Get-the-Lead-Out Guru Challenged

A decade-old scientific argument over the effects of low-level lead on IQ turns nasty following allegations of misconduct

AS AN ENVIRONMENTAL BOGEYMAN, LEAD'S hard to beat. It ranks right up there with asbestos, dioxin, and nuclear waste. Vice President Dan Quayle has even suggested that lead in the drinking water at the vice presidential mansion might have caused the Bushes' bouts with Graves' disease.

But, irrational fears aside, there's no question that high lead levels can cause brain damage—it's only at low levels of exposure that there is still a debate about what amount of lead in the blood can cause detectable behavioral and medical problems. And that debate has been tainted by a festering, 10-year-old dispute over the credibility of data published by Herbert Needleman of the University of Pittsburg, a world-renowned researcher on lead toxicity and leading adviser to the government on lead issues. Now, in the wake of a government lawsuit against the owners of a lead smelter in which Needleman was to have testified—but never did because the case was settled out of court—his critics have filed a complaint with federal investigators alleging that Needleman engaged in scientific misconduct a decade ago. They accuse the government of helping cover up the flaws in his research in order to deflect criticism of its policy decisions.

To Needleman, the charges are nothing more than old mud slung with new vigor—thoroughly debunked criticisms kept alive by a lead industry desperate to discredit his research.

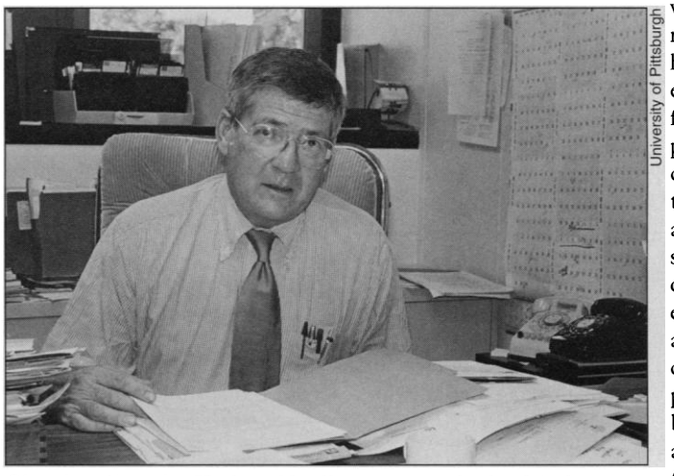
Regardless of who is right, the Needleman saga shows how hard it is to put to rest charges from persistent critics, or, conversely, to prove misconduct against an acknowledged leader in a scientific field. But it also raises additional questions, widely applicable to other scientific disputes, about who should have access to data collected with federal support. And, of course, it refocuses attention on a matter that is especially meaningful to a lot of parents: Just how strong is the link between low-level lead exposure and intelligence deficits?

The story begins with a paper by Needleman and his colleagues in the 29 March 1979 issue of *The New England Journal of Medicine* showing that schoolchildren with what all would agree were "high," but not actually toxic, lead levels did significantly poorer in the classroom and had measurably lower IQs than those with "low" lead levels. In order to get a clearer picture of exposure, the researchers had looked at lead concentrations in the children's baby teeth, as well as the more labile measure of lead in the blood. Suzanne Binder, chief of the Lead Poisoning Prevention Branch at the Centers for Disease Control (CDC) in Atlanta, says that most people's first reaction to Needleman's study was "so what?" since the drop in IQ was only 3 or 4 points. But Binder says policymakers came to realize that even a small drop would be important if it was affecting millions of children.

Two years after the *Journal* article appeared, Claire Ernhart, a psychologist now at Case Western Reserve University, and her colleagues fired the first shot across Needleman's bow. Writing in the journal *Pediatrics*, they suggested that there were serious methodological flaws in the Needleman paper. Ernhart argued that Needleman had not done an adequate job of controlling for confounding variables—other factors such as poor schools or parental neglect that might explain the difference in IQ scores—and had performed so many comparisons that he was bound to come up with a few that were statistically significant merely by chance. Ernhart's own work suggested that most lead effects were too small to be detected by a crude measure like IQ, except at some of the highest levels of exposure, just below what would be considered toxic.

The appearance of the *Pediatrics* article touched off what has been a decade-long personal feud between Ernhart and Needleman. They have squared off at numerous scientific meetings with a vigor that has left observers shaking their heads. "Personal hostility is putting it mildly," says Binder.

But the Needleman/Ernhart squabble might have remained nothing more than a classic confrontation between scientists with starkly opposing views had it not entered, in 1983, into a new and grander forum. The year before, the Environmental Protection Agency (EPA) had begun a major review of national air-quality standards for lead and wanted to review all recent data on the health effects of lead exposures. In an effort "to resolve major points of controversy concerning some of the most important and controversial" studies, Lester Grant, director of the EPA's environmental criteria and assessment office, convened a special panel to look into both Needleman's and Ernhart's work (*Science*, 25 November 1983, p. 906).



Clearing the air. *Herbert Needleman says the lead industry is behind attempts to discredit his research.*

The panel traveled to Needleman's lab, examined some of his data, and decided there were several problems with the study. Specifically, the panel members concluded that Needleman had used inappropriate measures to categorize lead exposure and had not provided sufficient justification for excluding subjects from the study. Moreover, they expressed concern about missing data, and some of the statistical analyses Needleman had employed, all of which led them to conclude that the study results "neither support nor refute the hypothesis that low or moderate levels of [lead] exposure lead to cognitive or behavioral impairments in children." The

panel reached the same conclusion about two of Ernhart's papers, which they also criticized for methodological flaws.

While Ernhart took the panel's rebuke quietly, Needleman fought back. He insisted that the panel's conclusions were flawed, and he wrote a spirited, point-by-point refutation of the criticisms levied at his work. He blasted Grant for printing the report before sending it to him for review, accusing him of violating an agreement he said he and Grant had made. Needleman also performed some new analyses of his original data, and by the time the panel's report was presented to the EPA advisory panel that would decide on the new lead standards, both Grant and the advisory panel had made a 180-degree turn. Now they were convinced that Needleman's original conclusions were accurate. Indeed, those conclusions subsequently became part of the scientific basis for the revised air lead standards EPA promulgated in 1986.

"It was really the data analysis strategy that I looked at, and that to me [was] outrageous."

—Sandra W. Scarr

But Ernhart was not daunted by this setback; she continued to criticize Needleman's work. And her willingness to argue that the link between low-level lead exposure and behavioral problems was being overstated won favor with the lead industry. As early as 1982, she had agreed to testify in favor of the industry's position before an EPA panel contemplating phasing out all leaded gasoline. Just last year she wrote to Senator Harry Reid (D–NV) telling him that basing legislative action on Needleman's findings would be an "egregious error....Serious problems in the Needleman work have long been noted by scientists working in this field." And she appeared from time to time as an expert witness in cases involving lead contamination and cleanup, which brought her feud with Needleman into a new arena: the courtroom.

Their latest faceoff—which has escalated beyond the hazards of lead to the high-stakes "game" of scientific fraud and misconduct charges—began in 1990 with a Superfund case brought by the government against Sharon Steel, UV Industries, and Atlantic Richfield Company. Over a period of several decades, each company had had a financial interest in a defunct lead smelter in Midvale, Utah. The government case sought money for the cleanup of some 250 acres of tailings from a milling facility that prepared the lead ore for the smelter. The government intended to show that the tailings posed a health risk to children living in the area and hired none other than Herbert Needleman as an expert witness to testify to the dangers the tailings posed.

For their part, the corporations' lawyers turned to Ernhart as an expert witness. In addition, the defense team brought in


UVA

University of Virginia psychologist Sandra Wood Scarr, whose work focuses on factors affecting children's educational development. She had also served as a member of the EPA panel that had examined Needleman and Ernhart's research back in 1983. Although Scarr had been among the most critical of Needleman's work then, she says she paid no further attention to it after the panel had wrapped up its business. Now, she and Ernhart felt that they could damage the government's case by demonstrating what they had long believed: that Needleman's 1979 paper—which they say has been "highly influential in the establishment of regulatory policies"—was seriously flawed.

They asked to see Needleman's raw data for the 1979 study. He agreed to release some of the unpublished material, but not the tapes containing his raw data. Needleman argued, in an affidavit dated 27 July 1990 that, in part because he was in the throes of moving his lab, "it would be a substantial hardship for me to find the proper data tape for this 11-year-old study." He added that since the study had been peer reviewed and the data examined by the EPA, there had already been adequate opportunity to establish the legitimacy of his results.

Needleman did say in his affidavit, however, that he would be willing to let "any scientist who wishes to examine the complete printouts of the raw data from the study come to my laboratory in Pittsburgh for as long as he or she wants." So on 20 September last year, Scarr and Ernhart, along with defense lawyers in the lead smelter case, traveled to Pittsburgh to take Needleman up on his offer. When they arrived, they were directed by Justice Department attorney W. Benjamin Fisherow, who was acting for the government, to a bare room where they were given six volumes of computer printouts containing Needleman's initial analyses of his data. Scarr and Ernhart began plowing through the analyses, although they were hampered by the fact that the data were coded, and they were given an incomplete key. Needleman himself would not talk to them.

For his part, Needleman steadfastly insists that he will happily share his data with anyone who has a legitimate interest and will answer any questions he is asked. But, he says, "I'm just not going to make it easy for people who are going to harass me," a category to which he assigns Scarr and Ernhart.

Since Scarr and Ernhart weren't able to get through all the computer printouts in one day, they returned to the lab the next morning. But this time, Fisherow asked them to sign a document saying they would

"Serious problems in the Needleman work have long been noted by scientists working in this field."

—Claire B. Ernhart

treat all the data they were being shown in absolute confidence and would discuss it only in oral testimony before the court. While such agreements are not uncommon for litigation involving private corporations, Scarr and Ernhart were appalled at what they saw as an attempt to gag them, and they refused to sign. After a few hours, lawyers for both sides decided that the visit would have to end, so Scarr and Ernhart gathered their notes and left.

Scarr says that even with only one day to study the analyses, she felt she had a clear idea of what had happened back in 1979. "It was really the data analysis strategy that I looked at, and that to me [was] outrageous." According to Scarr, the printouts show that Needleman's first set of analyses failed to show a relationship between lead level and subsequent intelligence tests. "Not one single variable came out as statistically different between the top 10% [of lead-exposed children]

and the bottom 10% of the sample," she says. It was only by rerunning the analyses, eliminating important variables that might also causes changes in IQ scores, that "he got the results he wanted."

Scarr's harsh view of Needleman might never have become public, however, had it not been for a curious legal twist—one with potentially major ramifications for the availability of government research data. Before Scarr and Ernhart had a chance to present their conclusions about Needleman and his data in the Utah court case, the litigants settled the case. The defendants agreed to pay the government $63 million—the cost of cleaning up the lead tailings. Losing the chance to put the charges on record in open court, Scarr and Ernhart wrote a report that they planned to send to the National Institutes of Health (NIH) Office of Scientific Integrity (OSI), since Needleman's study had been funded with NIH money. But 4 days before the settlement agreement was announced, the government lawyers took a remarkable step: They asked the court to force Scarr and Ernhart to return their notes on the Needleman data and refrain from speaking about what they had found—essentially the same rules Scarr and Ernhart refused to agree to back in Pittsburgh when they were poring over Needleman's printouts.

Scarr and Ernhart immediately concluded—and believe today—that the government was trying to protect Needleman because his research forms the backbone of government lead policy.

Government lawyer Fisherow will not say explicitly why the government sought to gag Scarr and Ernhart, but Needleman's affidavit gives a rationale: "Releasing these raw data to the defendants here will mean that the industry will have the capacity, if it so chooses, to manipulate this data as it sees fit. While any credible researcher should be willing to have the accuracy of his published results debated, the standards of conduct in the scientific community do not extend to making raw data available to advocates of opposing views who then are presented with the opportunity to misuse them."

Scarr and Ernhart weren't buying that argument. They hired David F. Geneson of the Washington, D.C., legal firm Hunton & Williams to fight the gag order. Geneson contended to the court that the government's request was an abridgement of Scarr and Ernhart's First Amendment rights, and that there was no good cause to suppress data that had been gathered with public money.

This argument certainly rings true with lawyers who specialize in misconduct issues. "It's hard to imagine a legitimate basis for the federal government asking for data to be buried," says one such attorney, Barbara Mishkin of the Washington, D.C., firm of Hogan and Hartson.

Needleman, however, has been trying to make just such an argument by saying that the lead industry has tried to twist his data to make it appear to prove things it doesn't actually prove. Mishkin isn't impressed. "The cigarette industry is always putting out its own dubious analysis of data. Nobody pays any attention to it."

On 26 April this year, federal district court judge Bruce S. Jenkins agreed with Mishkin's point, writing that "there is something inherently distasteful and unseemly in secreting either the fruits or seeds of scientific endeavors." And that freed Scarr and Ernhart to tell their doubts about Needleman and his data to anyone they chose. Their first step was to write a report based on their day-and-a-half visit to Needleman's lab, and they have sent a copy to the OSI. OSI officials are considering whether Needleman's actions fall under their jurisdiction, or whether Scarr and Ernhart's analyses fall under the rubric of legitimate scientific difference of opinion. Jane Duffield, a spokeswoman for the University of Pittsburgh, where Needleman did his work, says OSI has not contacted the university concerning any investigation and adds that "we're not investigating Dr. Needleman and we stand behind his work."

"I just do not want to... spend the rest of my life responding to trivia. My reputation is secure."

—Herbert L. Needleman

From Needleman's point of view, this latest round of charges is nothing more than harassment from the lead industry. "I just do not want to...spend the rest of my life responding to trivia," he says. "My reputation is secure at least among people whom I count as important. I'm a forward looking person, and I have much more important questions to answer." And indeed, Needleman has supporters inside and outside the EPA who have seen his data and find nothing to be suspicious of. Frequent co-author David Bellinger, a psychologist and epidemiologist at Harvard University, says there is no substance to Scarr's charge that Needleman eliminated variables from his analyses until he got the results he wanted. "I've worked with the data set, and nothing has ever come to light to make me concerned about that issue." Adds former EPA panel member Larry Kupper, a biostatistician at the University of North Carolina, Chapel Hill, "I never thought there was any misconduct."

Meanwhile, Ernhart vociferously defends herself against Needleman's charges that she is merely serving the lead industry in its attack on him. Yes, she accepts research support from the International Lead Zinc Research Organization, she admits, but says that hasn't affected her objectivity. Her objections to Needleman's conclusions began, she argues, long before she received any lead industry money. Scarr, too, bristles at the suggestion that her objectivity is tainted. "I have no ties to the lead industry," she says. "I don't care what happens to them." What bothers Scarr is that policy decisions are being made based on what she is convinced is flawed work that no one wants to take the time to examine closely. "There's just something wrong about the procedure here, and the role that science is playing in this."

Not so; says EPA's Grant. "The particular studies that are at issue there, and the publications that they are fighting about, are more or less passé," he maintains. "We now have a decade of additional research that confirms lead effects on IQ and behavioral development at much lower levels than the ones they were talking about."

But even this point of view is contested by some. Sanford L. Weiner, a political scientist based in Boston who works for the Milbank Memorial Fund, says he, like Ernhart and Scarr, believes policy actions have outpaced the science. Weiner says it is hard to find a study that clearly demonstrates adverse health effects from lead levels below 25 micrograms per deciliter of blood, the point that the CDC currently uses as its cutoff for lead poisoning. Indeed, agrees Marjorie Smith, a psychologist at the Institute for Child Health at the University of London who directed a lead study in England, 10 micrograms per deciliter—the level to which EPA wants to reduce the lead standard—is "unrealistically low" and would "cause unnecessary anxieties for parents."

Binder says that it is extremely hard to find people who don't have strong opinions about lead in the environment. "Either they're working on this because they consider it to be an incredible problem, and it's worth devoting their life to, or they think everybody else is an idiot, and they have to prove that everyone else is wrong."

So will the day come when both sides can reach a consensus? Not likely, says Binder: "They will all go to their graves thinking the other side is made up of total idiots."

■ JOSEPH PALCA