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### **Pollution study sparks debate over secret data**

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#### **Abstract (Summary)**

Harvard University researchers published startling findings in Dec 1993: Thousands of people were dying annually from inhaling microscopic particles in the air. In 1997, the researchers are facing mounting pressure from industry groups and the EPA to release the patient records and other raw data that form the foundation of their study.

#### **Full Text (1217 words)**

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Harvard University researchers published startling findings in December 1993: Thousands of people were dying annually from inhaling microscopic particles in the air.

The U.S. Environmental Protection Agency may soon adopt regulations to curb the industrial and automotive emissions that produce the specks. Predictably, industry groups are challenging the agency's proposed rules, which will cost billions of dollars to implement.

But the study has also had an unforeseen effect: The researchers at Harvard are facing mounting pressure to release the patient records and other raw data that form the foundation of their study.

Even the EPA has joined the chorus demanding disclosure. "When lots of money and lives are at stake, it's not appropriate to say, 'This is my data and nobody should be looking at it,'" says Mary Nichols, the EPA's assistant administrator for air and radiation. Several governors have also called for the release of data gathered in the study, which was mainly financed by the federal government.

But many scientists consider the disclosure demands an ominous threat to fundamental research. Douglas Dockery, the lead author of the 1993 research paper, is negotiating with the EPA to find a compromise solution. He argues that "giving up this data in violation of our agreements would completely cripple our ability to go out and do epidemiological studies of any type."

To reach its conclusions on particle pollution, the Harvard research team studied 8,000 people in six cities for nearly a quarter of a century, one of the biggest long-term studies ever on the health effects of pollution. They concluded that tiny particles of soot, chemicals and metal were responsible for a 26% higher death rate in the most polluted city, the steel town of Steubenville, Ohio, than in the least polluted city, Portage, Wis. The researchers have used the same data to prepare dozens of other studies.

The EPA says its proposed rules to curb the small particles -- it is scheduled to decide whether to adopt them on July 19 -- would add \$6 billion a year to the costs of the Clean Air Act. Industry groups, meanwhile, estimate the rules will cost at least \$23 billion annually. The rules target particles smaller than three thousandths of a millimeter that are produced mainly by burning fuels. Scientists believe the particles burrow into the lungs and cause ill effects as yet not understood. Based on research at Harvard and elsewhere, the EPA estimates its proposed rules would save 15,000 lives a year, including victims of such maladies as chronic bronchitis.

The release of scientific raw data has been a contentious issue for years. In the 1980s, University of Chicago Prof. Arthur Herbst, who found a higher incidence of cancer in the children of women who had taken the drug DES, was ordered to give up his data during litigation against the manufacturers. But, in a more recent case, researchers at the Mayo Clinic in Rochester, Minn., have so far fended off attempts to subpoena the patient database they used in breast-implant research.

Their study, published in the *New England Journal of Medicine* in 1994, found that breast implants didn't have the ill health effects plaintiffs had claimed. "I can't help but conclude that the purpose of those subpoenas was harassment," says Marcia Angell, the *Journal's* executive editor.

In the DES case, the data were released with patients' names blocked out. But Dr. Dockery says that won't work with the six-cities study because other specific information in the records -- such as city and date of death -- would identify the subjects. Joel Schwartz, a Harvard researcher whose earlier work led to the no-lead policy for gasoline and a MacArthur Foundation "genius" award, says there's no point in providing the information to "industry thugs," his moniker for scientists paid by industry.

Dr. Schwartz, who has used the six-cities data and has also published numerous separate studies on particle pollution, is especially upset by the tactics of Suresh Moolgavkar, who was hired by the American Iron and Steel Institute at about the time the six-cities study was released and soon began attacking the Harvard research. At a January 1994 conference in Irvine, Calif., says Dr. Schwartz, "I was ambushed" by Dr. Moolgavkar. "He called me a liar and a fraud."

Dr. Moolgavkar, who is a respected statistician, denies that his work is influenced by his support from industry.

In a 1994 memo to the EPA protesting critics' call to release the pollution data, Dr. Schwartz pointed out that when industry critics reanalyzed the research supporting rules to ban lead in gasoline, scientists had to defend their work repeatedly, a distraction he views as harassment. "No epidemiologist can afford to be buried in so much time-consuming controversy for every study, yet that is what industry promises for every data set they get their hands on," he wrote.

That rationale doesn't appease David Murray, the research director at the Statistical Assessment Service, a nonprofit group that analyzes scientific issues in the media. "I have a big problem if somebody is denying access to the data because it might undermine faith in the results," he says.

Dr. Schwartz appeared as the main scientific witness at a May news conference held by the Natural Resources Defense Council at which he said the tiny specks in the study "have killed more people than AIDS" over the past five years. The conference helped gain national publicity for the environmental group's call to regulate the particles, but it also caused some scientists to question Dr. Schwartz's even-handedness.

"I don't believe you go to the NRDC for an objective view," says Robert F. Phalen, a professor of environmental medicine at the University of California, Irvine, who organized several scientific colloquia on particle air-pollution issues. Dr. Schwartz says he was there mainly to "validate" the science in a report the group prepared.

Critics also argue that the Harvard work found a relatively weak effect of particles on health. Smoking, for example, increases the risk of lung cancer 20 times, giving it a "relative risk" of 20. But the strongest effects found by the Harvard study were a relative risk of 1.26. Fred Lipfert, a scientist hired by the Electric Power Research Institute, calculates that the entire difference between Steubenville and Portage could be a regional difference in exercise habits the researchers didn't take into account.

Dr. Moolgavkar has used publicly available data to reanalyze the Harvard work in several cities, including Philadelphia and Steubenville. In each case, he has found that other types of pollution, including ozone that is already regulated, may be as much or more to blame. "It's like giving someone sugar and cyanide and then, when they die, concluding the sugar is to blame," says Dr. Moolgavkar.

Drs. Schwartz and Dockery have always acknowledged that the effects of pollution are dwarfed by the effects of smoking. But they argue that their research results have held up in dozens of cities under different conditions. And recent animal studies show that rats, given chemicals to simulate lung disease, die when given a lungful of particles taken directly from the air outside. "We have not been able to say it's not the particles" that are killing people, says Dr. Dockery. "And so far, everything points in the direction that it is."

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