another, published in *JAMA* last December, they linked short-term exposure to air pollution levels below current limits to premature death among the elderly.

Previous studies suggesting that current levels of U.S. air pollution cause avoidable health problems and deaths typically relied on private health information painstakingly collected from a relatively limited group of participants. In contrast, Dominici's team tapped anonymized Medicare data on 60 million enrollees over 12 years. It revealed where people lived, their age, race, hospital visits, and when they died. The researchers also collected weather, pollution, census information, and other public

records from EPA and other agencies.


They then divided the United States into a 1-kilometer-by-1-kilometer grid and used a computer model to see how levels of pollution compared with the health trajectories of the Medicare enrollees, taking into account confounding factors such as poverty and smoking.

The result is one of the largest and most statistically sophisticated studies of dirty air's health impacts, says air pollution specialist C. Arden Pope III of Brigham Young University in Provo, Utah. Pope helped lead earlier landmark air pollution studies relying on confidential data. Dominici's team, he says, "is taking a brand new cohort, and a huge one at that, and replicating the results" of previous studies. And anyone can download the same data and reanalyze the results, Dominici says—the exact goal EPA says it wants to achieve.

Public data can't be used to answer every important question about how pollution affects people, Dominici emphasizes. "I cannot look at pulmonary function or the thickness of your artery," she says. "Very well designed cohort studies are extremely important to scientific advancement, and when you're looking at the history of individuals, you have to maintain their confidentiality."

Still, EPA could soon be giving her team's studies a close look, because the agency is undertaking a periodic review of key air quality standards. Supporters of EPA's new data access policy have said they want to rid the regulatory process of potentially flawed "secret science." Now, the question is whether they will also object to EPA considering analyses of public data that, like previous studies, suggest tightening the standards would benefit public health.

Susan Cosier is a journalist based in Chicago, Illinois.



Critics say a new Environmental Protection Agency policy will make it harder to cut fine particles, such as those in smog blanketing Los Angeles, California.

standards would outweigh the costs. Lowering the standard to 11 micrograms would increase pollution-control costs by as much as \$1.35 billion in 2020, analysts estimated, but the health gains and lives saved would be worth as much as \$20 billion a year.

That cost-benefit ratio is "an inconvenient fact if you're someone who doesn't like air pollution regulations," says Gretchen Goldman, an analyst and former pollution scientist in the Washington, D.C., office of the Union of Concerned Scientists, which opposes the new EPA rule.

The timing of the rule—which observers expect EPA to adopt once a public comment period closes—is no coincidence, Goldman and others believe. The agency is about to embark on a periodic review of key air pollution limits, including those governing particulates. Even seemingly modest changes in how the agency evaluates the science could lead to lower estimates of the health benefits of tighter standards.

"If stakeholders can change the ground rules so that the EPA can't look at that [health] data, that kind of takes away the foundation on which to quantify the adverse effects of exposure," says environmental engineer Chris Frey of North Carolina State University in Raleigh. Frey previously chaired EPA's Clean Air Scientific Advisory Committee (CASAC) and now serves on an agency panel that reviews particulate pollution science.

The current head of EPA's CASAC, however, says the agency will still have good science to draw on. Anthony Cox, a statistician and risk analyst based in Denver, whom Pruitt appointed to lead the panel last year, says there are ways to analyze confidential health data without disclosing identities. He's confident

that the agency and his committee will "act with integrity and intelligence in using the best available science" when reviewing air pollution standards. (EPA did not respond to a request for comment.)

A first test could come later this year, when EPA researchers expect to finalize a report on the latest particulate science. Cox's committee would then review the report, which would underpin any agency decision about where to set new pollution thresholds.

In the meantime, Frey questions whether the new rule, which would apply only to "significant" regulations judged to cost \$100 million or more, will survive an expected court challenge. In particular, he wonders how EPA will meet its legal obligation, spelled out by Congress, to base regulations on the "best available science" if it tries to disregard a large body of accepted research. "I don't see how," he says, "EPA could defend that in court." ■

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